

## APPENDIX V

### VA Regulations and Standards

- A. VA Human Subject Regulations (38 CFR Part 16)
- B. VA Patient Rights (38 CFR 17.33)
- C. VA Medical Hospital Care for Research Purposes (38 CFR 17.45)
- D. VA Treatment of Research Related Injuries (38 CFR 17.85)
- E. VA Outpatient Care for Research Purposes (38 CFR 17.92)
- F. VHA Directive 1200 VHA Research and Development
- G. VHA Handbook 1200.1 Research and Development Committee (*not yet issued*)
- H. VHA Handbook 1200.5 Requirements for the Protection of Human Subjects in Research
- I. VHA Handbook 1200.6 Requirements for the Protection of Patient Confidentiality and Data Security (*not yet issued*)
- J. VHA Handbook 1200.9 Inclusion of Women and Minorities in Research
- K. VHA Handbook 1200.10 Requirements for the Protection of Human Subjects in Genetic Research (*not yet issued*)
- L. VHA Handbook 1200.11 Research Involving Human Stem Cells (*not yet issued*)
- M. VHA Handbook 1200.13 Conflict of Interest in Research (*not yet issued*)
- N. VHA Handbook 1200.14 Misconduct in Research (*not yet issued*)
- O. VHA Handbook 1200.16 Off-Site Research
- P. VHA Directive 2000-043 Banking of Human Research Subjects' Specimens
- Q. VHA Directive 2001-028 Research Involving Children
- R. VHA Directive 2003-031 Establishment of a Facility Human Protections Program
- S. CNO/ORD Memorandum, "Update on Protection of Human Subjects in Research," May 8, 2000
- T. ORD Memorandum, "Required Education for Investigators," August 15, 2000
- U. ORD Memorandum, "Submission of Research Proposals," March 14, 2001
- V. Deputy Under Secretary for Health Memorandum, "Research Requirements," March 6, 2003
- W. ORD Memorandum, "Submission of Minutes to Headquarters," March 28, 2001
- X. ORO Memorandum, "What to Report to ORO: ACTION," November 12, 2003

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for Resolution Management at the following address: Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420.

(d) The agency shall accept and investigate all complete complaints for which it has jurisdiction. All complete complaints must be filed within 180 days of the alleged act of discrimination. The agency may extend this time period for good cause.

(e) If the agency receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Government entity.

(f) The agency shall notify the Architectural and Transportation Barriers Compliance Board upon receipt of any complaint alleging that a building or facility that is subject to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151-4157), is not readily accessible to and usable by individuals with handicaps.

(g) Within 180 days of the receipt of a complete complaint for which it has jurisdiction, the agency shall notify the complainant of the results of the investigation in a letter containing—

(1) Findings of fact and conclusions of law;

(2) A description of a remedy for each violation found; and

(3) A notice of the right to appeal.

(h) Appeals of the findings of fact and conclusions of law or remedies must be filed by the complainant within 90 days of receipt from the agency of the letter required by § 15.170(g). The agency may extend this time for good cause.

(i) Timely appeals shall be accepted and processed by the head of the agency.

(j) The head of the agency shall notify the complainant of the results of the appeal within 60 days of the receipt of the request. If the head of the agency determines that additional information is needed from the complainant, he or she shall have 60 days from the date of receipt of the additional information to make his or her determination on the appeal.

(k) The time limits cited in paragraphs (g) and (j) of this section may be extended with the permission of the Assistant Attorney General.

(l) The agency may delegate its authority for conducting complaint investigations to other Federal agencies, except that the authority for making the final determination may not be delegated to another agency.

[53 FR 25885, July 8, 1988, as amended at 53 FR 25885, July 8, 1988; 54 FR 34982, Aug. 23, 1989; 67 FR 3435, Jan. 24, 2002]

§§ 15.171-15.999 [Reserved]

## PART 16—PROTECTION OF HUMAN SUBJECTS

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AUTHORITY: 5 U.S.C. 301; 38 U.S.C. 501, 7331, 7334; 42 U.S.C. 300v-1(b).

SOURCE: 56 FR 28012, 28021, June 18, 1991, unless otherwise noted.

### § 16.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies

to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §16.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §16.102(e) must be reviewed and approved, in compliance with §§16.101, 16.102, and §§16.107 through 16.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at

risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

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(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this

policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, Department of Health and Human Services (HHS), and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.<sup>1</sup>

[56 FR 28012, 28021, June 18, 1991; 56 FR 29756, June 28, 1991]

### § 16.102 Definitions.

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

<sup>1</sup>Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A-D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by

other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

**§ 16.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.**

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Protection from Research Risks, HHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under §16.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with §16.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, HHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a re-

search activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §16.101 (b) or

(i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §16.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by §16.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under control number 9999-0020)

[56 FR 28012, 28021, June 18, 1991; 56 FR 29756, June 28, 1991]

**§§ 16.104–16.106 [Reserved]**

**§ 16.107 IRB membership.**

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable

category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

**§ 16.108 IRB functions and operations.**

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in §16.103(b)(4) and, to the extent required by, §16.103(b)(5).

(b) Except when an expedited review procedure is used (see §16.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

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### § 16.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 16.116. The IRB may require that information, in addition to that specifically mentioned in § 16.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 16.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under control number 9999-0020)

### § 16.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Protection from Re-

search Risks, National Institutes of Health, HHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 16.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

### § 16.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:  
(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may

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result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 16.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 16.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

### § 16.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

## 38 CFR Ch. I (7-1-03 Edition)

### § 16.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

(Approved by the Office of Management and Budget under control number 9999-0020)

### § 16.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

### § 16.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 16.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in §§ 16.103(b)(4) and 16.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by § 16.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

(Approved by the Office of Management and Budget under control number 9999-0020)

**§ 16.116 General requirements for informed consent.**

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the

purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

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(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

- (i) Public benefit of service programs;
- (ii) procedures for obtaining benefits or services under those programs;
- (iii) possible changes in or alternatives to those programs or procedures; or
- (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practically be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practically be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended

to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under control number 9999-0020)

**§ 16.117 Documentation of informed consent.**

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 16.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 16.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a

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signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under control number 9999-0020)

### **§ 16.118 Applications and proposals lacking definite plans for involvement of human subjects.**

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 16.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

### **§ 16.119 Research undertaken without the intention of involving human subjects.**

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

### **§ 16.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.**

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

### **§ 16.121 [Reserved]**

### **§ 16.122 Use of Federal funds.**

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

### **§ 16.123 Early termination of research support: Evaluation of applications and proposals.**

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements,

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when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

**§ 16.124 Conditions.**

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

**PART 17—MEDICAL**

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Director may concur with the decision to withhold or withdraw life support or request further review by Regional Counsel.

(g) *Special consent situations.* In addition to the other requirements of this section, additional protections are required in the following situations.

(1) No patient will undergo any unusual or extremely hazardous treatment or procedure, *e.g.*, that which might result in irreversible brain damage or sterilization, except as provided in this paragraph (g). Before treatment is initiated, the patient or surrogate must be given adequate opportunity to consult with independent specialists, legal counsel or other interested parties of his or her choosing. The patient's or surrogate's signature on a VA authorized consent form must be witnessed by someone who is not affiliated with the VA health-care facility, *e.g.*, spouse, legal guardian, or patient advocate. If a surrogate makes the treatment decision, a multi-disciplinary committee, appointed by the facility Director, must review that decision to ensure it is consistent with the patient's wishes or in his or her best interest. The committee functions as the patient's advocate and may not include members of the treatment team. The committee must submit its findings and recommendations in a written report to the facility Director. The Director may authorize treatment consistent with the surrogate's decision or request that a special guardian for health care be appointed to make the treatment decision.

(2) Administration of psychotropic medication to an involuntarily committed patient against his or her will must meet the following requirements. The patient or surrogate must be allowed to consult with independent specialists, legal counsel or other interested parties concerning the treatment with psychotropic medication. Any recommendation to administer or continue medication against the patient's or surrogate's will must be reviewed by a multi-disciplinary committee appointed by the facility Director for this purpose. This committee must include a psychiatrist or a physician who has psychopharmacology privileges. The facility Director must concur with the

committee's recommendation to administer psychotropic medications contrary to the patient's or surrogate's wishes. Continued therapy with psychotropic medication must be reviewed every 30 days. The patient (or a representative on the patient's behalf) may appeal the treatment decision to a court of appropriate jurisdiction.

(3) If a proposed course of treatment or procedure involves approved medical research in whole or in part, the patient or representative shall be advised of this. Informed consent shall be obtained specifically for the administration or performance of that aspect of the treatment or procedure that involves research. Such consent shall be in addition to that obtained for the administration or performance of the nonresearch aspect of the treatment or procedure and must meet the requirements for informed consent set forth in 38 CFR Part 16, *Protection of Human Subjects*.

(4) Testing for Human Immunodeficiency Virus (HIV) must be voluntary and must be conducted only with the prior informed and (written) signature consent of the patient or surrogate. Patients who consent to testing for HIV must sign VA form 10-012, "Consent for HIV Antibody Testing." This form must be filed in the patient's medical record. Testing must be accompanied by pre-test and post-test counseling.

(The information collection requirements in this section have been approved by the Office of Management and Budget under control number 2900-0583)

(Authority: 38 U.S.C. 7331, 7332, 7333)

[62 FR 53961, Oct. 17, 1997]

### § 17.33 Patients' rights.

(a) *General.* (1) Patients have a right to be treated with dignity in a humane environment that affords them both reasonable protection from harm and appropriate privacy with regard to their personal needs.

(2) Patients have a right to receive, to the extent of eligibility therefor under the law, prompt and appropriate treatment for any physical or emotional disability.

(3) Patients have the right to the least restrictive conditions necessary to achieve treatment purposes.

(4) No patient in the Department of Veterans Affairs medical care system, except as otherwise provided by the applicable State law, shall be denied legal rights solely by virtue of being voluntarily admitted or involuntarily committed. Such legal rights include, but are not limited to, the following:

(i) The right to hold and to dispose of property except as may be limited in accordance with paragraph (c)(2) of this section;

(ii) The right to execute legal instruments (e.g., will);

(iii) The right to enter into contractual relationships;

(iv) The right to register and vote;

(v) The right to marry and to obtain a separation, divorce, or annulment;

(vi) The right to hold a professional, occupational, or vehicle operator's license.

(b) *Residents and inpatients.* Subject to paragraph (c) of this section, patients admitted on a residential or inpatient care basis to the Department of Veterans Affairs medical care system have the following rights:

(1) *Visitations and communications.* Each patient has the right to communicate freely and privately with persons outside the facility, including government officials, attorneys, and clergymen. To facilitate these communications each patient shall be provided the opportunity to meet with visitors during regularly scheduled visiting hours, convenient and reasonable access to public telephones for making and receiving phone calls, and the opportunity to send and receive unopened mail.

(i) Communications with attorneys, law enforcement agencies, or government officials and representatives of recognized service organizations when the latter are acting as agents for the patient in a matter concerning Department of Veterans Affairs benefits, shall not be reviewed.

(ii) A patient may refuse visitors.

(iii) If a patient's right to receive unopened mail is restricted pursuant to paragraph (c) of this section, the patient shall be required to open the sealed mail while in the presence of an

appropriate person for the sole purpose of ascertaining whether the mail contains contraband material, i.e., implements which pose significant risk of bodily harm to the patient or others or any drugs or medication. Any such material will be held for the patient or disposed of in accordance with instructions concerning patients' mail published by the Veterans Health Administration, Department of Veterans Affairs, and/or the local health care facility.

(iv) Each patient shall be afforded the opportunity to purchase, at the patient's expense, letter writing material including stamps. In the event a patient needs assistance in purchasing writing material, or in writing, reading or sending mail, the medical facility will attempt, at the patient's request, to provide such assistance by means of volunteers, sufficient to mail at least one (1) letter each week.

(v) All information gained by staff personnel of a medical facility during the course of assisting a patient in writing, reading, or sending mail is to be kept strictly confidential except for any disclosure required by law.

(2) *Clothing.* Each patient has the right to wear his or her own clothing.

(3) *Personal Possessions.* Each patient has the right to keep and use his or her own personal possessions consistent with available space, governing fire safety regulations, restrictions on noise, and restrictions on possession of contraband material, drugs and medications.

(4) *Money.* Each patient has the right to keep and spend his or her own money and to have access to funds in his or her account in accordance with instructions concerning personal funds of patients published by the Veterans Health Administration.

(5) *Social Interaction.* Each patient has the right to social interaction with others.

(6) *Exercise.* Each patient has the right to regular physical exercise and to be outdoors at regular and frequent intervals. Facilities and equipment for such exercise shall be provided.

(7) *Worship.* The opportunity for religious worship shall be made available to each patient who desires such opportunity. No patient will be coerced into

engaging in any religious activities against his or her desires.

(c) *Restrictions.* (1) A right set forth in paragraph (b) of this section may be restricted within the patient's treatment plan by written order signed by the appropriate health or mental health professional if—

(i) It is determined pursuant to paragraph (c)(2) of this section that a valid and sufficient reason exists for a restriction, and

(ii) The order imposing the restriction and a progress note detailing the indications therefor are both entered into the patient's permanent medical record.

(2) For the purpose of this paragraph, a valid and sufficient reason exists when, after consideration of pertinent facts, including the patient's history, current condition and prognosis, a health or mental health professional reasonably believes that the full exercise of the specific right would—

(i) Adversely affect the patient's physical or mental health,

(ii) Under prevailing community standards, likely stigmatize the patient's reputation to a degree that would adversely affect the patient's return to independent living,

(iii) Significantly infringe upon the rights of or jeopardize the health or safety of others, or

(iv) Have a significant adverse impact on the operation of the medical facility, to such an extent that the patient's exercise of the specific right should be restricted. In determining whether a patient's specific right should be restricted, the health or mental health professional concerned must determine that the likelihood and seriousness of the consequences that are expected to result from the full exercise of the right are so compelling as to warrant the restriction. The Chief of Service or Chief of Staff, as designated by local policy, should concur with the decision to impose such restriction. In this connection, it should be noted that there is no intention to imply that each of the reasons specified in paragraphs (c)(2)(i) through (iv) of this section are logically relevant to each of the rights set forth in paragraph (b)(1) of this section.

(3) If it has been determined under paragraph (c)(2) of this section that a valid and sufficient reason exists for restricting any of the patient's rights set forth in paragraph (c)(1) of this section, the least restrictive method for protecting the interest or interests specified in paragraphs (c)(2)(i) through (iv) of this section that are involved shall be employed.

(4) The patient must be promptly notified of any restriction imposed pursuant to this paragraph and the reasons therefor.

(5) All restricting orders must be reviewed at least once every 30 days by the practitioner and must be concurred in by the Chief of Service or Chief of Staff.

(d) *Restraint and seclusion of patients.*

(1) Each patient has the right to be free from physical restraint or seclusion except in situations in which there is a substantial risk of imminent harm by the patient to himself, herself, or others and less restrictive means of preventing such harm have been determined to be inappropriate or insufficient. Patients will be physically restrained or placed in seclusion only on the written order of a physician. The reason for any restraint order will be clearly documented in the progress notes of the patient's medical record. The written order may be entered on the basis of telephonic authority received from a physician, but in such an event the ordering physician must examine the patient and sign the written order within twelve (12) hours of giving the order for restraint or seclusion. In emergency situations, where inability to contact a physician prior to restraint is likely to result in immediate harm to the patient or others, the patient may be temporarily restrained by a member of the staff until appropriate authorization can be received from a physician. Use of restraints or seclusion shall be for no more than twenty-four (24) hours, at which time the physician shall again be consulted to determine if continuance of such restraint or seclusion is required. Restraint or seclusion may not be used as a punishment, for the convenience of staff, or as a substitute for treatment programs.

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(2) While in restraint or seclusion, the patient must be seen at least once every twelve (12) hours by an appropriate health professional who will monitor and chart the patient's physical and mental condition and by other ward personnel as frequently as is reasonable under existing circumstances, but no less than once each hour.

(3) Each patient in restraint or seclusion shall have bathroom privileges according to his or her needs.

(4) Each patient in restraint or seclusion shall have the opportunity to bathe at least every twenty-four (24) hours.

(5) Each patient in restraint or seclusion shall be provided nutrition and fluid appropriately.

(e) *Medication.* Patients have a right to be free from unnecessary or excessive medication. Except in an emergency, medication will be administered only on the written order of a physician in that patient's medical record. The written order may be entered on the basis of telephonic authority received from a physician, but in such event a physician must countersign the written order within 24 hours of the ordering of the medication. The attending physician shall be responsible for all medication given or administered to a patient. The attending physician shall review the drug regimen of each patient under his or her care at least every thirty (30) days. It is recognized that administration of certain medications will be reviewed more frequently. Medication shall not be used as punishment, for the convenience of the staff, or in quantities which interfere with the patient's treatment program.

(f) *Confidentiality.* Information gained by staff from the patient or the patient's medical record will be kept confidential and will not be disclosed except in accordance with applicable law.

(g) *Patient grievances.* Each patient has the right to present grievances with respect to perceived infringement of the rights described in this section or concerning any other matter on behalf of himself, herself or others, to staff members at the facility in which the patient is receiving care, other Department of Veterans Affairs officials, government officials, members of Con-

gress or any other person without fear or reprisal.

(h) *Notice of patient's rights.* Upon the admission of any patient, the patient or his/her representative shall be informed of the rights described in this section, shall be given a copy of a statement of those rights and shall be informed of the fact that the statement of rights is posted at each nursing station. All staff members assigned to work with patients will be given a copy of the statement of rights and these rights will be discussed with them by their immediate supervisor.

(i) *Other rights.* The rights described in this section are in addition to and not in derogation of any statutory, constitutional or other legal rights.

(Authority: 38 U.S.C. 501, 1721)

[47 FR 55486, Dec. 10, 1982. Redesignated at 61 FR 21965, May 13, 1996]

TENTATIVE ELIGIBILITY DETERMINATIONS

§ 17.34 Tentative eligibility determinations.

Subject to the provisions of §§ 17.36 through 17.38, when an application for hospital care or other medical services, except outpatient dental care, has been filed which requires an adjudication as to service connection or a determination as to any other eligibility prerequisite which cannot immediately be established, the service (including transportation) may be authorized without further delay if it is determined that eligibility for care probably will be established. Tentative eligibility determinations under this section, however, will only be made if:

(a) *In emergencies.* The applicant needs hospital care or other medical services in emergency circumstances, or

(b) *For persons recently discharged from service.* The application was filed within 6 months after date of honorable discharge from a period of not less than 6 months of active duty.

[35 FR 6586, Apr. 24, 1970. Redesignated at 61 FR 21965, May 13, 1996, as amended at 64 FR 54212, Oct. 6, 1999]

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the nervous system, including quadriplegia, hemiplegia and paraplegia, tuberculosis, blindness and deafness requiring definitive rehabilitation, disability from major amputation, and other diseases as may be agreed upon from time to time by the Under Secretary for Health and designated officials of the Department of Defense and Department of Health and Human Services. For the purpose of this section, blindness is defined as corrected visual acuity of 20/200 or less in the better eye, or corrected central visual acuity of more than 20/200 if there is a field defect in which the peripheral field has contracted to such an extent that its widest diameter subtends the widest diameter of the field of the better eye at an angle no greater than 20°.

(c) In the case of persons who are former members of the Coast and Geodetic Survey, care may be furnished under this section even though their retirement for disability was from the Environmental Science Services Administration or NOAA.

[34 FR 9340, June 13, 1969, as amended at 39 FR 1841, Jan. 15, 1974; 47 FR 58247, Dec. 30, 1982. Redesignated at 61 FR 21965, May 13, 1996, as amended at 62 FR 17072, Apr. 9, 1997]

**§ 17.45 Hospital care for research purposes.**

Subject to the provisions of § 17.62(g), any person who is a bona fide volunteer may be admitted to a Department of Veterans Affairs hospital when the treatment to be rendered is part of an approved Department of Veterans Affairs research project and there are insufficient veteran-patients suitable for the project.

[35 FR 11470, July 17, 1970. Redesignated at 61 FR 21965, May 13, 1996]

**§ 17.46 Eligibility for hospital, domiciliary or nursing home care of persons discharged or released from active military, naval, or air service.**

(a) In furnishing hospital care under 38 U.S.C. 1710(a)(1), VA officials shall:

(1) If the veteran is in immediate need of hospitalization, furnish care at VA facility where the veteran applies or, if that facility is incapable of fur-

nishing care, arrange to admit the veteran to the nearest VA medical center, or Department of Defense hospital with which VA has a sharing agreement under 38 U.S.C. 8111, which is capable of providing the needed care, or if VA or DOD facilities are not available, arrange for care on a contract basis if authorized by 38 U.S.C. 1703 and 38 CFR 17.52; or

(2) If the veteran needs non-immediate hospitalization, schedule the veteran for admission at VA facility where the veteran applies, if the schedule permits, or refer the veteran for admission or scheduling for admission at the nearest VA medical center, or Department of Defense facility with which VA has a sharing agreement under 38 U.S.C. 8111.

(Authority: 38 U.S.C. 1703, 1710; secs. 19011-19012, Pub. L. 99-272)

(b) Domiciliary care may be furnished when needed to:

(1) Any veteran whose annual income does not exceed the maximum annual rate of pension payable to a veteran in need of regular aid and attendance, or

(2) Any veteran who the Secretary determines had no adequate means of support. An additional requirement for eligibility for domiciliary care is the ability of the veteran to perform the following:

(i) Perform without assistance daily ablutions, such as brushing teeth; bathing; combing hair; body eliminations.

(ii) Dress self, with a minimum of assistance.

(iii) Proceed to and return from the dining hall without aid.

(iv) Feed Self.

(v) Secure medical attention on an ambulatory basis or by use of personally propelled wheelchair.

(vi) Have voluntary control over body eliminations or control by use of an appropriate prosthesis.

(vii) Share in some measure, however slight, in the maintenance and operation of the facility.

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the facility prior to award of a contract to assure that prescribed requirements can be met. Inspections may also be carried out at such other times as deemed necessary by the Department of Veterans Affairs.

(c) All requirements in this rule and Department of Veterans Affairs reports of inspection of residential facilities furnishing treatment and rehabilitation services to eligible veterans shall, to the extent possible, be made available to all government agencies charged with the responsibility of licensing or otherwise regulating or inspecting such institutions.

(d) An individual case record will be created for each client which shall be maintained in security and confidence as required by the "Confidentiality of Alcohol and Drug Abuse Patient Records" (42 CFR part 2) and the "Confidentiality of Certain Medical Records" (38 U.S.C. 7332), and will be made available on a need to know basis to appropriate Department of Veterans Affairs staff members involved with the treatment program of the veterans concerned.

(Authority: 38 U.S.C. 1720A)

[47 FR 57708, Dec. 28, 1982. Redesignated and amended at 61 FR 21965, 21967, May 13, 1996; 61 FR 63720, Dec. 2, 1996; 62 FR 17072, Apr. 9, 1997]

### **§ 17.83 Limitations on payment for alcohol and drug dependence or abuse treatment and rehabilitation.**

The authority to enter into contracts shall be effective for any fiscal year only to such extent or in such amounts as are provided in appropriation acts, and payments shall not exceed these amounts.

(Authority: Pub. L. 96-22, 38 U.S.C. 1720A)

[47 FR 57708, Dec. 28, 1982. Redesignated at 61 FR 21965, May 13, 1996]

#### RESEARCH-RELATED INJURIES

### **§ 17.85 Treatment of research-related injuries to human subjects.**

(a) VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under

the supervision of one or more VA employees. This section does not apply to:

(1) Treatment for injuries due to non-compliance by a subject with study procedures, or

(2) Research conducted for VA under a contract with an individual or a non-VA institution.

NOTE TO § 17.85(a)(1) AND (a)(2): Veterans who are injured as a result of participation in such research may be eligible for care from VA under other provisions of this part.

(b) Except in the following situations, care for VA research subjects under this section shall be provided in VA medical facilities.

(1) If VA medical facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required, VA medical facility directors shall contract for the needed care.

(2) If inpatient care must be provided to a non-veteran under this section, VA medical facility directors may contract for such care.

(3) If a research subject needs treatment in a medical emergency for a condition covered by this section, VA medical facility directors shall provide reasonable reimbursement for the emergency treatment in a non-VA facility.

(c) For purposes of this section, "VA employee" means any person appointed by VA as an officer or employee and acting within the scope of his or her appointment (VA appoints officers and employees under title 5 and title 38 of the United States Code).

(Authority: 38 U.S.C. 501, 7303)

[63 FR 11124, Mar. 6, 1998]

#### VOCATIONAL TRAINING AND HEALTH-CARE ELIGIBILITY PROTECTION FOR PENSION RECIPIENTS

### **§ 17.90 Medical care for veterans receiving vocational training under 38 U.S.C. chapter 15.**

Hospital care, nursing home care and medical services may be provided to any veteran who is participating in a vocational training program under 38 U.S.C. chapter 15.

(a) For purposes of determining eligibility for this medical benefit, the term *participating in a vocational training program under 38 U.S.C. chapter 15*

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means the same as the term *participating in a rehabilitation program under 38 U.S.C. chapter 31* as defined in § 17.47(j). Eligibility for such medical care will continue only while the veteran is participating in the vocational training program.

(b) The term *hospital care and medical services* means class V dental care, priority III medical services, nursing home care and non-VA hospital care and/or fee medical/dental care if VA is unable to provide the required medical care economically at VA or other government facilities because of geographic inaccessibility or because of the unavailability of the required services at VA facilities.

(Authority: 38 U.S.C. 1524, 1525, 1516)

[51 FR 19330, May 29, 1986, as amended at 56 FR 3422, Jan. 30, 1991. Redesignated and amended at 61 FR 21965, 21967, May 13, 1996]

### § 17.91 Protection of health-care eligibility.

Any veteran whose entitlement to VA pension is terminated by reason of income from work or training shall, subject to paragraphs (a) and (b) of this section, retain for 3 years after the termination, the eligibility for hospital care, nursing home care and medical services (not including dental) which the veteran otherwise would have had if the pension had not been terminated as a result of the veteran's receipt of earnings from activity performed for remuneration or gain by the veteran but only if the veteran's annual income from sources other than such earnings would, taken alone, not result in the termination of the veteran's pension.

(a) A veteran who participates in a vocational training program under 38 U.S.C. chapter 15 is eligible for the one-time 3 year retention of hospital care, nursing home care and medical services benefits at any time that the veteran's pension is terminated by reason of income from the veteran's employment.

(b) A veteran who does not participate in a vocational training program under 38 U.S.C. chapter 15 is eligible for the one-time 3 year retention of hospital care and medical services benefits only if the veteran's pension is terminated by reason of income from the veteran's employment during the pe-

## 38 CFR Ch. I (7-1-03 Edition)

riod February 1, 1985 through January 31, 1989.

(Authority: 38 U.S.C. 1524, 1525, 1516)

[51 FR 19330, May 29, 1986. Redesignated at 61 FR 21965, May 13, 1996]

### OUTPATIENT TREATMENT

#### § 17.92 Outpatient care for research purposes.

Subject to the provisions of § 17.101, any person who is a bona fide volunteer may be furnished outpatient treatment when the treatment to be rendered is part of an approved Department of Veterans Affairs research project and there are insufficient veteran-patients suitable for the project.

[35 FR 11470, July 17, 1970. Redesignated and amended at 61 FR 21965, 21967, May 13, 1996]

#### § 17.93 Eligibility for outpatient services.

(a) VA shall furnish on an ambulatory or outpatient basis medical services as are needed, to the following applicants under the conditions stated, except that applications for dental treatment must also meet the provisions of § 17.161.

(Authority: 38 U.S.C. 1712)

(1) *For compensation and pension examinations.* A compensation and pension examination shall be performed for any veteran who is directed to have such an examination by VA. (Authority: 38 U.S.C. 111 and 501)

(2) *For adjunct treatment.* Subject to the provisions of §§ 17.36 through 17.38, medical services on an ambulatory or outpatient basis shall be provided to veterans for an adjunct nonservice-connected condition associated with and held to be aggravating a disability from a disease or injury adjudicated as being service-connected.

(b) The term "shall furnish" in this section and 38 U.S.C. 1712 (a)(1) and (a)(2) means that, if the veteran is in immediate need of outpatient medical services, VA shall furnish care at the VA facility where the veteran applies. If the needed medical services are not available there, VA shall arrange for care at the nearest VA medical facility or Department of Defense facility (with which VA has a sharing agreement)

**VETERANS HEALTH ADMINISTRATION**  
**RESEARCH AND DEVELOPMENT**

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Directive provides an overview of Research and Development policies and procedures.
- 2. SUMMARY OF CONTENTS:** The Office of Research and Development (ORD) and its four research services (Medical Research Service (MRS), Rehabilitation Research and Development Service (RR&D), Health Services Research and Development Service (HSR&D), and the Cooperative Studies Program (CSP)) address a common mission and adhere to common policies. In addition, shared principles, including prioritization of research proposals on the basis of scientific merit, fiscal responsibility, and high standards of scientific integrity, govern all Department of Veterans Affairs (VA) research activity.
- 3. RELATED DIRECTIVE:** VHA Handbook 1200.1, etc., to be published.
- 4. RESPONSIBLE OFFICE:** The VHA Office of Research and Development (12) is responsible for the contents of this Directive. Questions may be referred to ORD at (202) 273-8284, or by facsimile at (202) 273-6526.
- 5. RESCISSIONS:** M-3, Part I, Chapter 1 is rescinded.
- 6. RECERTIFICATION:** This document is scheduled for recertification on or before the last working day of November 2006.

S/ Tom Sanders for  
Thomas L. Garthwaite, M.D.  
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 11/6/2001  
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 11/6/2001



**VETERANS HEALTH ADMINISTRATION  
RESEARCH AND DEVELOPMENT**

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive provides policy and guidance related to the Medical and Prosthetic Research and Development (R&D) Program in the Department of Veterans Affairs (VA).

**2. BACKGROUND**

a. Medical and Prosthetics Research in VHA is an intramural program administered by the VHA Central Office, Office of Research and Development (ORD) and conducted at VA medical facilities nationwide. (Authority: Title 38 United States Code (U.S.C.) Chapter 73, Section 7303.) The mission of the R&D program is to discover knowledge and create innovations that advance health care for our veterans and the nation. In support of this mission, the ORD strives to:

- (1) Sustain a superior environment of inquiry conducive to the highest quality research, education and patient care.
- (2) Effectively integrate fundamental, clinical, and applied research to best meet veterans' health care needs.
- (3) Effectively transfer research results to advance veterans' health care.
- (4) Maximize VHA's value as a national research asset.
- (5) Lead and manage an effective and efficient research enterprise.
- (6) Increase awareness and understanding of the value of VHA's research contributions.

b. The VA R&D program is an intramural program. ORD allocates appropriated Medical and Prosthetic Research funds to VA medical facilities for scientifically meritorious research related to the high priority health care needs of veterans to be conducted by VA employees. VA investigators may also obtain funding support for their research from extramural sources such as other Federal agencies, private voluntary health organizations and foundations, and commercial entities. Unlike agencies such as the National Institutes of Health (NIH) and the Department of Defense (DOD), VA does not have the statutory authority to make research grants to colleges and universities, cities and states, or any other non-VA entity. Contracts may be utilized to obtain special services not available in VA (see VHA Handbook 1200.2, (to be published) "Research Business Operations") for detailed information regarding contracts).

c. Professional staff members of VA medical centers are encouraged to engage in R&D activities.

d. Research proposals received by a VHA Central Office R&D Service (Medical Research Service (MRS), Rehabilitation R&D Service (RR&D), Health Services R&D Service (HSR&D), and the Cooperative Studies Program (CSP)) that are determined to be more appropriate for review by another R&D Service, may be transferred to ensure adequate peer review. The R&D Service accepting review responsibility will notify the applicant. The proposal will be reviewed in accordance with procedures applicable to the reviewing Service.

e. The requirements of any policies and operational procedures formulated in conjunction with this VHA Directive apply to all R&D activities conducted completely or partially in VA facilities, conducted in approved off-site locations and/or facilities and/or conducted by VA investigators while on official VA duty time, whether funded by VA or by other sources, or unfunded.

f. Values guiding all R&D efforts include: scientific excellence; the ethical conduct of research; protection of human subjects; and animal welfare. The R&D program spans the continuum from basic biomedical research through the translation of research into practice, emphasizing health concerns of veterans.

g. The R&D program supports and rigorously abides by the Federal Policy for Protection of Human Subjects of Research (the Common Rule) and the principles outlined in the Belmont Report and the Nuremberg Code. The rights and welfare of all persons participating in research must be vigorously protected. All research involving human subjects must comply with all Federal regulations and VA requirements that address the protection of human subjects, including Title 38 Code of Federal Regulations (CFR) Part 16 (VA's implementation of the Common Rule, also codified by the Department of Health and Human Services at 45 CFR Part 46, Subpart A), and all related policy and procedural documents issued by ORD. These regulations and requirements must be met before any research involving human subjects is initiated, and adherence must be sustained throughout the conduct of the research.

h. The R&D program supports only those animal studies that are designed and performed with the highest degree of attention to the welfare of research animals and that fully comply with Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International guidelines.

i. The R&D program maintains a research safety program consistent with policies, statutes, and regulations issued by the Occupational Safety & Health Administration (OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), Centers for Disease Control and Prevention (CDC), and NIH. The R&D program supports only those studies with the highest standards of protecting personnel against biohazards, chemical hazards, and physical hazards in research laboratory settings.

**3. POLICY:** It is VHA policy that:

a. All research sponsored by ORD and its four research services (MRS, RR&D, HSR&D, and CSP) address a common mission and adhere to common policies.

b. Shared principles, including prioritization of research proposals on the basis of scientific merit, fiscal responsibility, and high standards of scientific integrity, govern all VA research activity.

c. All VA research activities involving human subjects or human specimens and/or tissues must comply with ORD requirements regarding the inclusion of women and minorities in research (refer to VHA Handbook 1200.9, "Inclusion of Women and Minorities in Research").

#### 4. ACTION

a. **VHA Central Office.** The Chief Research and Development Officer (CRADO) is responsible for the overall policy, planning, coordination, and direction of R&D activities within VHA. (Authority: Title 38, U.S.C. Chapter 73, Section 7303.) These responsibilities are carried out at VHA Central Office through ORD and its four research services (MRS, RR&D, HSR&D, and CSP).

b. **Veterans Integrated Service Network (VISN) Directors.** VISN Directors are responsible for ensuring that each medical facility conducting research and development under their jurisdiction is in compliance with current policy and procedural guidelines. VISN Directors also will arrange for appropriate scientific and administrative support for R&D Committees and subcommittees, ensure that these groups are accredited by relevant external credentialing organizations, and provide adequate release time for VA staff serving as committee members. Directors will ensure that investigators are allocated appropriate time during their VA tour of duty hours to conduct funded research.

c. **Facility Directors**

(1) The Director or Chief Executive Officer (CEO) of each health care facility is responsible for the R&D program of that institution, advised and assisted by an R&D Committee. All facilities with an active R&D program must have an official responsible for management of the program. Facilities with large, active research programs will establish a position equivalent to Associate Chief of Staff (ACOS) for R&D such as Research Director, or Clinical R&D Executive or equivalent, through the Chief of Staff (COS) and/or the Chief Medical Officer (CMO) and/or the Chief Clinical Executive (CCE), or equivalent. When a facility's R&D program activity does not justify the position of ACOS for R&D, the position of Coordinator for R&D (C for R&D) may be established in the Office of the COS, or CMO, or CCE in lieu of the ACOS for R&D or equivalent. The position of C for R&D may be designated as a collateral function of another administrative position. The medical center Director is responsible for implementing the R&D program, policies, and procedures, including establishing and appointing members to the R&D committee and any appropriate subcommittees.

(2) The medical center Director is responsible for ensuring that R&D funds are not used for routine clinical care or administrative support services that should be provided by the local facility. The services that may not be supported by R&D funds are: radiation safety,

infection control, library, supply, personnel management, fiscal, facility engineering, or building management (excluding building management for animal research facilities). All utilities and normal telephone and information technology services are provided by the health care facility without charge to R&D project and/or program budgets.

(a) It is expected that the portion of the medical center's budget attributable to the R&D portion of the Veterans Equitable Resource Allocation (VERA) transferred to the medical center will be used to provide indirect support for research, including but not limited to, services such as appropriate scientific and administrative support for R&D Committees and subcommittees. These funds may not be used for routine clinical and or administrative support services, utilities or normal telephone service that should be provided by the local facility.

(b) It is the responsibility of the medical center Director to provide adequate administrative support for the R&D Committee, Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Subcommittee on Research Safety (SRS), including personnel to support committee review and record-keeping functions and space sufficient to provide privacy for conducting sensitive duties related to biosafety and protection of human and animal subjects involved in research. If the facility utilizes the IRB of an affiliated institution, the medical center Director may contribute to the support of that IRB as appropriate. VA staff time in support of IRB activity will be accounted for and supported. VA-funded R&D project/program budgets will not be charged for administrative or medical staff support of R&D Committee, IRB, IACUC, SRS or other committee/subcommittee activity. Medical center Directors will ensure that investigators are allocated appropriate time during their VA tour of duty hours to conduct funded research.

(3) The medical center Director is responsible for ensuring that the research program reimburses the medical care appropriation when clinical services are provided to:

- (a) A study patient who is a non-veteran or a veteran ineligible for VA care; or
- (b) An eligible veteran solely for the sake of participation in a research project.

(4) The medical center Director is responsible for ensuring the ethical conduct of research and adequate protection of human participants in research.

**5. DEFINITIONS:** The following definitions are applicable in the context of this Directive and all supporting VHA Handbooks (1200 series).

a. **Title 38 CFR Part 16.** Title 38 CFR, Part 16, implements the Common Rule for VA.

b. **Ad hoc member.** An ad hoc member is an individual with expertise or competence in a particular area who assists with the review of issues that require expertise beyond that or in addition to that available on a committee or subcommittee. An ad hoc member may not vote with the committee or contribute to the quorum.

c. **Administrative Officer for Research and Development (AO for R&D)**. The AO for R&D is the individual responsible for the administrative functions of the research program. The AO for R&D serves as an assistant to the ACOS for R&D.

d. **Affiliated institution**. An affiliated institution is an academic institution that has a relationship with a VA medical center documented by a Memorandum of Affiliation in conformance with VA regulations (also referred to as “academic affiliate”). In addition, special purpose affiliations documented by a memorandum of understanding approved by the CRADO, may be developed in R&D areas such as health services or rehabilitation research and development.

e. **Appeal**. An appeal is a request to reconsider the disapproval or decision to not fund a research proposal. Appeals of Merit Review results should be focused on the actions of the review board and may be made when, in the opinion of the investigator, the board did not understand the research, missed relevant points, and/or exhibited bias.

f. **ACOS for R&D**. The ACOS for R&D is the individual with delegated authority for management of the research program at facilities with large, active programs.

g. **Biomedical research**: the investigation of the etiology, pathogenesis, diagnosis, and treatment of medical and behavioral diseases and conditions.

h. **Center of Excellence**. A Center of Excellence is a team of researchers funded for the purpose of collaborating on a common research agenda and developing expertise in a specific research area. Centers of Excellence are funded for a specified period of time following scientific merit review.

i. **CRADO**. The CRADO is the individual responsible for the overall policy, planning, coordination, and direction of R&D activities within VHA. These responsibilities are carried out at VHA Central Office through programs administered by ORD and four research services (MRS, RR&D, HSR&D, and CSP).

j. **Chief Veterinary Medical Officer (CVMO)**. The CVMO is the individual responsible for veterinary medical and animal research concerns and issues. The CVMO reports to the CRADO, or designee.

k. **Collaborating Investigator (or co-investigator)**. The Collaborating Investigator (or co-investigator) is an investigator other than the principal investigator who participates in a project; generally persons are considered as “collaborating” if they will be included as joint authors of the final presentation of the project.

l. **Collaborative study**. A collaborative study is a project or program of research or development conducted at two or more health care facilities; it does not require a common protocol.

m. **Conflict of Interest**. A conflict of interest is any financial arrangement, situation or action that affects or is perceived to exert inappropriate influence on the design, review,

conduct, results or reporting of research activities or findings. Policies and procedures to enable all VA investigators to comply with VHA and applicable Federal and state regulations regarding conflict of interest will be described in VHA Handbook 1200.13 (to be published).

n. **Cooperating Investigator.** The Cooperating Investigator is the person at any one VA facility who is accountable for the facility's participation in a study that involves two or more facilities.

o. **Cooperative Research and Development Agreements (CRADA).** CRADA is an agreement between VA and one or more non-Federal parties under which VA "laboratory directors" (defined herein as medical center Directors) may accept, retain and use funds, personnel, services, facilities, equipment, or other resources from collaborating parties. In exchange for what VA receives from a collaborating party, VA may provide personnel, services, facilities, equipment, or other resources, but not funds toward the conduct of specified research and development efforts which are consistent with VA's mission.

p. **Cooperative Study.** A cooperative study is a project or program of research or development conducted at two or more health care facilities using common protocol so that data obtained at all participating facilities can be treated as though from a single source.

q. **C for R&D.** The C for R&D is the individual responsible for coordination of research activities at facilities with insufficient activity to justify the position of ACOS for R&D. The position of C for R&D may be a part-time position and may be designated as a collateral function of another administrative position.

r. **Co-principal Investigator (co-PI).** A co-PI is one of two or more principal investigators who share equally in the accountability for a project.

s. **Copyright.** Copyright is a form of protection provided by the laws of the United States (Title 17, U.S.C.) to the authors of "original works of authorship" including literary, dramatic, musical, artistic, and other intellectual works, for a limited period of time. A copyright protects the form of expression, rather than ideas or the subject matter of the work. The copyright owner controls a number of exclusive divisible rights, the most fundamental one being the right to reproduce the work in copies.

t. **Data Security and Privacy.** Data Security and Privacy is the protection of confidential information, including technical procedures for maintaining the security and integrity of research data. Policies and procedures for protecting the confidentiality of information pertaining to and/or collected from participants in VA research and in VA research protocols, and the technical procedures for maintaining the security and integrity of research data will be addressed in VHA Handbook 1200.6 (to be published).

u. **Development.** Development is the application of research to practical ends with the intent of producing useful devices, products or techniques rather than the testing of concepts. It can involve non-routine evaluation of new or existing devices, products and techniques and may employ the scientific method. The output includes the initial formulation of products,

whether devices or techniques, correction of defective products, and improvement of existing products.

v. **Eligibility**: Eligibility is the right of an investigator to receive VA research support based on the investigator's VA employment status, physical presence, and professional commitment. The criteria for eligibility to receive research support from the ORD are described in VHA Handbook 1200.15.

w. **Ex officio member**: An ex-officio member is the individual who serves as a member of a committee by virtue of that individual's position. An ex officio member may be a voting or non-voting member.

x. **Extramural Funds**. Extramural funds are funds available to support VA research other than those specifically appropriated to VA by Congress. These funds may be provided by other federal agencies, state or local government agencies, non-profit corporations or foundations, charitable organizations, companies, or individual contributors.

y. **Extramural Research**. Extramural research is research performed by investigators not in the employ of VA, but who may be under contract with VA.

z. **Federal Policy for the Protection of Human Subjects (56 Federal Regulation 28.003 (June 18, 1991))**. This Federal Policy for the Protection of Human Subjects policy (also known as the Common Rule) sets forth the minimal requirements for the protection of human subjects involved in research conducted or funded by Federal Departments. VA has adopted the rule in regulatory form at 38 CFR Part 16.

aa. **Formal Communication**. Formal communication is correspondence or other written documents forwarded through proper channels and bearing approval signatures as appropriate.

bb. **Health services research**. Health services research is a multidisciplinary field concerned with the effects of social factors, financing systems, organizational structures and processes, technology, and human behavior on health care access, quality, costs, and outcomes. In VA, health services research focuses on understanding how to organize, deliver, and finance health care that is effective and cost-effective, in order to meet the needs of veterans and to ensure that their health care system is sound and consistently excellent. It emphasizes research that has practical applications and that can assist patients, health care providers, managers and policymakers.

cc. **Human Subject**. A human subject is an individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information. An intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes. Research involving human biological specimens (e.g., urine, blood, tissue, and other bodily fluids) and research involving identifiable data about living individuals is considered human subjects research (refer to VHA Handbook 1200.5 (to be published)).

dd. **Institutional Animal Care and Use Committee (IACUC)**. IACUC is the local committee charged with ensuring compliance with animal research regulations and guidelines. At VA medical centers, the IACUC is a subcommittee of the R&D Committee (refer to VHA Handbook 1200.7 (to be published)).

ee. **Institutional Review Board (IRB)**. The IRB is the local committee charged with the oversight of all research activities involving the use of human subjects. At VA medical centers, the IRB is a subcommittee of the R&D Committee (refer to VHA Handbook 1200.5 (to be published)).

ff. **Intellectual Property**. Intellectual property is any art, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States. Policy guidance and instructions regarding intellectual property and the transfer of new scientific discoveries to benefit the public good are contained in VHA Handbook 1200.18.

gg. **Interagency Agreement**. An Interagency Agreement is an agreement which allows a federal agency with authority to conduct a certain activity to contract with another agency or department, which has the capability to perform the required activity.

hh. **Intramural funds**. Intramural funds are funds appropriated by Congress to support VA research. These funds are allocated by ORD to support programs and projects at local facilities.

ii. **Intramural research**. Intramural research is research performed by VA employees or appointees (including those serving without compensation), at VA facilities and approved off-site locations.

jj. **Memorandum of Understanding (MOU)**. A MOU is a written agreement entered into by and between two or more parties to set forth the terms, conditions, and understandings of the parties with respect to a specific activity. For example, an MOU may be developed to delineate each party's responsibilities in collaborations between two or more federal agencies, or between a federal agency and a private entity.

kk. **Non-profit Research and Education Corporation**. A Non-profit Research and Education Corporation is a nonprofit corporation created pursuant to Sections 7361 and 7368 of Title 38, United States Code. These corporations exist solely to facilitate research and education at a VA medical center by acting as a flexible funding mechanism. Policies, procedures, and instructions governing nonprofit research and education corporations will be described in VHA Handbook 1200.17 (to be published).

ll. **Off-site research**: Off-site research is research performed in sites other than VA medical centers or VA leased space. Performance sites for off-site research must be approved in advance by the CRADO. Policies regarding off-site research are clarified in VHA Handbook 1200.16.

mm. **Patent.** A patent is an official written document securing to an inventor for a term of years the exclusive right to make, use or sell an invention.

nn. **Principal Investigator (PI).** A PI is an individual who actually conducts an investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

oo. **Program.** A program consists of one or more projects clearly related to one another. There is the program of an investigator or of a medical center as well as the program of cardiovascular research and CSP. A single project may be included in more than one program.

pp. **Project.** A project is a coherent unit of research or development that is proposed, pursued, and reported as a separate activity. Its scope is larger than that of a single experiment but may be smaller than that of an individual's scientific activity over a long period. As a unit, the project can be considered the work that will produce one or more published papers, formal reports, or completed devices or techniques.

qq. **Quorum.** A quorum is defined as a majority of the voting members. At meetings of the R&D Committee and its subcommittees, a quorum must be established and maintained throughout the entire meeting in order for business to be conducted. Some committees, such as the IRB, have additional requirements for the establishment of a quorum, such as the presence of a member whose primary concerns are in nonscientific areas. A member with a conflict of interest cannot contribute to a quorum.

rr. **R&D Committee.** The R&D Committee is the local committee charged with oversight of all R&D activities within a facility.

ss. **Rehabilitation Research.** Rehabilitation Research is the investigation of methods to advance optimal rehabilitation health care for veterans with disabilities.

tt. **Research.** Research is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question.

uu. **R&D.** R&D is the investigation and refinement of problems and hypotheses related to human health, diseases, defects, and handicaps, as well as the systematic study and refinement of problems and hypotheses related to the organization and delivery of health care.

vv. **Research Center Director.** The Research Center Director is the investigator who serves as the Principal Investigator of a Center of Excellence or other recognized VA R&D Center.

ww. **Research Misconduct.** Research misconduct is fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results. Policies and procedures for reporting, investigating, and resolving allegations of research

misconduct by VA employees will be addressed in VHA Handbook 1200.14 (to be published).

xx. **Subcommittee on Research Safety (SRS)**. The SRS is the local committee charged with ensuring compliance with all applicable regulations, policies, and guidelines pertinent to biological, chemical, physical, and radiation hazards, and with oversight of all research activities involving safety hazards. At VA medical centers, the SRS is a subcommittee of the R&D Committee (refer to VHA Handbook 1200.8 (to be published)).

yy. **VA Medical center (or VA Health Care Facility)**. A VA medical center (or VA health care facility) is a hospital or other health care facility within the VA system.

zz. **Without Compensation (WOC) Appointment**. A WOC appointment is a personnel appointment by which an individual contributes time to VA activities but receives no monetary compensation.

**REQUIREMENTS FOR THE PROTECTION OF  
HUMAN SUBJECTS IN RESEARCH**

**1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook prescribes procedures for the protection of human subjects in Department of Veterans Affairs (VA) research.

**2. SUMMARY OF MAJOR CHANGES:** VA is one of the seventeen Federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects (Common Rule), effective June 18, 1991 (56 Federal Register (FR) 28001). This policy is incorporated in Title 38 Code of Federal Regulations (CFR) Part 16. This Handbook defines the procedures implementing 38 CFR 16.

**3. RELATED ISSUES:** VHA Directive 1200.

**4. RESPONSIBLE OFFICIALS:** The Office of Research and Development (12) is responsible for the contents of this Handbook. Questions may be addressed to 202-254-0183.

**5. RESCISSIONS:** None.

**6. RECERTIFICATION:** This document is scheduled for recertification on or before the last working day of July 2008.

Robert H. Roswell, M.D.  
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 7/15/03  
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 7/15/03

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## REQUIREMENTS FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

### 1. PURPOSE

The Department of veterans Affairs (VA) is one of the seventeen Federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects (Common Rule), effective June 18, 1991 (56 Federal Register (FR) 28001). This policy is incorporated in Title 38 Code of Federal Regulations (CFR) Part 16. This Veterans Health Administration (VHA) Handbook defines the procedures implementing 38 CFR Part 16.

### 2. AUTHORITY

- a. Statutory provisions for protection of VA patient rights Title 38 United States Code (U.S.C.) Sections 501, 7331, and 7334.
- b. VA regulations pertaining to protection of patient rights; 38 CFR 17.33a and 17.34.
- c. VA regulations pertaining to rights and welfare of human subjects participating in research: 38 CFR 16 (Federal Policy for the Protection of Human Subjects).
- d. VA regulations pertaining to research related injuries: 38 CFR 17.85.
- e. Statutes and regulations pertaining to the release of patient information: 5 U.S.C. § 552a; 38 U.S.C. §§ 5701a, 7332; 45 C.F.R. Parts 160-164.
- f. VA regulations pertaining to hospital care for research purposes and outpatient care for research purposes: 38 CFR 17.45, 17.92.
- g. Department of Health and Human Services (DHHS) regulations pertaining to rights and welfare of human subjects participating in research supported by DHHS: 45 CFR 46.
- h. Food and Drug Administration (FDA) regulations pertaining to rights and welfare of human subjects participating in research involving investigational drugs and devices: 21 CFR Parts 11, 50, 54, 56, 312, 360.1, 600, 812, and 814.
- i. Nuclear Regulatory Commission (NRC) regulations pertaining to medical use of byproduct material and protection of human subjects: 10 CFR Parts 20 (Standards for Protection Against Radiation) and 35 (Medical Use of Byproduct Material).
- j. VA confidentiality of medical quality assurance records statute: 38 U.S.C. 5705.

### 3. DEFINITIONS

The following terms, some of which are found in 38 CFR 16.102 and 21 CFR Parts 50, 54, 56, 312, 314, 812, and 814, are defined more specifically for purposes of this Handbook.

a. **Adverse event (AE)**. An AE is defined as any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article. An AE does not necessarily have to have a causal relationship with the research, or any risk associated with the research or the research intervention, or the assessment.

(1) **Serious Adverse Event (SAE)**. A SAE is defined as death; a life threatening experience; hospitalization (for a person not already hospitalized); prolongation of hospitalization (for a patient already hospitalized); persistent or significant disability or incapacity; congenital anomaly and/or birth defects; or an event that jeopardizes the subject and may require medical or surgical treatment to prevent one of the preceding outcomes.

(2) **Unexpected Adverse Event (UAE)**. An UAE is any adverse event and/or reaction, the specificity or severity of which is not consistent with the informed consent, current investigator brochure or product labeling. Further, it is not consistent with the risk information described in the general investigational plan or proposal.

b. **Assurance**. An Assurance is also called an Assurance of Compliance, or a Federal-wide Assurance (FWA). It is a written commitment by an institution to protect human subjects participating in research. Under federal regulations, any institution conducting or engaged in federally supported research involving human subjects must obtain an Assurance in accordance with 38 CFR 16.103. **NOTE:** *All research conducted under VA auspices is considered to be Federally-supported.* This requirement also applies to any collaborating “performance site” institutions. Under 38 CFR 16.102(f), an institution is engaged in human subject research whenever its employees or agents: intervene or interact with living individuals for research purposes; or obtain, release, or access individually-identifiable private information for research purposes. Assurances are filed through the VA Office of Research Oversight (ORO) with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). The FWA replaces previous types of OHRP and VA assurances.

c. **Blinded**. A study design comparing two or more interventions in which the investigators, the subjects, or some combination thereof, do not know the treatment group assignments of individual subjects; it is sometimes called a masked study design.

d. **Exempt Research**. Exempt research is research determined by the Institutional Review Board (IRB) to involve human subjects only in one or more of certain minimal risk categories (38 CFR 16.101(b)). **NOTE:** *Refer to Appendix A for a detailed description of the minimal risk categories.*

e. **Expedited Review Procedures for Research**. Expedited research is research determined by the IRB to present no more than minimal risk to human subjects and involve only procedures

in certain specific categories. Minor changes to previously approved research during the period for which approval is authorized may also be approved through the expedited process (38 CFR 16.110(b)). **NOTE:** Refer to Appendix B for a detailed description of expedited research categories.

f. **Human Research Protection Program (HRPP).** An HRPP is a comprehensive system to ensure the protection of human subjects participating in research. The HRPP consists of a variety of individuals and committees such as: the Medical Center Director, Associate Chief of Staff (ACOS) for Research and Development (R&D), the Administrative Officer (AO) for R&D, compliance officers, etc., the R&D Committee, the IRB, other committees or subcommittees addressing human subjects protection (e.g., Biosafety, Radiation Safety, Radioactive Drug Research, Conflict of Interest), investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer) and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.

g. **Human Subject.** A human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information (38 CFR 16.102(f)). The definition provided in the Common Rule includes investigators, technicians, and others assisting investigators, when they serve in a "subject" role by being observed, manipulated, or sampled. As required by 38 CFR 16.102(f) an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes.

**NOTE:** The FDA definition of human subject differs according to the applicable regulation. See 21 CFR 812.3(p), 21 CFR 50.3(g), 312.3(b,) and 56.102(e).

h. **Institution.** In the context of this VHA Handbook, an institution is a VA medical center or integrated VA health care system and its satellite facilities including community-based outpatient clinics.

i. **Institutional Official (IO).** The IO is the Medical Center Director or Chief Executive Officer (CEO). The IO is the VA official responsible for ensuring that the HRPP at the facility has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official for all Assurances, and assumes the obligations of the institution's Assurance. The IO is the point of contact for correspondence addressing human subjects research with OHRP, FDA, and VA Central Office.

j. **Investigational Device.** As defined by the FDA, an investigational device is a device that is the object of a clinical study designed to evaluate the safety or effectiveness of the device (21 CFR 812.3(g)). Investigational devices include transitional devices (21 CFR 812.3(r)) that are objects of investigations. However, for the purposes of this VHA Handbook, an investigational device may be an approved device that is being studied for an unapproved use or efficacy.

k. **Investigational Drug.** An investigational drug is a drug or biological drug that is used in a clinical investigation. The FDA considers the term "Investigational New Drug (IND)" synonymous with investigational drug (21 CFR 312.3). However, for purposes of this VHA Handbook, an Investigational Drug may be an approved drug that is being studied for an unapproved or approved use in a controlled, randomized or blinded clinical trial.

l. **Investigational Device Exemption (IDE).** An IDE is an FDA-approval of the application for an exemption that permits an un-marketed device to be shipped for the purpose of doing research on the device. **NOTE:** See 21 CFR 812.1 and 812.2 for scope and applicability.

m. **Investigational New Drug (IND).** An IND used to refer to either an investigational new drug application or to a new drug that is used in clinical investigations. IND is synonymous with "Notice of Claimed Investigational Exemption for a New Drug."

**NOTE:** See 21 CFR 312.2(a)-(b) for applicability and exemptions.

n. **Investigator.** An investigator is an individual under the direction of the Principal Investigator (PI) who is involved in some or all aspects of the research project, including the: design of the study, conduct of the study, analysis and interpretation of the collected data, and writing of resulting manuscripts. An investigator must be either compensated by VA, be appointed to work without compensation (WOC), or may be an employee assigned to VA through the Intergovernmental Personnel Act (IPA) of 1970. The FDA considers an investigator and a PI to be synonymous.

o. **Ionizing Radiation.** Ionizing radiation is particles or rays with sufficient energy to cause the ejection of orbital electrons from absorber atoms. Ionizing radiation should be addressed within the protocol and the informed consent when its use is part of the research study. Ionizing radiation includes diagnostic and therapeutic procedures done for research purposes. Sources of radiation include: nuclear medicine, radiation therapy, and radiology.

p. **IRB.** An IRB is a board established in accordance with and for the purposes expressed in the Common Rule (38 CFR 16.102(g).) Within VHA, an IRB was formerly known as the Subcommittee on Human Studies. At VA medical centers, the IRB is a subcommittee of the R&D Committee.

q. **Legally Authorized Representative.** A legally authorized representative is an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For the purposes of this Handbook, a legally authorized representative includes not only a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian of the person, but also next-of-kin in the following order of priority unless otherwise specified by applicable state law: spouse, adult child (18 years of age or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older).

r. **Office of Research and Development (ORD).** ORD is the office within VA Central Office responsible for the overall policy, planning, coordination, and direction of research

activities within VHA. **NOTE:** *The Research Integrity Development and Education Program (PRIDE) is the program within ORD that is responsible for training, education, and policy development related to human subjects protection.*

s. **Office of Research Oversight (ORO)**. ORO is the primary VHA office for advising the Under Secretary for Health on all matters regarding compliance and oversight of research in the protection of human subjects, animal welfare, and research safety. ORO oversees investigations of allegations of research misconduct.

t. **Principal Investigator (PI)**. Within VA, a PI is an individual who conducts a research investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The FDA considers a PI and an investigator to be synonymous.

u. **Quorum**. A quorum is defined as a majority of the voting members as listed on the IRB membership. In the case of the IRB, a quorum must include at least one member whose primary concerns are in non-scientific areas. At meetings of the IRB, a quorum must be established and maintained for the deliberation and vote on all matters requiring a vote.

v. **Research**. Research is defined as the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. The Common Rule (38 CFR 16) defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. **NOTE:** *The FDA definition of research differs according to the applicable regulations; see 21 CFR 812.3(h), 21 CFR 50.3(c), 21 CFR 56.102(c), and 21 CFR 312.3(b).*

w. **Research Records**. Research records consist of IRB records as well as case histories (also referred to as investigator's research records) or any data gathered for research purposes.

(1) **IRB Records**. IRB records include but are not limited to: all minutes of IRB meetings, a copy of all proposals reviewed including all amendments, investigator brochures, any supplemental information including recruitment and informational materials, consent forms, information submitted for continuing review, all correspondence, and IRB membership with a resume for each member.

(2) **Case History**. A case history is a record of all observations and other data pertinent to the investigation on each research subject. An investigator is required to prepare and maintain adequate and accurate case histories. Case histories include the case report forms and supporting data including signed and dated consent forms, any medical records including, but are not limited to: progress notes of the physician, the individual's hospital chart(s), and nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.

x. **Researcher**. A researcher is the PI and/or investigator.

y. **Test Article.** For purposes of this VHA Handbook, a test article is a drug, device, or other article including a biological product used in clinical investigations involving human subjects or their specimens.

z. **VA-approved Research.** VA-approved research is research that has been approved by the VA R&D Committee.

#### 4. SCOPE

a. VA is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the Belmont report “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” regardless of who conducts the research or the source of support. VA is one of the seventeen Federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects (Common Rule), effective June 18, 1991, (see 56 Federal Register (FR) 28001). **NOTE:** *This policy is incorporated in 38 CFR Part 16.*

b. With the exception of categories listed in Appendix A, the provisions of this Handbook apply to all research involving human subjects that is conducted completely or partially in VA facilities, conducted in approved off-site locations, facilities, and/or conducted by VA researchers while on official VA duty time. The research may be VA funded, funded from extra-VA sources, or conducted without direct funding.

**NOTE:** *For policy and guidelines regarding off-site research, refer to VHA Handbook 1200.16, “Off-Site Research.”*

c. Investigators receiving support from other Federal agencies, such as the National Institutes of Health (NIH), must meet requirements for the protection of human subjects of the funding source in addition to those of VA.

d. Where FDA-regulated test articles are used, the FDA regulations apply regardless of funding source (21 CFR Parts 11, 50, 54, 56, 312, 314, 600, 812, and 814).

e. It is imperative that human research subjects receive the highest level of protection possible and that any questions or any legal or ethical ambiguities always be resolved in favor of the human research subject.

#### 5. MEDICAL CENTER DIRECTOR RESPONSIBILITIES

a. Every Medical Center Director is responsible for ensuring that:

(1) Each VA medical center conducting research involving human subjects has a systematic and comprehensive approach to ensure the protection of human subjects participating in VA-approved research. This system, also known as the HRPP, is composed of a number of individuals, offices, committees and/or subcommittees. The exact composition of the HRPP is dependent on the specific facility, the resources of the facility, and the size and complexity of the

research program at the facility. The medical center Director must ensure effective coordination by and among the various individuals, offices, and committees that comprise the HRPP.

(2) Every VA medical center conducting research involving human subjects or human biological specimens applies through ORO to DHHS, OHRP for an Assurance of Compliance and must obtain this Assurance prior to conducting any such research.

(3) Every VA medical center conducting research involving human subjects has an established or designated IRB. The medical center may secure the services of an OHRP registered IRB associated with another VA facility or VA regional IRB; or secure the services of an OHRP registered IRB established by an affiliated medical or dental school. Under exceptional circumstances a medical center may request a waiver from the Chief Research and Development Officer (CRADO) to utilize the services of an IRB within another Federal agency that is signatory to the Common Rule. The established or designated IRB of the VA facility is to be known as the IRB of record. If the IRB is established by the VA facility, it is a subcommittee of the R&D Committee.

(a) If the medical center chooses to use the services of an affiliated university IRB, or receives a waiver to use the IRB of another Federal agency, the VA's facility's interest must be adequately represented by the inclusion of two or more VA employees as voting members of the IRB on each IRB that reviews VA research. At least one of these members must have scientific expertise. The VA members must serve as full members of the IRB; this includes reviewing non-VA research matters coming before the IRB. At least one of the VA members of the IRB must be present during the review of VA research. *NOTE: Consideration needs to be given to the inclusion of a veteran or a representative of a legally-recognized veterans' organization, where appropriate.* If the university has more than one IRB, this provision applies only to the IRB(s) designated to review VA research.

(b) An IRB established by an affiliated medical or dental school that is serving as an IRB of record for a VA facility must agree to comply with the provisions of 38 CFR Part 16, and the provisions of this Handbook when reviewing VA research. The provision of services by the IRB must be established through a Memorandum of Understanding (MOU) or other written agreement that outlines the responsibilities of the VA and the affiliate.

(c) As part of its oversight responsibilities, the VA R&D Committee must have access to all IRB records and must review all minutes of the IRB(s) reviewing protocols of that VA facility. In addition when the affiliate university IRB is the IRB of record, at its discretion the research office may develop a file for each approved protocol and maintain a copy of the proposal with all amendments, copies of IRB communications, and the original consent form template in the file.

(d) If an IRB of another VA medical center is used, the R&D Committee of each VA must have access to all records of the IRB reviewing its protocols and must review all of the IRB's minutes. If the requesting VA medical center does not have an R&D Committee, the R&D Committee of the other VA medical center must agree to serve in that capacity and must also approve the protocols. The provisions of this agreement need to be established through an MOU or other written agreement that outlines the responsibilities of both VA medical centers.

(e) A VA facility may not engage the services of another IRB for the purposes of avoiding the rulings of the IRB of record.

(f) Each facility, including its IRB of record, must undergo an HRPP accreditation process by an organization approved by ORD to perform this function.

(g) The use of a commercial IRB is prohibited.

(4) Adequate administrative support, including personnel and space sufficient to provide privacy for conducting sensitive duties and storage of records, is provided for IRB activities. The VA medical center must also provide appropriate educational opportunities for IRB members and staff, and for researchers.

(5) Developing and monitoring procedures to ensure the safety of subjects in research either directly or by delegating the responsibility to other qualified VA staff.

(6) The local research office maintains accurate, up-to-date records regarding the mandatory training and credentialing of investigators and other appropriate research staff in the protection of human research subjects. *NOTE: This is required by ORD.*

b. The Director of every VA medical center conducting research involving human subjects is responsible for:

(1) Oversight of both the IRB and all VA investigators (compensated, WOC, or IPA);

(2) Assurance that IRB members and investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and all applicable regulations; and

(3) Development and implementation of an educational plan for IRB members, staff and investigators.

c. The Medical Center Director must be the IO for all assurances and must fulfill all educational requirements mandated by VA ORD, the facility's assurance, funding institutions, and OHRP.

## 6. IRB COMPOSITION

a. The IRB is responsible for ascertaining the acceptability of proposed research in terms of medical center commitments and policies, applicable law, validity of study design as it relates to risks and benefits, sensitivity to community standards and attitudes, as well as standards of professional conduct and practice. *NOTE: The IRB's composition plays a pivotal role in its ability to fulfill its role.*

b. Each IRB, whether that of the VA or the affiliate, must have at least five members with varied backgrounds to promote complete and adequate review of research activities commonly conducted by the institutions (VA and affiliate) for which it reviews research. The IRB members must be sufficiently qualified to review the research through their experience, expertise, and

diversity, including consideration of race, gender, cultural backgrounds, and sensitivity to community issues and/or attitudes. The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects; and possess the professional competence necessary to review specific research activities (38 CFR 16.107(a)).

c. In the appointment of IRB members, equal consideration must be given to qualified persons of both genders. No appointment to the IRB will be made solely on the basis of gender. Every non-discriminatory effort will be made to ensure that the IRB membership does not consist entirely of men or entirely of women (38 CFR 16.107(b)).

d. No IRB may consist entirely of members of one profession (38 CFR 16.107(b)).

e. Each IRB must include at least one member whose primary expertise is in scientific areas and at least one member whose primary expertise is in non-scientific areas (38 CFR 16.107(c)). These members are to be selected primarily to reflect the values of the research community and the community from which the research subjects are drawn with respect to the rights and welfare of human research subjects.

f. Each IRB must include at least one member who is not otherwise affiliated with the VA medical center and who is not part of the immediate family of a person who is affiliated with the medical center (38 CFR 16.107(d)). Members of the community such as clergy persons, teachers, attorneys, veterans, or representatives of legally-recognized veterans organizations, and practicing physicians need to be considered for appointments to the IRB.

g. No IRB may have a member participate in the review of any project in which the member has a conflict of interest, except to provide information requested by the IRB (38 CFR 107(e)).

h. An IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB (38 CFR 16.107(f)).

i. R&D administration officials including, but not limited to the ACOS for R&D and the AO for R&D, may not serve as voting members of the IRB. The ACOS for R&D, AO for R&D and/or a Research Compliance Officer may serve as non-voting members and must be sensitive to the occurrence or appearance of conflict of interest.

j. Alternate members may be formally appointed to the IRB. The IRB's written procedures must describe the appointment and function of alternate members, and the IRB roster must identify the primary member(s) for whom each alternate member may substitute. The alternate member's qualifications must be comparable to those of the primary member to be replaced. When an alternate member replaces the primary member, the alternate member must receive and review the same material that the primary member received. In addition, the IRB minutes must document instances in which an alternate member replaces a primary member.

k. IRB members and R&D Committee members need to forward names for consideration for new IRB members to the Medical Center Director. Other VA personnel may submit names to

the IRB or R&D committee to be forwarded to the Medical Center Director for consideration. The Medical Center Director must officially appoint members in writing.

l. Members of VA IRBs and VA representatives to affiliate IRBs must be appointed by the Medical Center Director for a period of 3 years and may be re-appointed indefinitely.

m. The IRB Chair of a VA IRB must be appointed by the Medical Center Director for a term of 1 year and may be re-appointed indefinitely.

## 7. IRB RESPONSIBILITIES AND AUTHORITY

All research involving human subjects must be reviewed either through full or expedited review. Research meeting the criteria for exempt research may be ruled exempt (see App. A). In all cases, each research proposal to be submitted to VA, other Federal agencies, or other sponsors for funding must first be approved by both the R&D Committee and the IRB, unless exempt from IRB review.

a. **IRB Authority and Review Criteria.** The IRB has the responsibility and authority to approve, require modifications (in order to secure approval), or disapprove all research activities covered by this Handbook regardless of whether the research is funded or non-funded. In order to approve research governed by this Handbook, the IRB must review the full proposal, the consent form and all supplemental information such as but not limited to the investigator's brochure and recruiting information. The IRB must determine that all of the following requirements are satisfied:

(1) **Minimization of Risks.** Risks, both physical and non-physical, to human subjects are minimized by: using procedures that are consistent with sound research design; that do not unnecessarily expose subjects to risk; and, whenever appropriate, using procedures already being performed on the subjects for diagnostic or treatment purposes. **NOTE:** *Consultation with subject matter experts and review by such committees or subcommittees as Biosafety, Radiation Safety and/or Radioactive Drug Research may be necessary to ensure risks to human subjects are minimized.*

(2) **Reasonable Risk Benefit Ratio.** Risks, both physical and non-physical, to human subjects are reasonable in relation to any anticipated benefits (the risk benefit ratio) to subjects, and the importance of the knowledge that may reasonably be expected to result. Validity of research design must be taken into consideration in determining the risk benefit ratio. In evaluating risks and benefits, the IRB needs to consider only those risks and benefits that may result from the research, as distinguished from risks and benefits the subjects would receive even if not participating in the research (38 CFR 16.111(a)(2)). The IRB must consider the risks and benefits related to both biomedical (including genetic) research and non-biomedical research. The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) **Equitable Selection of Subjects.** In assessing whether selection of subjects is equitable, the IRB needs to take into account the purposes of the research and the research setting. The

IRB needs to be particularly cognizant of the special problems of research involving vulnerable populations such as: children, prisoners, pregnant women, mentally disabled persons or persons with impaired decision-making capacity, and economically or educationally disadvantaged persons (see App. D).

#### **(4) Review and Approval of the Informed Consent Form**

(a) The IRB is responsible for the review and approval of the informed consent form prepared by the investigator; VA Form 10-1086, Research Consent Form, must be used. The wording on VA Form 10-1086 must contain all of the required elements and meet all other requirements outlined in Appendix C. If the wording of the informed consent has been initially prepared by an entity (e.g., a pharmaceutical company or a cooperative study group including National Cancer Institute (NCI) groups) other than the VA PI, the IRB needs to ensure that the wording of the consent meets all the requirements of, or has been reviewed by, the appropriate VA committees and subcommittees such as the Subcommittee on Research Safety and the Radiation Safety Committee. IRB approval of the wording of the consent must be documented through the use of a stamp on each page of the VA Form 10-1086 that indicates the date of the most recent IRB approval of the document. If the consent form is amended during the protocol approval period, the form must bear the approval date of the amendment rather than the date of the approved protocol.

(b) The IRB needs to ensure that the required language for a valid authorization to release health information (Health Insurance Portability and Accountability Act (HIPAA) Authorization) is included in the informed consent document. The IRB may waive the requirement for an authorization or may alter the form or content of the authorization only in accordance with and as permitted by the HIPAA Privacy Rule (45 CFR 164.508). Such actions and the justification for them must be fully documented in the minutes of the IRB meeting where the action was taken or reported (if approved by expedited review). **NOTE:** See *VHA Handbook 1605.1, regarding Privacy*.

#### **(5) Securing Informed Consent and Documentation of the Informed Consent Process.**

Informed consent must be sought from each prospective subject or the subject's authorized representative, in accordance with, and to the extent required by Appendix C. A person knowledgeable about the consenting process and the research to be conducted must obtain the informed consent. If someone other than the investigator conducts the interview and obtains consent, the investigator needs to formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity. It is the responsibility of the IRB to ensure that the informed consent process is appropriately documented. **NOTE:** *For detailed information regarding documentation requirements, refer to Appendix C.*

(6) **Monitoring Safety.** The research plan must make adequate provisions for monitoring the data collected to ensure the safety of subjects (38 CFR 16.111(a)(6)). The plan may include establishing a Data Safety and Monitoring Board (DSMB) or a Data Monitoring Committee (DMC) as required by DHHS or FDA policy, and a plan for reporting DSMB or DMC findings to the IRB. The IRB must review the data and safety-monitoring plan in the protocol developed by the investigator. In addition, for studies that do not have or are not required to have a DSMB or DMC and are blinded, have multiple sites, enter vulnerable populations, or employ high-risk

interventions, the IRB needs to carefully review the data and safety-monitoring plan. The plan needs to include procedures for reporting AEs.

(7) **Privacy and Confidentiality.** Adequate provisions must be taken to protect the privacy of subjects and to maintain the confidentiality of individually-identifiable data. Such provisions must consider the requirements of Standards for Privacy of Individually-Identifiable Health Information (HIPAA Privacy Rule), 45 CFR Parts 160 and 164, and other laws regarding protection and use of veterans' information, including Privacy Act of 1974, 5 U.S.C. 552a; VA Claims Confidentiality Statute, 38 U.S.C. 5701; Confidentiality of Drug Abuse, Alcoholism and Alcohol Abuse, Infection with Human Immunodeficiency Virus (HIV), and Sickle Cell Anemia Medical Records, 38 USC 7332; and Confidentiality of Healthcare Quality Assurance Review Records, 38 USC 5705.

(8) **Protection of Vulnerable Subjects.** The IRB must ensure that additional safeguards have been included in each study to protect the welfare of vulnerable subjects. The IRB needs to consider inclusion, as regular or ad hoc members, of one or more individuals who are knowledgeable about and experienced in working with these vulnerable subjects. **NOTE:** *Appendix D contains further information and requirements on the protection of vulnerable subjects.*

(9) **Conflict of Interest.** The IRB must ensure that steps to manage, reduce or eliminate potential or real conflicts of interest (financial, role (investigator/patient relationships), and/or institutional) have been taken. All VA investigators must comply with VHA policies and procedures regarding conflict of interest.

(10) **Investigator's Educational Requirements and Certification.** The IRB must determine that the PI and all other investigators of the proposed research activity have met all current educational requirements for the protection of human research subjects as mandated by the facility's Assurance, VA ORD, funding institutions, and applicable OHRP requirements. The IRB must also determine that the investigator(s) is qualified through education, training, and experience to conduct the research.

b. **Initiation of Research Projects.** All proposed research involving human subjects must be reviewed and approved by the IRB and the R&D Committee prior to initiation of the research project. The date of continuing review will be based on the date of IRB approval. **NOTE:** *The R&D committee may not approve the research until all other appropriate subcommittees of the R&D committee and other committees (e.g., Biosafety, Radiation Safety) have reviewed the research.*

(1) If the IRB approves research contingent upon substantive modifications or clarifications to the protocol and/or the informed consent, IRB approval of the proposed research must not occur until subsequent review by the convened IRB of the material the PI submitted.

(2) If the convened IRB approves research contingent on specific minor conditions, the IRB Chair, or another IRB member designated by the Chair, may approve the revised research protocol on behalf of the IRB. The date of approval is the date the fully-convened IRB approved the protocol rather than the date that the minor changes were approved by the IRB Chair, or

designee. The research may not begin until the IRB Chair, or designee, has approved the changes and the R&D Committee has approved the research. The approval by the Chair, or designee, must be documented in the minutes of the first IRB meeting that takes place after the date of the approval.

c. **Communication with Investigators**

(1) An IRB must notify the PI and the R&D Committee in writing of its decision to approve or disapprove a proposed research activity, or of modifications required to secure IRB approval. An IRB-approved research activity may be disapproved by the R&D Committee, the medical Center Director, or the ORD. If a research activity is disapproved by the IRB, the decision cannot be overruled by the R&D Committee, or any higher authority. The R&D Committee and higher authority may strengthen requirements and/or conditions, or add other modifications to secure R&D approval or approval by a higher authority. Previously approved research proposals and/or consent forms must be re-approved by the IRB before initiating the changes or modifications.

(2) Along with written notification of approval, a copy of the approved consent form containing the stamped approval and date of the approval on each sheet must be sent to the investigator and must be filed in the protocol files maintained by the IRB or the facility research office.

(3) If the IRB disapproves a research activity, it must include a statement of the reasons for its decision in its written notification to the investigator and give the investigator an opportunity to respond in person or in writing.

(4) If the IRB conducts or receives a report of any internal audits of an investigator's research files, the IRB must notify the investigator of any findings that require changes.

d. **Maintaining Written Procedures for Operations**. The IRB must establish written procedures for, but not limited to:

(1) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the R&D Committee.

(2) Determining which projects require review more often than annually and which projects need verification from sources, other than the investigator, that no material changes have occurred since previous IRB review.

(3) Ensuring that investigators promptly report proposed changes in a research activity including amendments to the protocol, or the consent form, to the IRB, and ensuring that such changes in approved research are not initiated without the IRB's review and approval, except when necessary to eliminate apparent immediate hazard to the subject.

(4) Reporting promptly to the IRB regarding non-compliance by study personnel.

(5) Notifying medical center officials and VA Central Office of any AEs that cause harm or risk of harm to human subjects or groups as required by this Handbook, other VA policies, or Federal regulations; any instance of serious or continuing noncompliance with this Handbook or the requirements of determinations of the IRB; and suspension or termination of IRB approval.

(6) Reporting any AE as required by VA and Federal policy and regulations.

(7) Termination and/or suspension of IRB approval.

(8) Observing the informed consent process when the IRB determines it to be appropriate.

(9) Conducting audits of protocols and other IRB activities.

(10) Ensuring that initial and continuing education requirements for the IRB Chair, IRB members, and IRB alternate members are met.

(11) Notifying members of expedited reviews and decisions about exemptions.

(12) Reporting to the Privacy Officer any unauthorized use, loss, or disclosure of individually-identifiable patient information.

(13) Reporting violations of VA information security requirements to the appropriate VHA Information Security Officer.

e. **Auditing Recurring Processes.** The IRB has the authority to:

(1) Conduct audits of recurring processes to be sure that all written procedures are followed,

(2) Review research records and research case histories for compliance with written procedures and regulations contained in this Handbook;

(3) Monitor the informed consent process and the research; and

(4) Consider results of audits conducted by other entities within the institution.

f. **Obtaining a Quorum for Review.** Except when an expedited review procedure is used (see App. B), the IRB must review proposed research at convened meetings at which a quorum is present, including at least one member whose primary concern is in a non-scientific area. In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

(1) A quorum must be maintained for each vote to occur. If research involving an FDA-regulated article is involved, a licensed physician must be included in the quorum. If a quorum is not maintained, the proposal must be tabled or the meeting must be terminated.

(2) It is strongly recommended that IRB members be physically present at the meeting. If physical presence is not possible, a member may be considered present if participating through

teleconferencing or videoconferencing. In this case the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions.

g. **Monitoring On-going Projects.** An IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. The IRB has the authority to observe or have a third party observe the consent process.

(1) The investigator must submit to the IRB a written progress report that includes:

(a) Brief summary of the research methodology and procedures;

(b) Number of subjects entered and withdrawn (including the reason for withdrawal) for the review period and since the inception of the research project;

(c) The gender and minority status of those entered into the protocol;

(d) Number of subjects considered as members of specific vulnerable populations;

(e) A copy of the proposal and all approved amendments;

(f) A copy of the current consent document for the IRB to review;

(g) A copy of the current HIPAA Authorization document, if separate from the informed consent;

(h) Information that may impact on the risk benefit ratio such as AEs, unanticipated problems, and complaints regarding the research;

(i) Research findings to date, if available;

(j) Summary of the DSMB or DMC meetings (if applicable) or findings based on information collected by the data and safety monitoring plan submitted in the initial proposal;

(k) An assurance that all SAEs and UAEs have been reported as required; and

(l) New scientific findings in the literature, or other relevant findings, that may impact on the research.

(2) If the continuing review does not occur within the timeframe set by the IRB, the research is automatically suspended. The local research office is responsible for promptly notifying the PI of the suspension.

**NOTE:** For suspended research, enrollment for new subjects cannot occur; continuation of research interventions or interactions in already enrolled subjects should only continue when the IRB or IRB Chair, in consultation with the Chief of Staff (COS), finds that it is in the best interest of individual subjects to do so.

(a) Once notified of the suspension, the PI must immediately submit to the IRB Chair, a list of research subjects for whom suspension of the research would cause harm. The IRB Chair, with appropriate consultation with the COS, determines if the subject may continue in the research.

(b) If the study is FDA-regulated, the COS and IRB Chair must follow FDA requirements in 21 CFR 56.108(b)(3) in making their decision.

(c) The sponsoring agency, private sponsor, ORD, ORO, or other Federal agencies must be informed, as appropriate.

(d) Once suspended, IRB review and re-approval must occur prior to re-initiation of the research.

h. **Amendments.** All amendments to the project or changes in the informed consent must be reviewed and approved by the IRB prior to initiating the changes, except when necessary to eliminate immediate hazard(s) to the subject(s). If the amendment addresses an issue related to biosafety or radiation safety, the appropriate committee or subcommittee must first approve the amendment.

i. **IRB Records.** The IRB must prepare and maintain adequate documentation of the IRB's activities including, but not limited to the following:

(1) Copies of all items reviewed, including, but not limited to: research proposals, investigators' brochures and recruitment materials; scientific evaluations (if any) that accompany the proposals; approved consent documents; approved HIPAA Authorization document, if separate from the informed consent, any proposed amendments and the IRB action on each amendment; progress reports submitted by investigators; reports of injuries to subjects and serious and unexpected adverse events; documentation of protocol violations; and documentation of non-compliance with applicable regulations.

(2) Minutes of an IRB Meeting. Proceedings must be written and available for review within 3 weeks of the meeting date. Once approved by the members at a subsequent IRB meeting, the minutes must not be altered by anyone including a higher authority. Minutes of IRB meetings must contain sufficient detail to show:

(a) The presence of a quorum throughout the meeting including the presence of one member whose primary concern is in a non-scientific area.

(b) Attendance at the meetings including those members or alternate members who are participating through videoconference or teleconference and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions.

(c) Alternate members attending the meeting and for whom they are substituting.

(d) Actions taken by the IRB including those involving full review. The IRB may choose to use the minutes to notify IRB members of actions taken through expedited review and those studies that have been determined to be exempt from IRB review.

*NOTE: These required notifications may be carried out through other mechanisms.*

(e) Documentation of the four required findings (36 CFR 16.116(d)) when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain an informed consent.

(f) The vote on actions including the number of members voting for, against, and abstaining.

(g) A note indicating that when an IRB member has a real or potential conflict of interest relative to the proposal under consideration, that the IRB member was not present during the deliberations or voting on the proposal (and that the quorum was maintained).

(h) The basis for requiring changes in or disapproving research and documentation of resolution of these issues when resolution occurs.

(i) A written summary of the discussion of controverted issues and their resolution;

(j) Review of additional safeguards to protect vulnerable populations if entered as study subjects when this is not otherwise documented in IRB records;

(k) The determination of the level of risk, if not recorded elsewhere in IRB records.

(l) The frequency of continuing review of each proposal as determined by the IRB if not recorded elsewhere in IRB records.

(m) Documentation, as required by 45 CFR 164(i)(2), indicating the approval of a waiver or alteration of the HIPAA Authorization.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and investigators, and the R&D Committee.

(5) A membership list of IRB members must be maintained; it needs to identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list needs to contain information such as a member's name, earned degrees, affiliated or non-affiliated status, status as scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist); voting status, alternate status, or status as chairperson. A resume for each IRB member needs to be maintained.

(6) Statements of significant new findings provided to subjects (as required by App. C) must be maintained with the related research proposal and, when reviewed at an IRB meeting, must be documented in the minutes.

j. **Record Retention.** The required records, including the investigator's research records, must be retained for a minimum of 5 years after the completion of the study and in accordance with VHA's Records Control Schedule (RCS 10-1), applicable FDA and DHHS regulations, or as required by outside sponsors.

(1) All records must be accessible for inspection and copying by authorized representatives of VA, OHRP, FDA and other authorized entities at reasonable times and in a reasonable manner.

(2) Records are the property and the responsibility of the local research office. The medical center must designate where the records will be maintained and/or stored.

(3) Complete (non-redacted) minutes, whether from the VA or affiliate IRB reviewing VA research, must be submitted to the R&D Committee and maintained in the facility research office. The R&D Committee must review and act upon all IRB minutes regardless whether the IRB is established at the medical center or at the affiliate university.

## 8. RESEARCH EXEMPT FROM THE PROVISIONS OF THIS HANDBOOK

a. **Exempt Categories.** Research activities in which the only involvement of human subjects will be in one or more of the minimal risk categories listed in Appendix A are exempt from the provisions of this Handbook.

b. **Approval of Exempt Category.** Investigators must submit the proposed research and the request for exemption to the IRB. The IRB Chair, or an IRB member designated by the Chair, must review all requests for exemption in a timely manner, make a determination based on 38 CFR 16.101, and record the decision. The decision must be communicated in writing to the investigator and the IRB. Documentation must include the specific categories justifying the exemption. Projects that are exempt from IRB review must be reviewed by the R&D Committee prior to initiation and then they must be included in its annual review of research projects.

## 9. EXPEDITED REVIEW

a. **Circumstances for Expedited Review.** An IRB may use the expedited review process to review:

(1) Any of the categories of research described in Appendix B and found by the reviewer(s) to involve no more than minimal risk.

(2) Minor changes in previously approved research during the period for which approval is authorized. If approved, the continuing review date does not change, but remains the same as determined at the most recent review. ***NOTE: If the change involves biosafety or ionizing radiation, the appropriate committee must be consulted prior to approving the change; the consultation with these committees must be documented in the IRB file.***

(3) Waiver or alteration of authorization for the use and/or disclosure of Protected Health Information (PHI) (see HIPAA Authorization).

b. **Procedures for Expedited Review.** In the expedited review process, the IRB Chair may carry out the review or delegate the review to one or more experienced reviewers from among IRB members.

(1) In reviewing the research, the reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after review in accordance with the full-review procedure.

(2) If a proposal has been initially approved through the full-review procedure, the continuing review may not be done by the expedited review procedure. *NOTE: Exceptions may be found in Appendix B, subparagraphs 2h(1)-(3).*

(3) The decision must be recorded and then communicated in writing to the investigator and the IRB.

c. **Record Keeping.** Each IRB that uses an expedited review process must adopt a method for keeping all members advised of research proposals that have been approved under this process. The minutes and/or the protocol file must reflect the expedited review eligibility category that the research meets.

d. The IRB approval is effective only after approval by the R&D Committee; therefore work on the research may not commence until R&D Committee approval is obtained. The date of continuing review is based on the date of IRB approval. *NOTE: Refer to subparagraph 7b for information on commencement of research.*

## 10. INVESTIGATOR RESPONSIBILITIES

a. The investigator must have the appropriate training and be credentialed to conduct research involving human subjects by a program that meets all VA requirements.

b. The investigator must develop a research plan that is scientifically valid, minimizes risk to the subjects, and contains a description of the data and safety monitoring plan that includes the reporting mechanism of AEs to the IRB, and when required to ORO, ORD, and other Federal agencies or sponsors. The plan may vary depending on the potential risks, complexity, and nature of the study. A DSMB or DMC needs to be part of the monitoring plan when required by NIH or FDA. The use of a DSMB or DMC needs to be considered if there are multiple clinical sites, the study is blinded, interventions are particularly high-risk, or vulnerable populations are included.

c. Investigators involving human beings as subjects in research must obtain

(1) Legally effective informed consent of the subject or the subject's legally authorized representative; and

(2) Legally effective authorization for the use and disclosure of the subject's PHI.

d. If someone other than the investigator conducts the interview and obtains consent, the investigator should formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity. The most recently IRB approved consent form must be used. **NOTE:** *The basic elements of informed consent are described in Appendix C.*

e. The informed consent must be documented in accordance with Appendix C of this Handbook.

f. SAE and/or UAE must be reported to the IRB and other required entities. If a DSMB or DMC is used, all events must be reported to the DSMB or DMC and a summary of the DSMB or DMC findings must be reported to the IRB and other entities as required. Other AEs, as defined by the monitoring plan in the protocol, must be reported in accordance with the monitoring plan approved by the IRB and as defined in FDA regulations, or other applicable Federal regulations.

g. All amendments to, or modification of, the research proposal including the consent form must be approved by the IRB prior to initiating the changes except when necessary to eliminate apparent immediate hazards to the subject.

h. The investigator is responsible for obtaining initial and continuing IRB review and approval and for submitting to the IRB requests for modifications to the protocol. The investigator is expected to know the date of the continuing review and to be aware that the project is automatically suspended when the continuing review does not occur on schedule.

i. If the investigator leaves the VA facility the original research records must be retained at the institution.

j. If the investigator requires a waiver or alteration of the HIPAA Authorization, the investigator must provide the IRB with information sufficient for the IRB to find that such waiver or alteration is necessary. The IRB must document its decision in its minutes. **NOTE:** *The elements of such documentation are listed in Appendix E and may be used by an investigator to determine what information needs to be provided to the IRB with a request.*

## 11. RESEARCH INVOLVING HUMAN SUBJECTS WITH SURROGATE CONSENT

a. Under appropriate conditions, investigators may obtain consent from the legally authorized representative of a subject (surrogate consent).

(1) This policy is designed to protect human subjects from exploitation and harm and, at the same time, make it possible to conduct essential research on problems that are unique to persons who are incompetent, or who have an impaired decision-making capacity (e.g., a study of treatment options for comatose persons can only be done with incompetent subjects).

(2) Such consent may be obtained from: a health care agent appointed by the person in a DPAHC or similar document; court-appointed guardians of the person, or from next-of-kin in the

following order of priority, unless otherwise specified by applicable state law: spouse, adult child (18 years or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older). **NOTE:** *The preceding list contains the only surrogate entities who are allowed to provide consent for research purposes.*

(3) Such consent may be requested and accepted only when the prospective research participant is incompetent or has an impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note. The determination must be made in accordance with the following requirements in subparagraphs 11a(3)(a-d), or as established by a legal determination. **NOTE:** *The consent requirements described in this Handbook are not intended to preempt any applicable Federal, State or local laws that require additional information to be disclosed for the informed consent to be legally effective in accordance with 38 CFR 16.116(e).*

(a) The practitioner, in consultation with the chief of service, or COS, may determine after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.

(b) Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research subject lacks decision-making capacity is based on a diagnosis of mental illness.

(c) Disclosures required by this Handbook to be made to the subject by the investigator must be made to the subject's surrogate.

(d) If feasible, the practitioner must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study.

b. Before an incompetent person or persons with impaired decision-making capacity may be considered for participation in any VA research, the IRB must find that the proposed research meets all of the conditions contained in Appendix D, paragraph 6.

## 12. PAYMENT FOR SUBJECTS

a. VA policy prohibits paying human subjects to participate in research when the research is integrated with a patient's medical care and when it makes no special demands on the patient beyond those of usual medical care. Payment may be permitted, with IRB approval, in the following circumstances:

(1) **No Direct Subject Benefit.** When the study to be performed is not directly intended to enhance the diagnosis or treatment of the medical condition for which the volunteer subject is being treated, and when the standard of practice in affiliated non-VA institutions is to pay subjects in this situation.

(2) **Others Being Paid.** In multi-institutional studies, when human subjects at a collaborating non-VA institution are to be paid for the same participation in the same study at the same rate proposed.

(3) **Comparable Situations.** In other comparable situations in which, in the opinion of the IRB, payment of subjects is appropriate.

(4) **Transportation Expenses.** When transportation expenses are incurred by the subject that would not be incurred in the normal course of receiving treatment and which are not reimbursed by any other mechanism.

b. Prospective investigators who wish to pay research subjects must in their proposal:

(1) Substantiate that proposed payments are reasonable and commensurate with the expected contributions of the subject;

(2) State the terms of the subject participation agreement and the amount of payment in the informed consent form; and

(3) Substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure or influence on the perspective research subjects to volunteer for, or to continue to participate in, the research study; and that the payments do not constitute (or appear to constitute) coercion to participate in, or continue to participate in, the research study.

c. The IRB and R&D Committee must review all proposals for payment of subjects to ensure conformity with VA policies.

d. The facility research office is responsible for ensuring that IRB-approved payment to subjects is made from a VA approved funding source for research activities.

### **13. USE OF VA RECORDS FOR RESEARCH AND DEVELOPMENT**

a. VA personnel are bound by all legal and ethical requirements to protect the rights of human subjects, including the confidentiality of information that can be identified with a person.

b. Obtaining and using medical, technical, and administrative records from other VA facilities or VA databases (national, regional, or subject specific) for R&D purposes must be in compliance with all VHA regulations and with the Standards for Privacy of Individually-Identifiable Health Information (45 CFR Parts 160 and 164). Obtaining and disclosing individually-identifiable patient records must be in compliance with all applicable and confidential statues and regulations including those discussed in subparagraph 7a(7).

c. Persons not employed by VA can be given access to medical and other VA records for R&D purposes only within the legal restrictions imposed by such laws as the Privacy Act of 1974 and 38 U.S.C. Requests for such use must be submitted to the CRADO in VA Central Office at least 60 days before access is desired. Requests for information filed pursuant to the

Freedom of Information Act ordinarily requires a response within 10 working days. VA guidelines and policy must be followed when making such requests to allow for a timely reply. This does not apply to those individuals having access for the purpose of monitoring the research. Obtaining and using the records must be in compliance with all VHA regulations and with the Standards for Privacy of Individually-Identifiable Health Information (45 CFR Parts 160 and 164).

#### **14. INVESTIGATIONAL DRUGS IN RESEARCH WITH HUMAN SUBJECTS**

Use of investigational drugs must be conducted according to FDA IND regulations, 21 CFR Part 312, and other applicable FDA and VA regulations.

- a. The use of drugs in research must be carried out in a responsible manner. The storage and security procedures for drugs used in research must follow all Federal rules, regulations, and laws regarding controls and safety that pertain in ordinary clinical situations.
- b. An investigational drug for clinical research use is one for which the PI or a sponsor has filed an IND application (21 CFR Part 312). Pursuant to these regulations an IND application goes into effect 30 days after FDA receives the application (unless the investigations described in the IND application are subject to clinical hold), or on earlier notification by FDA that the clinical investigation may begin (21 CFR 312.40). For purposes of this Handbook, an investigational drug is also defined as an approved drug that is being studied for an unapproved or approved use in a controlled, randomized, or blinded clinical trial.
- c. The PI is responsible for informing Pharmacy Service that IRB and R&D Committee approval has been obtained. This must be through the use of VA Form 10-1223, Report of Subcommittee on Human Studies, to be sent to Pharmacy Service. VA Form 10-9012, Investigational Drug Information Record, or superseding forms must be provided to the pharmacy by the PI as required in VHA Manual M-2, Part VII, Chapter 6, or superseding policy document. In addition a signed copy of VA Form 10-1086, must be sent to Pharmacy Service to document each subject's consent to participate in the study.
- d. The PI must inform the Chief, Pharmacy Service, and the R&D Committee when a study involving investigational drugs has been terminated.
- e. All applicable requirements in M-2, Part VII, Chapter 6, or superseding policy document must be met.
- f. FDA regulations provide for exceptions to the general requirements for obtaining informed consent under two specific situations:

(1) When the human subject is confronted by a life-threatening situation necessitating the use of the drug, when a legally effective informed consent cannot be obtained from the subject, when time is not sufficient to obtain consent from the subject's legally-authorized representative, and when there is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject (21 CFR. § 50.23(a).

(2) If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject and time is not sufficient to obtain the independent determination required in 21 CFR § 50.23(a) in advance of using the drug (21 CFR § 50.23(b)).

g. FDA regulations (21 CFR 312.34 and 312.35) address the treatment use of an investigational drug (not approved for marketing, but under clinical investigation for a serious or immediately life-threatening disease condition) in patients for whom no comparable or satisfactory alternative drug or other therapy is available. Use of the investigational drug for this purpose must meet all applicable FDA requirements.

h. FDA regulations at 21 CFR 312.34, 312.35, and 312.36 address the need for an investigational drug to be used in an emergency situation that does not allow time for submission of an IND. The FDA may authorize shipment of the drug for a specific use in such a circumstance in advance of submission of an IND. Prospective IRB review is required unless the conditions for exemption are met (21 CFR 56.104(c) and 56.102(d)). Informed consent is required unless the conditions for exemption are met (21 CFR 50.23). All applicable regulations must be met including those at 21 CFR Parts 50 and 56, and 21 CFR 312.34 and 312.35.

i. **Emergency Exemption from Prospective IRB Approval.** FDA defines emergency use as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval. If all conditions described in 21 CFR 56.102(d) exist then the emergency exemption from prospective IRB approval found at 21 CFR 56.104(c) may be utilized. Informed consent is required unless the conditions for exemption are met. The IRB must be notified within 5 working days when an emergency exemption is used. Any subsequent use of the test article at the institution is subject to IRB review.

## 15. INVESTIGATIONAL DEVICES IN RESEARCH WITH HUMAN SUBJECTS

Use of an investigational device in a clinical trial to obtain safety and effectiveness data must be conducted according to FDA's IDE regulations, 21 CFR Part 812, other applicable FDA regulations, and applicable VHA regulations.

a. The IRB reviewing investigational medical device protocols must have written procedures for: conducting the reviews, determining if the device represents a "significant risk," and reporting findings to the investigator.

b. If the study of the device is not exempt (21 CFR 812.2(c)), the device must be characterized as "significant risk" (SR) or "non-significant risk" (NSR) by the IRB. The IRB must determine and document if the device represents SR or NSR. **NOTE:** See *FDA Information Sheets, 1998, for lists of SR and NSR devices or the FDA web site ([www.FDA.gov](http://www.FDA.gov)).*

c. SR device studies must be conducted in accordance with the full IDE requirements (21 CFR Part 812). Pursuant to these regulations, an investigation may begin 30 days after FDA receives the application (unless FDA provides notification that the investigation may not begin), or after the FDA approves, by order, an IDE for the investigation (21 CFR 812.30). In addition, the investigator must have approvals from the IRB and R&D committee. The FDA considers all SR studies to be greater than minimal risk.

*NOTE: The IRB needs to verify the existence of the IDE when applicable.*

d. NSR device studies do not require submission of an IDE application, but must be conducted in accordance with the “abbreviated requirements” of the IDE regulations (21 CFR 812.2(b)).

*NOTE: NSR devices may represent greater than minimal risk depending upon the research study.*

e. Unless otherwise notified by the FDA, a NSR study is considered to have an approved IDE if all abbreviated requirements are fulfilled.

f. The IRB must review the research in accordance with these requirements and needs to use the same criteria it would use in considering approval of any research involving an FDA-regulated product (21 CFR 56.111).

g. NSR device studies may commence immediately following IRB and R&D Committee approval, if no changes are required by either committee.

h. The VA facility must have procedures for receipt, control, custody, and dispensing of the investigational devices.

i. The PI is responsible for compliance with all applicable FDA regulations.

j. Emergency use of unapproved devices must follow FDA guidance.

## **16. PARTICIPATION OF NON-VETERANS AS RESEARCH SUBJECTS**

a. Non-veterans may be entered into VA-approved research studies only when there are insufficient veterans available to complete the study in accordance with 38 CFR 17.45 and 38 CFR 17.92.

b. All regulations pertaining to the participation of veterans as research subjects including requirements for indemnification in case of research-related injury pertain to non-veteran subjects enrolled in VA-approved research.

## CATEGORIES OF EXEMPT RESEARCH

1. Research activities in which the only involvement of human subjects will be in one or more of the following categories may be exempt from review by the Institutional Review Board (IRB) unless otherwise required by the IRB. Guidance on research that may be exempt, but includes vulnerable populations such as children or prisoners may be found in Appendix D. The exempt status must be approved by the IRB Chair or an IRB member designated by the Chair. When research is determined to be exempt the IRB and the Research and Development (R&D) Committee must be notified and the exemption documented in the IRB records.

*NOTE: Research involving prisoners or focused on pregnant women may not be exempt. There are restrictions on the use of exemption for research involving children.*

2. The exempt categories, as stated in Title 38 Code of Federal Regulations (CFR) 16.101(b), are:

a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

(1) Research on regular and special education instructional strategies, or

(2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless:

(1) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(2) Any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. *NOTE: The Department of Veterans Affairs (VA) also includes loss of insurability in this category.*

c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under preceding subparagraph 2b, if:

(1) The subjects are elected or appointed public officials or candidates for public office, or

(2) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information must be maintained throughout the course of research and thereafter.

d. Research involving the use or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers linked to the subjects.

e. Research and demonstration projects that are conducted by, or subject to, the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under such programs, possible changes in or alternatives to such programs, and possible changes in methods or levels of payment for benefits or services under such programs.

*NOTE: The determination of exempt status for these research and demonstration projects must be made by the Under Secretary for Health on behalf of the Secretary of Veterans Affairs, after consultation with Office of Research and Development, the Office of Research Oversight, the Office of General Counsel, and other experts, as appropriate.*

f. Taste and food quality evaluation and consumer acceptance studies as defined in 38 CFR 16.101(b).

## ACTIVITIES APPROPRIATE FOR EXPEDITED REVIEW

Research activities included in paragraph 2 may be reviewed by an expedited review process, unless otherwise required by the Institutional Review Board (IRB). (Authority: Title 45 Code of Federal Regulations (CFR) 46.110, 38 CFR 16.110, and 21 CFR 56.110.) The following is extracted from 63 FR 60364-60367, November 9, 1998, "Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure." **NOTE:** *An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 38 CFR 16.110.*

### 1. Applicability

a. The following research activities are appropriate for expedited review:

(1) Research that presents no more than minimal risk to human subjects, and

(2) Research that involves only procedures described in paragraph 2. The research activities should not be considered of minimal risk merely because of their inclusion in paragraph 2. Inclusion on this list of research activities means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

b. The expedited review process may not be used when identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability; or be damaging to the subject's financial standing, employability, insurability, and/or reputation; or be stigmatizing, unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.

c. The expedited review process may not be used for classified research involving human subjects.

d. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply to expedited review.

e. The research categories appropriate for expedited review pertain to both initial and continuing IRB review.

### 2. Research Categories

a. Clinical studies of drugs and medical devices, only when one of the following conditions is met.

(1) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.

*NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.*

(2) Research on medical devices for which an investigational device exemption application (21 CFR Part 812) is not required; or the medical device is cleared and/or approved for marketing and the medical device is being used in accordance with its cleared and/or approved labeling.

b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(1) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 milliliters (ml) in an 8-week period and collection may not occur more frequently than 2 times per week; or

(2) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than two times per week. *NOTE: Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" see 45 CFR 46.402(a). Source: 63 Federal Register (FR) 60364-60367, November 9, 1998. VA does not conduct research-involving children as subjects unless a waiver has been obtained from the CRADO (see App. D).*

c. Prospective collection of biological specimens for research purposes by noninvasive means. Examples are as follows:

(1) Hair and nail clippings in a non-disfiguring manner.

(2) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction.

(3) Permanent teeth if routine patient care indicates a need for extraction.

(4) Excreta and external secretions (including sweat).

(5) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue.

(6) Placenta removed at delivery.

(7) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.

(8) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(9) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.

(10) Sputum collected after saline mist nebulization.

d. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. **NOTE:** For VA approved research, the term x-rays as used in this Appendix means ionizing radiation as defined in paragraph 3 of this Handbook. Where medical devices are employed, they must be cleared and/or approved for marketing. **NOTE:** Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples of procedures eligible for expedited review are:

(1) Physical sensors that are applied either to the surface of the body or at a distance, and do not involve input of significant amounts of energy into the subject, or an invasion of the subject's privacy.

(2) Weighing or testing sensory acuity.

(3) Magnetic resonance imaging.

(4) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.

(5) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). **NOTE:** Some research in this category may be exempt from the VA regulations for the protection of human subjects (38 CFR 16.101(b)(4)). This listing refers only to research that is not exempt.

f. Collection of data from voice, video, digital, or image recordings made for research purposes.

g. Research on individual or group characteristics or behavior (including, but not limited to, research on: perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

*NOTE: Some research in this category may be exempt from the VA regulations for the protection of human subject (38 CFR 16.101(b)(2) and (b)(3)). This listing refers only to research that is not exempt.*

h. Continuing review of research previously approved by the convened IRB as follows:

(1) Research in which the enrollment of new subjects is permanently closed; all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or

(2) Research in which no subjects have been enrolled and no additional risks have been identified; or

(3) Research in which the remaining research activities are limited to data analysis.

i. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (listed in subpars. 2b through 2h of this App.) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

## THE INFORMED CONSENT

1. **General Requirements for Informed Consent.** An investigator may not involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the person or the person's legally authorized representative. If someone other than the investigator conducts the interview and obtains consent from a patient, the investigator needs to formally delegate this responsibility, and the person so delegated must have received appropriate training to perform this activity. The person so delegated must be knowledgeable about the research to be conducted and the consenting process, and must be able to answer questions about the study.

*NOTE: This policy does not apply to research ruled exempt from Institutional Review Board (IRB) review. See Appendix A.*

a. An investigator must seek such consent only under circumstances that:

(1) Provide the prospective subject or the subject's legally-authorized representative sufficient opportunity to consider whether or not to participate, and

(2) Minimize the possibility of coercion or undue influence.

b. The information that is given to the subject or the subject's representative must be in language understandable to the subject or the subject's representative.

c. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the subject's representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

d. Department of Veterans Affairs (VA) Form 10-1086, Research Consent Form, or an electronic version of VA Form 10-1086, must be used as the consent form, and all required elements must be completed.

## 2. **Basic Elements for Informed Consent**

a. In seeking informed consent, the following information must be provided to each subject:

(1) Name of the study.

(2) The name of the Principal Investigator (PI).

(3) A statement that the study involves research.

(4) An explanation of the purposes of the research and the expected duration of the subject's participation.

(5) A description of the procedures to be followed and identification of those being done for research purposes.

(6) Identification of any procedures that are experimental.

(7) A description of any reasonably foreseeable risks or discomforts to the subject including for example, privacy risks (legal, employment, and social).

(8) A description of any benefits to the subject, or to others, which may reasonably be expected from the research.

(9) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(10) A statement describing the extent to which confidentiality of records identifying the subject will be maintained. If appropriate, a statement that Federal agencies such as the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP) and the Government Accounting Office (GAO) may have access to the records. If an FDA-regulated test article is involved, the FDA requires a statement that the FDA may choose to inspect research records that include the subject's individual medical records.

(11) For research involving more than minimal risk an explanation as to whether any compensation is available and an explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained.

(a) According to Title 38 Code of Federal Regulations (CFR) 17.85 "Treatment of Research-Related Injuries to Human Subjects," VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, the necessary care must be provided in VA medical facilities. Exceptions include: situations where VA facilities are not capable of furnishing economical care; situations where VA facilities are not capable of furnishing the care or services required; and situations involving a non-veteran research subject. Under these circumstances, Directors may contract for such care. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. The informed consent form needs to include language explaining VA's authority to provide medical treatment to research subjects injured by participation in a VA research project. **NOTE:** *VA regulations on research related injuries (see 38 CFR 17.85 apply to minimal-risk research.*

(b) The regulation at 38 CFR 17.85 does not apply to research conducted for VA under a contract with an individual or a non-VA institution (although veterans injured as a result of participation in such research may nevertheless be eligible for care from VA under other statutory and regulatory provisions). Information on the responsibility for research-related injury under such circumstances must be included in the consent form. **NOTE:** *It is strongly suggested*

*that the investigator make provisions for coverage of such cost in research awards and contracts.*

(12) An explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of research-related injury to the subject. At least one contact's name and phone number must be other than the investigator's or study personnel.

(13) A statement that participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(14) A statement that a veteran-subject will not be required to pay for care received as a subject in a VA research project except as follows:

(a) In accordance with Title 38 United States Code (U.S.C.) 1710(f) and 1710(g) certain veterans are required to pay co-payments for medical care and services provided by VA. Veterans receiving medical care and services from VA that are not rendered as part of the VA-approved research study, must pay any applicable co-payment for such care and services.

(b) Suggested wording for the consent form needs to note this requirement. For example: "Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payments requirements will continue to apply medical care and services provided by VA that are not part of this study."

(c) Investigators need to note, pursuant to 38 CFR 17.102, charges will not be made for medical services, including transportation furnished as part of a VA-approved research study. Section 17.102 requires that if services are furnished to a person who is not eligible for the services as a veteran, the medical care appropriation will be reimbursed from the research appropriation.

b. **Additional Elements of Informed Consent.** One or more of the following elements of information must also be provided to each subject when appropriate:

(1) A statement that the particular treatment or procedure may involve currently unforeseeable risks to the subject, or to the embryo or fetus, if the subject is or becomes pregnant.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research, consistent with the Federal laws concerning veterans' eligibility for medical care and treatment.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research which may relate to this subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

(7) If the investigators believe that the human biologic specimens obtained could be part of, or lead to the development of a commercially valuable product, or if the specimens are to be retained after the end of the study, current VA policy and Veterans Health Administration (VHA) regulations must be followed. *NOTE: If genetic testing is to be done, VA requirements pertaining to genetic testing must also be met.*

(8) As appropriate, a statement regarding any payment the subject is to receive and how payment will be made.

c. As defined in 38 CFR 16.116(c) an IRB may:

(1) Approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent; or

(2) Waive the requirements to obtain informed consent, provided the IRB finds and documents that:

(a) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

1. Public benefit or service programs;

2. Procedures for obtaining benefits or services under those programs;

3. Possible changes in or alternatives to those programs or procedures; or

4. Possible changes in methods or levels of payment for benefits or services under those programs.

(b) The research could not practicably be carried out without the waiver or alteration.

d. As defined in 38 CFR 16.116(d), an IRB may:

(1) Approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in this appendix; or

(2) Waive the requirements to obtain informed consent, provided the IRB finds and documents that :

- (a) The research involves no more than minimal tangible or intangible risk to the subjects;
- (b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (c) The research could not practicably be carried out without the waiver or alteration; and

(d) Whenever appropriate, the subjects must be provided with additional pertinent information after participation.

e. The informed consent requirements stated are not intended to pre-empt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

*NOTE: Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.*

### **3. Documentation of the Informed Consent**

a. Except as provided in subparagraph 3d of this appendix, informed consent must be documented by the use of a written consent form approved by the IRB and signed and dated by:

- (1) The subject or the subject's legally-authorized representative,
- (2) A witness whose role is to witness the subject's or the subject's legally-authorized representative's signature, and
- (3) The person obtaining the informed consent.

b. VA Form 10-1086, or an electronic version of VA Form 10-1086, must be used as the consent form. If the sponsor or IRB requires a witness to the consenting process in addition to the witness to the subject's signature; if the same person needs to serve both capacities then a note to that effect must be placed under the witness's signature line.

(1) The consent form must be the most recent IRB-approved consent form. The approval must be documented by the use of a stamp or preprinted box on each page of the consent form that indicates the date of the most recent IRB approval of the form. The IRB must maintain a copy of the approved form in its records.

(2) The original signed consent form must be filed in the subject's case history.

(3) A copy of the signed informed consent must be provided to the subject or the subject's legal representative.

c. Flagging a Medical Record. The IRB needs to determine if the patient's medical record (electronic or paper) must be flagged to protect the subject's safety by indicating the subject's participation in the study, and the source of more information on the study. The IRB may not want to require the medical record to be flagged if:

(1) The subject's participation in the study involves:

(a) Only one encounter,

(b) Only the use of a questionnaire, or

(c) The use of previously collected biological specimens.

(2) The identification of the patient as a subject in a particular study (if the study is not greater than minimal risk) would place the subject at greater than minimal risk.

d. Consent Form. Except as provided in subparagraph 3f herein, the consent form may be either of the following:

(1) **Written Consent Document.** VA Form 10-1086 (either paper or electronic version)," must be used as the consent form and must embody the elements required by this appendix and 38 CFR 16.116. In addition, it must contain any additional elements as required by the IRB. The consent form may be read to the subject or the subject's legally-authorized representative. The investigator must ensure that the subject (or representative) is given adequate opportunity to read the form and ask questions before signing it.

(2) **Written Consent Document (Short Form).** A shortened written consent document stating that the elements of informed consent required by this appendix and 38 CFR 16.116 have been presented orally to the subject or the subject's legally-authorized representative. When this method is used, there must be a witness to the oral presentation. This process includes the following:

(a) The IRB must approve a written summary of what is to be said to the subject or the subject's legally-authorized representative.

(b) Only the short form is to be signed by the subject or the subject's legally-authorized representative.

(c) The witness must sign both the short form and a copy of the summary. The person actually obtaining the consent must sign a copy of the summary. The original short form and summary must be filed, as required.

(d) A copy of the summary must be given to the subject or the subject's legally-authorized representative, in addition to a copy of the signed short form.

e. **Progress Note.** A progress note documenting the informed consent process must be placed in the subject's medical record.

(1) At a minimum, the progress note must include:

(a) The name of the study,

(b) The person obtaining the subject's consent,

(c) A statement that the subject or the subject's legally-authorized representative was capable of understanding the consent process,

(d) A statement that the study was explained to the subject, and

(e) A statement that the subject was given the opportunity to ask questions.

(2) An entry must also be placed in the progress note when the human subject is actually entered into the study and when the human subject's participation is terminated. **NOTE:** *Consent and entry notes can be combined when both occur at the same visit.*

f. **Waiver of Requirement for a Signed Informed Consent**

(1) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

(a) That the only record linking the subject and the research would be the consent document and the principal risk to the subject would be potential harm resulting from a breach of confidentiality. Each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(b) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

(2) In cases in which the documentation requirement is waived, the IRB must document the reason for the waiver and may require the investigator to provide subjects with a written statement regarding the research.

## VULNERABLE POPULATIONS

**1. PURPOSE.** This appendix provides additional protections to vulnerable populations participating in Department of Veterans Affairs (VA) research and additional guidance to Institutional Review Boards (IRBs) reviewing research involving vulnerable populations as defined in Title 38 Code of Federal Regulations (CFR) 16.111(b). **NOTE:** *Although the Veterans Health Administration (VHA) regulations may be more restrictive than the Department of Health and Human Services (DHHS) regulations and guidance, the VHA regulations and policy must be followed; additionally, VHA has not adapted regulations similar to DHHS regulations 45 CFR 46 Subparts B through D into its regulations at 38 CFR Part 16.*

### 2. DEFINITIONS

a. **Children** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

b. **Delivery** means complete separation of the fetus from the woman by expulsion, extraction, or any other means.

c. **Fetus** is the product of conception from the time of implantation until delivery.

(1) **Viable fetus** is now termed a “viable neonate.”

(2) **Nonviable fetus** is a fetus ex utero that, although living, is not able to survive to the point of independently maintaining heart and respiration. **NOTE:** *In 45 CFR 46 Subpart B, this definition is used as the definition of a non-viable neonate.*

(3) **Dead fetus** is a fetus which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord if still attached.

d. **In vitro fertilization** is any fertilization of human ova, which occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means.

e. **Neonate** means newborn.

(1) **Viable neonate** means being able, after delivery, to survive to the point of being independently maintaining heart and respiration (given the benefit of available medical therapy).

(2) **Non-viable neonate** means the same as a non-viable fetus.

f. **Pregnancy** is the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

g. **Prisoner** is any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**3. VULNERABLE POPULATIONS.** Vulnerable populations as listed in the Federal regulations include:

- a. Pregnant women and fetuses;
- b. Prisoners;
- c. Mentally disabled and those with impaired decision-making capacity;
- d. Children; and
- e. Economically and educationally disadvantaged persons.

**4. PREGNANT WOMEN AND FETUSES AS VULNERABLE POPULATIONS**

a. Research in which the subject is a fetus, in-utero or ex-utero (including human fetal tissue) must not be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities.

b. Research related to in vitro fertilization must not be conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities.

c. For research involving the participation of pregnant women as research subjects, the IRB must:

- (1) Determine that the proposed research meets the requirements outlined in this appendix;
- (2) Determine that adequate provision has been made to monitor the risks to the subject and the fetus.
- (3) Determine that adequate consideration has been given to the manner in which potential subjects are going to be selected, and that adequate provision has been made to monitor the actual informed consent process such as:

(a) Overseeing the actual process by which individual consents required by this appendix are secured either by approving enrollment of each individual into the activity, or by verifying, perhaps through sampling, that approved procedures for enrollment of individuals into the activity are being followed, and

(b) Monitoring the progress of the activity and intervening, as necessary, through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen.

*NOTE: These determinations must be documented in the IRB minutes.*

d. **General limitations**

(1) Activities related to pregnant women must not be undertaken unless:

(a) Except if appropriate studies on animals and non-pregnant individuals have been completed, and data for assessing potential risks to pregnant women and fetuses is provided.

(b) The purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal, and, in all cases, is the least possible risk for achieving the objectives of the activity.

(c) Individuals engaged in the activity will have no part in:

1. Any decisions as to the timing, method, and procedures used to terminate the pregnancy;  
or

2. Determining the viability of the fetus at the termination of the pregnancy.

3. Introducing any procedural changes, for research purposes, into the procedures for terminating the pregnancy.

(2) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of research activity

(3) No pregnant woman may be involved as a subject in a research activity unless:

(a) The purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs; or

(b) The risk to the fetus is minimal.

(c) The mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if:

1. The purpose of the activity is to meet the health needs of the mother,

2. His identity or whereabouts cannot reasonably be ascertained,

3. He is not reasonably available, or

4. The pregnancy resulted from rape.

**5. PRISONERS AS A VULNERABLE POPULATION IN RESEARCH.** Prisoners are considered a vulnerable population because both their incarceration and the constraints imposed on them during their incarceration may render them unable to make a truly informed and voluntary decision regarding whether or not to participate as subjects in research. Therefore, research involving prisoners must not be conducted by VA investigators while on official duty, or at VA-approved off-site facilities unless a waiver has been granted by the Chief Research and Development Officer. If the waiver is granted, the research must be in accordance with applicable Federal regulations pertaining to prisoners as research subjects (see 45 CFR Part 46, Subpart C 46.301 – 46.306, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects). *NOTE: Requirements for requesting a waiver may be obtained by contacting the Office of Research and Development at VA Central Office or by accessing the VA research web site at <http://www.va.gov/resdev>.*

**6. MENTALLY DISABLED PERSONS OR THOSE PERSONS WITH IMPAIRED DECISION MAKING CAPACITY AS A VULNERABLE POPULATION IN RESEARCH**

- a. Research involving subjects who are mentally ill or subjects with impaired decision-making capacity warrants special attention. Research involving these populations frequently presents greater than minimal risk; may not offer direct medical benefit to the subject; and may include a research design that calls for washout, placebo, or symptom provocation. In addition, these populations are considered to be vulnerable to coercion.

- b. **IRB composition**

- (1) The IRB membership must include at least one member who is an expert in the area of the research. Consideration may be given to adding another member who is a member of the population, a family member of such a person or a representative of an advocacy group for that population.

- (2) The IRB may utilize ad hoc members as necessary to ensure appropriate expertise.

- c. Research involving persons with impaired decision-making capability may only be approved when the following conditions apply:

- (1) Only incompetent persons or persons with impaired decision making capacity are suitable as research subjects. Competent persons are not suitable for the proposed research. The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects. Incompetent persons or persons with impaired decision-making capacity must not be subjects in research simply because they are readily available.

- (2) The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct

benefit to the participant. Incompetent people or persons with impaired decision-making capacity are not to be subjects of research that imposes a risk of injury, unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.

(3) Procedures have been devised to ensure that participant's representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity. Health care agents (appointed under Durable Power of Attorney for Health Care (DPAHC)) and next-of-kin, or guardians, must be given descriptions of both proposed research studies and the obligations of the person's representatives. They must be told that their obligation is to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.

d. The IRB must make a determination in writing of each of the criteria listed in subparagraph 6c. If these criteria are met, the IRB may approve the inclusion of incompetent subjects or subjects with impaired decision-making capacity in research projects on the basis of informed consent from authorized representatives as defined in paragraph 11 of this VHA Handbook.

e. Both investigators and IRB members must be aware that for some subjects, their decision-making capacity may fluctuate. For subjects with fluctuating decision making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary.

f. Although incompetent to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may subjects be forced or coerced to participate.

**7. CHILDREN AS A VULNERABLE POPULATION IN RESEARCH.** VA is authorized to care for veterans and to conduct research that supports the mission of VHA and that enhances the quality of health care delivery to veterans. Therefore, research involving children must not be conducted by VA investigators while on official duty or at VA or approved off-site facilities unless a waiver has been granted by the Chief Research and Development Officer. If the waiver is granted, the research must be in accordance with applicable Federal regulations pertaining to children as research subjects (see 45 CFR Part 46, Subpart D 46.401 – 46.409, Additional Protections for Children Involved as Subjects in Research). *NOTE: For requirements for requesting a waiver contact 202-254-0183.*

**ELEMENTS OF DOCUMENTATION REQUIRED FOR  
WAIVER OF AUTHORIZATION  
(Title 45 Code of Federal Regulations (CFR) 164.512(i)(2))**

1. The Health Insurance portability and Accountability Act (HIPAA) Privacy Rule requires that, if an IRB grants a waiver or alteration of the HIPAA Authorization, the Institutional Review Board (IRB) document the findings on which it based its decision. A request from an investigator to waive or alter the HIPAA authorization needs to be accompanied by information sufficient to make the required findings listed in the following.

2. The documentation must include all of the following:

a. Identification of the IRB

b. Date of IRB approval of waiver of authorization

c. Statement that alteration or waiver of authorization satisfies the following criteria:

(1) The use or disclosure of the requested information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements:

(a) An adequate plan to protect the identifiers from improper use and disclosure

(b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(c) Adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;

(2) The research could not practicably be conducted without the waiver or alteration; and

(3) The research could not practicably be conducted without access to and use of the requested information.

d. A brief description of the Protected Health Information (PHI) for which the IRB has determined use or disclosure to be necessary

e. Identification of the review procedure used to approve the waiver of authorization (either normal review procedures (38 CFR 16.108(b) or expedited review procedures (38 CFR 16.110)).

f. Signature of Chair of the IRB, or member designated by the Chair, to approve the waiver of authorization.

## INCLUSION OF WOMEN AND MINORITIES IN RESEARCH HANDBOOK

1. **REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook prescribes policies regarding the inclusion of women and minorities in the Department of Veterans Affairs (VA) sponsored research.
2. **SUMMARY OF MAJOR CHANGES:** This constitutes a complete rewrite of the superseded document.
3. **RELATED DIRECTIVE:** VHA Directive 1200 to be issued.
4. **RESPONSIBLE OFFICE:** The Office of Research and Development (12) is responsible for the contents of this VHA Handbook.
5. **RESCISSION:** This VHA Handbook rescinds M-3, Part I, Chapter 14, dated July 24, 1992.
6. **RECERTIFICATION:** This document is scheduled for recertification on or before the last working date of May 2006.

Thomas L. Garthwaite, M.D.  
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 6/5/01  
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 6/5/01

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## INCLUSION OF WOMEN AND MINORITIES IN RESEARCH

### 1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides information regarding the requirement for the inclusion of women and minorities in the Department of Veterans Affairs (VA) sponsored research. *NOTE: This requirement extends to all research proposals reviewed and funded by the Office of Research and Development (ORD), including Medical Research Service (MRS), Rehabilitation Research and Development Service (RR&D), Health Services Research and Development Service (HSR&D), and the Cooperative Studies Program (CSP).*

### 2. SCOPE

a. The primary goal of the VA research program is to conduct research that addresses the high priority health care needs of veterans. For this reason, the subject population of VA research should reflect the demographics of the veteran population. The demographic profile of veterans is unlike the United States (U.S.) population as a whole. In particular, women constitute a small portion of all veterans, and most racial/ethnic minorities are disproportionately represented. Nevertheless, VA recognizes the importance of extending the benefits of research to all individuals, regardless of gender, race, or ethnicity.

b. Considering the constraints of the VA patient population, applicants for VHA research support are expected to include women and minorities in their study populations. Special efforts shall be made to include women and members of minority groups in studies of diseases, disorders, and conditions that disproportionately affect them. This policy applies to all research activities involving human subjects or human specimens and/or tissues conducted completely or partially in VA facilities or in approved off-site locations.

### 3. RESPONSIBILITIES

a. **VHA Headquarters.** Scientific peer review groups convened through the ORD, VHA Headquarters, will evaluate all research proposals involving human subjects or human specimens and/or tissues for compliance with this policy.

b. **VISN Directors.** Veterans Integrated Service Network (VISN) Directors will ensure that each medical center under their respective jurisdiction is in compliance with policy and procedural guidelines relating to the inclusion of women and minorities in research.

c. Facility Directors

(1) The Director or Chief Executive Officer (CEO) of each medical center is responsible for the research and development (R&D) program of that institution, advised and assisted by an R&D Committee. Directors will ensure that the local R&D committee and human studies subcommittee (i.e., Institutional Review Board) review all research proposals for compliance with this policy.

(2) Directors will ensure, through their research offices, that all applicants and potential applicants for research support are familiar with and comply with the requirements of this Handbook. All research proposals involving human subjects or human specimens and/or tissues should include an acknowledgement of VA policy to include women and minorities in research.

(3) Directors will ensure, through their research offices, that progress reports of VA funded research reflect the demographics of the actual study population.

**4. DEFINITION**

**Racial/Ethnic Minority:** This category applies to any subset of the U.S. population that is distinguished by racial, ethnic, and/or cultural heritage. VA research adopts the classifications defined by the Office of Management and Budget (OMB), which include the following categories for data on race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. The OMB categories for data on ethnicity are: Hispanic or Lantino and Not Hispanic or Latino. These categories are intended to be inclusive, rather than exclusive.

## OFF-SITE RESEARCH HANDBOOK

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook clarifies the scope of the Office of Research and Development (ORD) on the performance of Department of Veterans Affairs (VA)-funded research in sites other than VA medical centers and VA-leased space.
- 2. SUMMARY OF MAJOR CHANGES:** The principal change is in paragraph 2 (and subsequent subparagraphs 3a(5), 3b, Appendix B, and subparagraph 2b(5)) which establishes that ORD approval is required in order to use leased space for research purposes.
- 3. RELATED DIRECTIVE:** VHA Directive 1200, to be issued.
- 4. RESPONSIBLE OFFICE:** The Office of Research and Development (12) is responsible for the contents of this VHA Handbook.
- 5. RESCISSION:** VHA Directive 98-004, dated January 15, 1998, is rescinded.
- 6. RECERTIFICATION:** This document is scheduled for recertification on or before the last working date of April 2006.

S/ by Dennis H. Smith for  
Thomas L. Garthwaite, M.D.  
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 4/25/2001  
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 4/25/2001

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## OFF-SITE RESEARCH HANDBOOK

### 1. PURPOSE

This Veterans Health Administration (VHA) Handbook clarifies the policy of the Office of Research and Development (ORD) on the performance of Department of Veterans Affairs (VA)-funded research in sites other than VA medical centers and VA-leased space. **NOTE:** *The provisions of this Handbook apply to all research services within the ORD (Medical Research Service (MRS), Rehabilitation Research and Development Service (RR&D), Health Services Research and Development Service (HSR&D), and the Cooperative Studies Program (CSP)).*

### 2. BACKGROUND

VA research is an intramural program derived from clinician observation of the health problems and needs of veterans. The opportunity to explore research based upon these observations in laboratory and other appropriate settings within VA medical centers provides a strong foundation for this program. However, in rare situations VA medical centers may be unable to provide sufficient or appropriate space and facilities for specific research projects. To accommodate such programs, the ORD will review and evaluate all VA-funded research proposed to be performed at sites outside VA medical centers or outside VA-leased space previously approved by ORD for research use.

### 3. SCOPE

a. **Requirements.** VHA policy mandates that VA-funded research be performed in laboratory or office space within VA medical centers or VA-leased space, except when off-site facilities provide unique research opportunities. A waiver to perform VA-funded research in an off-site location, henceforth called an off-site waiver, must be approved by the Chief Research and Development Officer (CRADO). Each investigator who performs, or seeks permission to perform, VA-funded research outside of VA medical center or VA-leased space must request an off-site waiver. A waiver must be requested even if only a portion of the work will be performed off-site. Considerations for granting an off-site waiver include the following:

- (1) **Importance of the Research to the VA Research Portfolio and Patient Care Mission.** The proposed area of research should be relevant to VHA's understanding and/or treatment of a particular disease or health problem important to the veteran population.
- (2) **Need to use Unique or Specialized Facilities or Equipment not Available at VA.** Unique or specialized facilities or equipment include those not available and not easily reproducible at the VA medical center. Such facilities or equipment should be necessary to carry out the proposed research.
- (3) **Lack of a Suitable or Sufficient Performance Site Within VA Space.** If adequate space for an investigator's research program is not available on-site, the medical center must demonstrate that VA-funded investigators occupy all usable VA laboratory space or explain

alternative space assignments. If a portion of the proposed research needs to be performed off-site, a partial off-site waiver should be requested.

(4) **Long- and Short-term Plans to Acquire Additional Research Space.** If sufficient and/or adequate research space is not available at the VA medical center, the facility is responsible for devising a long- and short-term plan to acquire additional research space. Plans to acquire additional space may include construction of new research space, renovation of current research space, renovation of other (non-research) space within the VA medical center, or negotiation with an affiliate institution for leased space.

(5) **Status of Formal Lease Agreements that Will Be or Have Been Negotiated for Research Space.** Facilities may negotiate formal lease agreements in order to provide sufficient and adequate research space for VA-funded investigators. If a lease agreement is used, it is preferred that it be for a block of contiguous space rather than for scattered, independent laboratories. In order for leased space to be used for research purposes, prior approval must be granted by ORD.

b. **Submission of requests for off-site waivers.** Off-site waiver requests must be submitted to the Director of the appropriate research service (MRS, RR&D, HSR&D, or CSP) at least 60 days prior to the due date for receipt of proposals. Proposals for off-site research submitted without an approved off-site waiver will be returned without review.

(1) Off-site investigators who received funding prior to January 15, 1998 (the effective date of VHA Directive 98-004), must request an off-site waiver prior to submission of a renewal of their ongoing research.

(2) Requests for off-site waivers must be approved by the Associate Chief of Staff for Research and Development (ACOS/R&D) and submitted through the medical center Director.

(3) Requests for off-site waivers must be submitted in accordance with procedures outlined in Appendix B.

c. Investigators with approved off-site waivers need to have appropriate medical center approval prior to relocating equipment purchased with VA funds to off-site research space. The medical center must maintain documentation of such approval.

d. If a portion of the proposed research needs to be performed off-site, a partial off-site waiver needs to be requested. Waivers for investigators to be located completely off-site are considered only under special circumstances.

e. Investigators working in leased space approved for research use do not require off-site waivers. The use of leased space approved for research use must be clearly indicated in the Resources section of any research proposals submitted for funding.

f. Principal investigators on mentored awards such as Career Development awards or Medical Research Merit Review Entry Program (MREP) awards may train in mentors' laboratories that are off-site. However, they may not establish new off-site laboratories. At the conclusion of the

training period, they are expected to establish a research laboratory within VA space as a condition of the award.

#### **4. RECIPROCITY**

Off-site waivers are investigator, project, and funding source-specific. A separate request for an off-site waiver must be submitted for each research program or project. Off-site waivers are granted for research funded by an individual research service within ORD, and are not reciprocal among the other research services.

#### **5. INQUIRIES**

Information regarding points of contact for issues related to off-site research is contained in Appendix A.

**CONTACT INFORMATION**

1. Inquiries regarding off-site issues should be directed to:
  - a. **Medical Research Service (121E)**  
(202) 408-3611
  - b. **Rehabilitation Research and Development Service (122)**  
(202) 408-3678
  - c. **Health Services Research and Development Service (124B)**  
(202) 273-8287
  - d. **Cooperative Studies Program (125B)**  
(202) 273-8248
2. Contact information may also be found at the following web site:

<http://www.va.gov/resdev>

**INSTRUCTIONS FOR PREPARATION AND SUBMISSION OF  
REQUESTS FOR OFF-SITE WAIVERS**

1. **Format.** Applications should consist of single-spaced typed pages. Use only letter-quality print. The font size should be at least eleven point with no more than fifteen characters per inch and no more than six lines per inch.

2. **Content.** Each application should consist of the following materials:

a. A cover sheet listing the following information in the order specified:

(1) Off-Site Waiver Request.

(2) Type of waiver requested (partial or full off-site waiver).

(3) Approving Research Service (Medical Research Service (MRS), Rehabilitation Research and Development Service (RR&D), Health Services Research and Development Service (HSR&D), or the Cooperative Studies Program (CSP)).

(4) VA medical center name and address.

(5) Investigator's name and degree(s).

(6) Investigator's title and VA appointment (in 8ths).

(7) Review cycle or submission deadline for proposed off-site research.

(8) Title of investigator's research proposal (for ongoing programs).

(9) Proposed off-site location.

(10) Name, title, and signature of the Associate Chief of Staff for Research and Development.

(11) Name, title, and signature of the medical center Director.

b. A narrative describing the following:

(1) **Importance of the Research to the VA Research Portfolio and Patient-care Mission.** The importance of the proposed area of research to veterans' health issues and the contribution of the specific research to our understanding or treatment of a particular disease or health problem must be clearly described.

(2) **Need to Use Unique or Specialized Facilities or Equipment not Available at VA.** Describe any specialized equipment or unique facilities that are not available or cannot be

reproduced at VA. Briefly explain why the proposed research cannot be done without access to these facilities or equipment. Explain what portion of the investigator's research effort requires these facilities. Clearly identify what portion of the proposed research, if any, will be performed in on-site research space.

(3) **Lack of a Suitable or Sufficient Performance Site Within VA Space.** If adequate space for an investigator's research program is not available on-site, the medical center must demonstrate that VA-funded investigators occupy all usable VA laboratory space or explain alternative space assignments. If a portion of the proposed research needs to be performed off-site, a partial off-site waiver should be requested.

(4) **Long- and Short-term Plans to Acquire Additional Research Space.** Clearly describe long- and short-term plans to acquire additional research space. Plans to acquire additional space may include construction of new research space, renovation of current research space, renovation of other (non-research) space within the VA medical center, or negotiation with an affiliate institution for leased space. During construction or renovation of additional research facilities, plans for interim use of off-site space prior to relocation of investigators to VA-controlled space will be considered. If interim use of off-site space is requested, a timetable for relocation of off-site investigators to VA-controlled space must be provided.

(5) **Status of Formal Lease Agreements that will be or have been Negotiated for Research Space.** Clearly explain the terms and current status of any lease agreements. Plans for interim use of off-site space during the final stages of lease negotiations will be considered. If a lease agreement is to be negotiated, it is preferred that it be for a block of contiguous space rather than for scattered, independent laboratories. Investigators working in leased space approved for research use do not require off-site waivers. The use of leased space must be clearly indicated in the Resources section of any research proposals submitted for funding.

c. **A Spreadsheet or Table Detailing VA Research Space Utilization.** Any discrepancies from the data contained in the Research and Development Information System (RDIS) Space Utilization report should be explained. The following information must be included for each room:

- (1) Room number,
- (2) Use (Office, laboratory, core facility, etc.),
- (3) Research space in square footage,
- (4) Investigator assigned to that room, and
- (5) Investigator's funding source(s).

3. **Due Dates.** Applications must be submitted at least 60 days prior to the due date for receipt of proposals.

4. **Mailing Addresses.** Applications are to be mailed to the address listed for the appropriate research service:

a. **Medical Research Service**

Medical Research Service (121E)  
810 Vermont Ave, NW  
Washington, DC 20420

If courier or commercial overnight delivery service is used, send to:

Medical Research Service (121E)  
1400 Eye Street, NW  
Suite 400  
Washington, DC 20005  
(202) 408-3611

b. **Rehabilitation Research and Development Service**

Rehabilitation R&D Service (122)  
810 Vermont Ave, NW  
Washington, DC 20420

If courier or commercial overnight delivery service is used, send to:

Rehabilitation R&D Service (122)  
1400 Eye Street, NW  
Suite 700  
Washington, DC 20005  
(202) 408-3678

c. **Health Services Research and Development Service**

Health Services R&D Service (124B)  
810 Vermont Ave, NW  
Washington, DC 20420  
(202) 273-8287

d. **Cooperative Studies Program**

Cooperative Studies Program (125B)  
810 Vermont Ave, NW  
Washington, DC 20420  
(202) 273-8248

November 6, 2000

## BANKING OF HUMAN RESEARCH SUBJECTS' SPECIMENS

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive implements a new policy related to human biological specimens collected for research purposes and stored for possible later uses, including genetic studies. It also addresses the collection and storage of clinical data that may be linked to the human biological specimens.

*NOTE: For the purpose of this Directive, the term human biological specimens is defined as any materials derived from human subjects, such as blood, urine, tissues, organs, hair, nail clippings or any other cells whether collected for research purposes or as residual specimens from diagnostic, therapeutic or surgical procedures.*

### 2. BACKGROUND

a. The availability of human biological specimens for research purposes is crucial for the advancement of medical knowledge and in understanding, diagnosing, and treating diseases that affect the veteran population.

b. With the advent of new technologies and their abilities to uncover information that may adversely effect the donor in anticipated or unanticipated ways, it is imperative that all ethical and legal issues related to the use of these specimens and, if collected, their linked clinical data be identified and understood.

c. It is imperative that human research subjects donating the specimens receive the highest level of protection possible and that any questions or any legal or ethical ambiguities always be resolved in favor of the human research subject.

d. The use of Department of Veterans Affairs (VA)-sponsored tissue banks will facilitate the protection of an individual's rights without compromising the advancement of medical science. Further, it will allow investigators to pursue research projects that have been subjected to scientific merit review and the Institutional Review Board, to assure compliance with all applicable Federal regulations such as Title 38 Code of Federal Regulations (CFR) 16, and 45 CFR 46.

*NOTE: For the purpose of this Directive, a VA-sponsored tissue bank is defined as a tissue bank in VA facilities or approved off-site locations that operates in accordance with VA guidance and regulations.*

**3. POLICY:** It is VHA policy to ensure that human biological specimens, as well as the linked clinical data collected as part of research projects conducted by VA investigators in VA facilities or approved off-site locations, are maintained at VA approved tissue banks. *NOTE: This policy is applicable to all research projects that are conducted by VA investigators in VA facilities or approved off-site locations, whether the research is funded or unfunded, and regardless of the source of funding.*

**THIS VHA DIRECTIVE EXPIRES OCTOBER 30, 2005**

**VHA DIRECTIVE 2000-043**

**November 6, 2000**

**4. ACTION**

a. Effective on this date, all new projects collecting and storing human biological tissue specimens shall utilize VA-sponsored tissue banks. These tissue banks may also serve as the repository for the clinical data that have been collected and that may be linked to the specimens.

b. All previously established projects must develop plans to either obtain approval or to move specimens and linked clinical data to VA-sponsored tissue banks and begin implementation of these plans as soon as feasible.

*NOTE: Failure to comply with the policies stated in this Directive could result in immediate withdrawal of VA research funding for the programs in question and/or suspension of the research program.*

**5. REFERENCES:** None.

**6. FOLLOW-UP RESPONSIBILITY:** The Office of Research and Development (12) is responsible for the contents of this Directive. Questions may be referred to 202-408-3614.

**7. RESCISSIONS:** None. This Directive expires October 30, 2005.

Thomas L. Garthwaite, M.D.  
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 11/8/2000  
FLD: VISN, MA, DO, OC, OCRO, and 200 - FAX 11/8/2000  
EX: Boxes 104, 88, 63, 60, 54, 52, 47 and 44 - FAX 11/8/2000

April 27, 2001

## RESEARCH INVOLVING CHILDREN

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive implements the policy on the exclusion of children as research subjects in Department of Veterans Affairs (VA)-approved research, unless a waiver has been obtained from the Chief Research and Development Officer (CRADO).

### 2. BACKGROUND

a. VA is authorized to care for veterans and to conduct research that supports the mission of VHA and enhances the quality of health care delivery to veterans.

b. The majority of VA facilities are not accustomed to caring for children, and the majority of the staff and Institutional Review Board (IRB) members may not have sufficient expertise in pediatrics and pediatric research to ensure the safety of children participating in research.

c. A child is defined as any person who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted.

d. VA-approved research is defined as any research that has been approved by the VA Research and Development (R&D) Committee, conducted by VA investigators while on duty, or conducted at VA facilities or approved off-site locations.

**3. POLICY:** It is VHA policy that children can not be included in VA-approved research conducted by VA investigators while on duty, or conducted at VA facilities or approved off-site locations, unless a waiver has been granted by the CRADO. *NOTE: Congressionally-mandated research programs that involve children are exempt from this policy.*

### 4. ACTION

a. Each VA facility conducting research must submit to the Office of Research and Development (ORD) a list of all active research projects that involve children, no later than 30 days after the issuance of this directive. This list is to include the:

- (1) Name of the protocol.
- (2) Name of the Principal Investigator.
- (3) Level of risk.
- (4) Sponsor of the research.
- (5) Start date and anticipated completion date of the research.

**THIS VHA DIRECTIVE EXPIRES APRIL 30, 2006**

**VHA DIRECTIVE 2001-028**

**April 27, 2001**

b. VA facilities currently conducting research that involve children must apply for and receive, for each protocol involving children, a waiver from the CRADO before October 1, 2001. If a waiver has not been received for a protocol involving children by that date, the protocol is terminated, and the principal investigator must arrange for the safe transition of the subjects out of the study, with appropriate continuation of medical care by the subjects' physicians.

c. No new research involving children can be initiated after April 20, 2001, unless a waiver has been granted by the CRADO.

d. Prior to requesting a waiver, the following criteria must be met:

(1) The study represents no greater than minimal risk.

(2) The study meets all requirements in Title 45 Code of Federal Regulations (CFR) Part 46, Subpart D, "Additional DHHS Protections for Children Involved as Subjects in Research."

(3) The IRB reviewing the study must have appropriate membership to represent childrens' interests and pediatric expertise.

(4) The IRB reviewing the study must have specific policies and procedures regarding children in research.

(5) The medical center Director must certify that the facility is able to respond to pediatric emergencies.

(6) If a contractor and/or a non-VA employee conducts the research, the facility must make certain that the individual, or entity performing the research, has procured appropriate liability insurance.

e. To request a waiver, the following information must be submitted to ORD for each protocol:

(1) A cover letter signed by the medical center Director that contains the following information:

(a) Certification by the medical center Director that the facility is able to respond to pediatric emergencies.

(b) Any additional safeguards that have been incorporated into the clinical site where children will be studied.

(c) Information on the study's funding source.

(d) Information on whether the research will be conducted by a contractor and/or by non-VA employees and, if so, the liability coverage for the study.

(e) Certification that the IRB has determined the study to be of no greater than minimal risk and has approved the study.

(f) A statement that the required elements have been met.

(g) A description of the relevance of both the study and the inclusion of children in the study to veterans' health.

(2) A copy of the study protocol, the informed consent form, and the assent document.

(3) Minutes of the IRB and R&D Committee meetings approving the study. The IRB minutes should reflect the discussion regarding level of risk, the consent and assent forms, the investigators' qualifications to conduct research involving children, and any additional safeguards incorporated into the protocol.

**5. REFERENCES:** Title 45 CFR Part 46, Subpart D.

**6. FOLLOW-UP RESPONSIBILITY:** The Office of the Chief Research and Development Officer (12) is responsible for the contents of this directive.

**7. RESCISSIONS:** None. This Directive expires April 30, 2006.

S/ Dennis H. Smith for  
Thomas L. Garthwaite, M.D.  
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 5/1/2001  
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 5/1/2001

June 13, 2003

## ESTABLISHMENT OF A FACILITY HUMAN PROTECTIONS PROGRAM

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive establishes a new policy for the establishment of a Facility Human Protections Program (FHPP) to help Department of Veterans Affairs (VA) medical centers fully cover costs associated with human subjects protection. This policy applies to all newly funded and VA approved industry-funded studies conducted at VA facilities. *NOTE: This policy is not retroactive and thus does not apply to previously negotiated agreements.*

### 2. BACKGROUND

a. Clinical research involving human subjects requires intensive oversight in order to ensure the protection of study participants; as a result, human subjects research incurs substantial costs. Top professional staff must perform necessary, labor-intensive activities associated with research involving human subjects, including education and training of clinician investigators and research staff, ensuring compliance with applicable regulations, credentialing of research staff, and operation of Institutional Review Board (IRB) committees. In addition, VA medical center staff must perform heavy regulatory administrative duties.

b. Forty percent of all VA research involving human subjects is funded by industry, with funds (hereafter referred to collectively as “grants”) accepted by VA in accordance with the gift acceptance authority in Title 38 United States Code (U.S.C.) § 8301. When simple chart reviews are excluded, 80 percent of all human subjects research conducted at VA facilities is industry-funded. Compliance costs associated with these trials have been estimated to be approximately 10 percent of the funds spent in direct support of these studies, excluding IRB-related costs.

c. University affiliates and VA non-profit corporations (NPCs) administer industry-funded grants that are conducted at VA medical centers. The university affiliates typically charge an indirect rate of approximately 26 percent for industry-funded trials, while NPCs charge variable indirect rates ranging from 5 to 25 percent.

d. A review has revealed the existence of systemic weaknesses in the human research protections program, especially in studies funded by industry. There is a clear need for ongoing quality assurance at every VA research site. To address these weaknesses the Office of Research and Development (ORD) has identified four broad compliance-related activities that need to be carried out at every research site:

- (1) Training and education of lead investigators and research staff,
- (2) Credentialing of research staff,
- (3) Ensuring compliance with applicable human research protection standards, and

**THIS VHA DIRECTIVE EXPIRES JUNE 30, 2008**

## VHA DIRECTIVE 2003-031

June 13, 2003

(4) Accrediting of the facility Human Subjects Protection Program by the National Committee for Quality Assurance (NCQA)

e. Existing methods used by the entity administering study funds for the collection of fees to cover IRB-related costs need to continue. *NOTE: IRB-related costs, including initial and continued review, are not to be included with the compliance-related activity costs identified in the preceding.*

**3. POLICY:** As of July 1, 2003, it is VHA policy that VA medical centers can not accept industry grants (including grants funded through NPCs) that are not sufficiently funded to support the Facility Human Protections Program (FHPP).

### 4. ACTION

a. **Facility Associate Chief of Staff for Research (ACOS/R).** The facility ACOS/R is responsible for:

(1) Notifying, in writing, the entity administering the study funds about the implementation of the new FHPP policy.

(2) Ensuring that any grant accepted by VA includes an amount equal to 10 percent of the direct cost of the study, or a flat fee of \$1200, whichever is greater, to be applied towards FHPP-related costs incurred by the VA medical center.

(3) Obtaining from the entity administering the study funds an annual accounting of the total amount of direct costs of industry-funded studies conducted at VA medical center(s) as well as the amount of funds that were made available for support of FHPP costs. This accounting will be compared to records maintained by the local R&D Office.

b. **Facility R&D Office.** The facility R&D Office annually reports to the Director of Finance, ORD:

(1) The information received from the entity administering the study funds, and

(2) An accounting of all expenditures in support of the compliance-related activities.

*NOTE: ORD annually verifies that sites have complied with this directive and assesses the appropriateness of FHPP rate.*

**5. REFERENCES:** None.

**6. FOLLOW-UP RESPONSIBILITY:** The Office of Research and Development (12) is responsible for the contents of this Directive. Questions may be addressed to (202) 254-0201.

**7. RECISSIONS:** None. This VHA Directive expires June 30, 2008.

S/ Nevin M. Weaver for  
Robert H. Roswell, M.D.  
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 6/13/2003  
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 6/13/2003

Date: Chief Network Officer (10N)  
From: Chief Research and Development Officer (12)  
Subj: Update on Protection of Human Subjects of Research  
To: VISN Directors (10N/1-22)

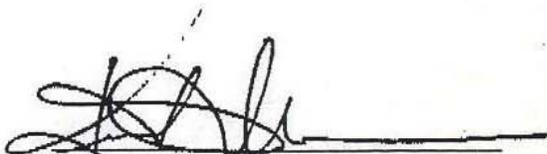
1. Protection of human subjects of research continues to be a high priority on the national scene and for VHA. We would like to provide an update and reminder to each VISN Director of some of the key issues in this area.
2. Each VA facility conducting research involving human subjects now has a Multiple Projects Assurance (MPA) from the Office for Protection from Research Risks (OPRR) or a VA MPA Contract. Please be certain that each human subjects investigator in your VISN has received a copy of his or her facility's MPA.
3. Each facility must have a plan to provide education about human subjects protections for investigators and IRB members and staff. Insofar as possible, VA should avoid waste and duplication of effort by taking advantage of educational programs offered by academic affiliates, as well as regional and national workshops sponsored by such organizations as PRIM&R, the Society of Research Administrators, and OPRR. Many of these training opportunities are posted on the RDO website at [www.va.gov/resdev/fr/preventrisk.htm](http://www.va.gov/resdev/fr/preventrisk.htm).
4. Institutional Review Boards must have adequate administrative support. As noted in Dr. Feussner's memo to you of February 17, 2000, RDO recently commissioned a survey to solicit expert opinion on optimal administrative support for IRBs. Preliminary results suggest the following:
  - For a medium research volume institution with 1-2 IRB committees, the projected optimal IRB staff includes a director, administrative assistant, up to 1.5 FTEE professional staff to review protocols, and a computer analyst (or centralized computer support).
  - For a high volume institution with 3-4 IRB committees, the projected optimal staff would include a director, administrative assistant, up to 5 FTEE professional staff, and computer support.

These numbers are estimates only; the appropriate numbers would vary with the breadth and complexity of the research program being reviewed. Each IRB would require a chair (estimated at 0.5 FTEE commitment) and approximately 9 committee members (0.05 FTEE per member). If you have not already done so, we encourage you to compare the administrative support available to IRBs in your VISN with these benchmarks.

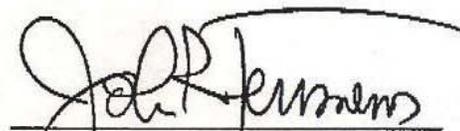
5. Conflicting time demands are making it increasingly difficult to recruit and retain IRB members nationally. We encourage you to consider the following recommendations for enhancing recruitment and retention which were submitted by VISNs in response to RDOs VISN Survey last fall:

- Communicate the importance of the meetings
- Publish the agenda sufficiently ahead of time
- Hold meetings at convenient locations
- Decrease frequency of meetings
- Provide lunch
- Assign protocols to individuals who present to the full committee and then make recommendations
- Have more well trained alternate members
- Pay community members for attending meetings
- Call members 2 days prior to the meeting as a reminder
- Milwaukee "encourages HQ and VISN to create a reward system for IRB members considering the magnitude of the work and the time commitment"
- Address IRB activities and incentives in the FY 2001 performance measures for directors
- Have one affiliate purchase time from a member's department to assure availability
- Allow alternates to rotate positions with the members
- Specifically allocate hours in the tour of duty for this administrative responsibility
- Use administrative funds to reimburse departments for time spent by faculty. This has decreased attrition at some facilities.

6. We anticipate that VHA will establish a contract for accreditation of IRBs by an external auditing organization in the very near future. Achievement of external accreditation for human and animal research programs and radiation safety has been discussed as a possible VISN performance measure for research. We will be working with the Performance Measurement Workgroup to assess the feasibility of developing such a measure for FY 2001. We would be interested in any comments or suggestions you may have on this or other potential performance measures for research.



Kenneth J. Clark



John R. Feussner, M.D.

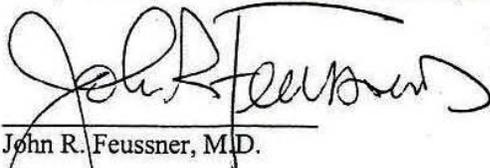
Department of  
Veterans Affairs

Memorandum

Date: August 15, 2000  
From: Chief Research and Development Officer (12)  
Subj: Required Education for Investigators  
To: Associate Chief of Staff for Research and Development (151)  
Through: Medical Center Director (00)

RECEIVED  
AUG 17 2000  
ORCA (10R)

1. VHA's Office of Research and Development (ORD) is committed to facilitating the pursuit of scientific inquiry while protecting the rights and welfare of human research subjects. The protections offered to research subject are derived from comprehensive programs that include IRB review of research protocols, informed consent requirements, and the process of consenting subjects. A crucial element of this program also includes assuring that all investigators are knowledgeable about the ethical principals and regulatory requirements associated with research involving human subjects. A major mechanism that assists in providing these protections is educational programs for investigators.
2. ORD is establishing a new requirement related to human subjects protection education: All Principal Investigators, Co-Principal Investigators, and Co-Investigators must participate in an educational process either by (1) attending educational courses designed for investigators conducting research involving human subjects or (2) completing a web-based educational course such as the one offered by NIH. ORD is not mandating a specific educational course at this time, but notes that a number of curricula are available to investigators and institutions.
3. As of January 1, 2001, all PIs, Co-PIs, and Co-Investigators submitting new or non-competing renewal research proposals to an IRB and R&D Committee shall provide documentation of participation to the local Research & Development office in the form of a letter attached to the proposal. This documentation must be on file at the local office prior to submission and review of any new proposals, and must be included with proposals submitted to ORD. Any proposal not containing the required documentation will be returned without review. The educational course must have been completed within 3 years prior to the submission of any proposal.
4. The facility Research & Development office shall maintain documentation of each investigator's educational program. This documentation shall include the name of the investigator, the name and sponsor of the educational course, the number of credit hours, and the date the program was completed. This requirement applies to all active VA investigators involved in any human research regardless whether funded or not, or source of funding.
5. There are a number of institutions offering courses and website programs, including NIH: <http://helix.nih.gov:8001/oshsr/newcbt/>, The University of Rochester, and PRIM&R's "IRB 101©" listed on their website: <http://primr.org>.
6. ORD welcomes recommendations of other programs suitable for meeting this requirement and will continue to maintain a listing of educational opportunities on the ORD website. If you have any questions, contact Brenda Cuccherini, Ph.D., at 202-408-3614.



John R. Feussner, M.D.

cc: Chief Network Officer (10N) and Chief ORCA (10R)

**Department of  
Veterans Affairs**

**Memorandum**

Date: March 14, 2001  
From: Chief Research and Development Officer (12)  
Subj: Submission of Research Proposals  
To: Associate Chiefs of Staff and Coordinators for Research and Development (151)

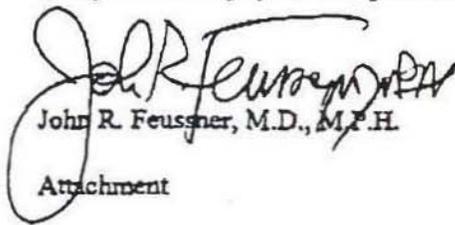
1. On August 15, 2000, the Office of Research and Development (ORD) issued a memorandum requiring all Principal Investigators (PI), Co-Principal Investigators (Co-PI), and Co-Investigators (Co-I) to meet specific educational requirements related to human subjects protection. That memorandum states that as of January 1, 2001, all PIs, Co-PIs, and Co-Is submitting new or non-competing renewal research proposals to an IRB and R&D Committee shall provide documentation of participation in an educational program to the local Research & Development (R&D) Office.

2. This memorandum offers further guidance on meeting educational requirements and on identifying educational programs (web-based courses, seminars, lectures, etc.) that will meet or exceed the minimal standards as set forth by ORD. The local facility's R&D Office shall verify that the investigator's educational program meets the requirements as stated in this memorandum and Attachment 1. The R&D Office shall also maintain documentation of each investigator's educational program and certification. This documentation must be on file at the local R&D Office prior to submission and review of any new proposals or submission of proposals for continuing review. It must also be included with proposals submitted to ORD for funding. Any proposals submitted to ORD that do not contain the required documentation will be returned to the facility without review.

3. Courses proposed to fulfill this requirement will include the elements noted in the attachment. In addition, effective June 1, 2001, educational programs that will fulfill this requirement must offer a post-test capability. The investigator must receive a passing grade as defined by the educational program. This will be verified by the receipt of a certificate from the program. All investigators must recertify every three years.

4. Many courses already exist or are under development by a variety of public and private organizations, including university academic affiliates of some VA facilities. Several academic affiliates have already established mandatory certification requirements for their faculty, employing several of these courses and examinations. To avoid duplication of effort, ORD will accept these mandated courses so that investigators are not required by their university to take one course and by the VA to take another. The content of the university's course must be similar to the requirements stated in this memorandum, and there must be a post-test capability. The investigator must receive a passing grade, and this must be verified by the receipt of a certificate.

5. If you have any questions, please contact Brenda A. Cuccherini, Ph.D., at (202) 408-3614.

  
John R. Feussner, M.D., M.P.H.

Attachment

cc: Medical Center Directors (00)

**Department of  
Veterans Affairs**

MAR 28 2001

# Memorandum

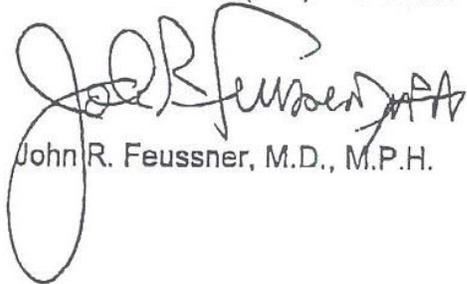
Date:

From: Chief Research and Development Officer (12)

Subj: Submission of Minutes to Headquarters

To: Associate Chiefs of Staff and Coordinators for Research and Development (151)

1. The purpose of this Memorandum is to change the procedure for review of Research and Development (R&D) Committee minutes, Human Studies Subcommittee minutes, Subcommittee on Animal Studies minutes and Biosafety Subcommittee minutes by the Office of Research and Development (ORD).
2. ORD will randomly review representative samples of R&D minutes and subcommittee minutes from every station once every three years. Effective the date of this memorandum, committee and subcommittee minutes are no longer to be sent routinely to Headquarters or to the former Eastern Research and Development Office in Perry Point, Maryland.
3. ORD will contact your station requesting Research committee and subcommittee minutes. The written request will detail specific mailing instructions, identify a specific time period for the minutes, and state a deadline for all committee minutes to be received by Headquarters.
4. If you have any questions about this new procedure, please contact Dr. Brenda A. Cuccherini at (202) 408-3614.



John R. Feussner, M.D., M.P.H.

**Department of  
Veterans Affairs**

# Memorandum

Date: NOV 12 2003

From: Acting Chief Officer, Office of Research Oversight (ORO) (10R)

Thru: Deputy Under Secretary for Health (10A) *Hub 11-12-03*  
Deputy Under Secretary for Health for Operations and Management (10N) *J Miller 11-12-03*

Subj: What to Report to ORO: ACTION

To: Institutional Officials of VHA Facilities Conducting or Supporting Research

1. I am reissuing the memorandum "What to Report to ORCA," dated October 28, 2002, to acknowledge the name change of the office and to make minor revisions in reporting requirements.
2. Effective May 2003, the Office of Research Oversight (ORO) serves as the primary Veterans Health Administration (VHA) office to advise the Under Secretary for Health on matters of compliance and assurance in human subjects protections, animal welfare, research safety, and research misconduct.
3. ORO prefers to fulfill its mandates by working with facilities prospectively so that potential problems can be averted and quality of research maintained. This memorandum identifies issues which a VHA facility (VA Medical Centers, VA Health Care Systems, and VA Medical and Regional Office Centers) must report to ORO as required by various Federal regulations and VHA policies. It addresses reporting requirements to ORO only. Your facility may also be required to report information to other organizations such as the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and the Office of Laboratory Animal Welfare (OLAW) in the Department of Health and Human Services (DHHS), and the Office of Research and Development in VHA.
4. Each VA facility must provide written information about events listed in Attachment A of this memorandum to the appropriate ORO Regional Office (RO). Exceptions are found in paragraphs A4 and D of Attachment A that require direct reporting to ORO's Central Office (CO). In reporting an event or situation, the facility should describe its actions to address the issue. Information on the event must be reported to ORO promptly, even if the facility has not come to a final determination about the disposition of the issue. ORO staff is available for consultation on these or related matters by e-mail or telephone.
5. In addition to what is listed at Attachment A, VHA facilities are required to report to ORO any citations by external oversight agencies related to human subjects protections, animal welfare, research safety, and research misconduct. The facility must specify how the citations will be promptly addressed.

6. When you provide ORO with any of the above information you should simultaneously notify your Network Director.
7. Please refer to Attachment B for the appropriate ORO contact.



David A. Weber, PhD  
Acting Chief Officer, ORO (10R)

Attachments: A-What to Report to ORO  
B-ORO Contact List

cc: Under Secretary for Health (10)  
Chief Officer for Research and Development (12)  
Network Directors  
ACOSs for Research and Development/Research Coordinators

## Attachment A

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### VA Facilities Report to ORO

#### **A. Protection of Human Subjects in Research:**

1. Findings of serious or continuing noncompliance with the regulations for the protection of human subjects or with the requirements of the Institutional Review Board (IRB) (38CFR16.103(b)(5) and VHA Handbook 1200.5).
2. a. All adverse events (AEs) and imminent threats of AEs in research that result in:
  - 1) An IRB taking substantive action(s), as defined in ORO Handbook 1058.X (in preparation). The Institutional Official or designee facilitates the submission of a completed VA Adverse Events (AEs) report to the ORO RO in a specified format within 10 working days of the IRB's determination to take such action(s).
  - 2) An unexpected death of a research subject, regardless of IRB action. The Institutional Official or designee facilitates reporting of such deaths to the ORO RO no later than two (2) working days after the IRB is informed of the death.
- b. Definitions:
  - 1) An AE in research is defined for purposes of Handbook 1058.X, as any untoward occurrence (physical, psychological, social, or economic) in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom, disease, or death associated with the research or the use of a medical investigational test article. An AE may or may not be related to an error or protocol deviation. An AE does not necessarily have to be caused by any particular aspect of the research.
  - 2) Substantive actions are actions taken by an IRB that materially alters the substance and meaning of a protocol, informed consent form or process, or investigator status, including, but not limited to, restriction, suspension or termination of a study or investigator participation, and actions taken to prevent future occurrence(s) of the adverse event.
  - 3) An unexpected death refers to the death of a research subject in a trial in which a high risk of death is not projected, as indicated by the written protocol, informed consent form, and/or sponsor brochure. The death of a subject already at the end-of-life is *not* an unexpected death unless the research intervention clearly hastens the subject's death. A subject's death that is determined to be clearly not associated with the research is also not an "unexpected death" for purposes of the reporting requirements.
3. Suspension or termination of IRB approval. Report for cause suspensions and terminations (e.g., associated with unexpected harm, research not being conducted in accordance with the IRB's requirements, lack of continuing review) (38CFR16.113). Do not report routine study closures or study completions.

4. Any change in status of the Federal Wide Assurance or IRBs of record including notification of changes in institutional officials, IRB chair/membership, or contact staff. Changes in Memoranda of Understanding (MOU) about shared responsibilities in the human research protections program with other VA organizations or the academic affiliate must be reported. **Report information in item A.4 directly to ORO CO.**

**B. Animal Welfare Issues:**

1. Any changes in the Association for Assessment and Accreditation of Laboratory Animal Care International accreditation status of a facility used by the VA, whether internal or that of the affiliate institution.
2. Any change in the facility's Animal Welfare Assurance status as reported to OLAW.
3. Any citations listed on inspection reports of the Animal and Plant Health Inspection Service, United States Department of Agriculture (USDA).
4. Any significant changes in a MOU regarding animal care and use arrangements with affiliate institutions.
5. Any termination or suspension of an animal protocol by the VA Institutional Animal Care and Use Committee (IACUC).
6. Any serious or continuing noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals or VHA Handbook 1200.7.
7. Any serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals.
8. Any serious deviations from the provisions of Title 9 Parts 1, 2, and 3, USDA Animal Welfare Act Regulations and Standards.
9. Any work-related injuries to personnel working within an animal facility that require a hospital visit.
10. Any loss of animal life due to physical plant deficiencies and/or engineering failures/mishaps.

### **C. Research Safety and Security Issues:**

1. Any suspension or termination of the Subcommittee on Research Safety approval.
2. Any serious or continuing non-compliance with Federal regulations and VHA policies, such as VHA Handbook 1200.8, VHA Directive 2002-075, 42 CFR 73, etc.
3. Any serious injury to personnel requiring hospitalization or leading to serious complications or death.
4. Any exposure, release, loss, or theft of select agents or toxins, or other serious incident requiring reporting and reevaluation of the facility's safety or emergency plan.
5. Any citation following an Office of Research and Development site visit or audit of the research safety program.
6. Any citation by National Institutes of Health on research involving recombinant DNA molecules.
7. Any citation by the Centers for Disease Control and Prevention or USDA on hazardous materials, including select agents and toxins.
8. Any citation by Occupational Safety and Health Administration on research safety.
9. Findings following an inspection by the Nuclear Regulatory Commission or VA National Health Physics Program Office.
10. Any Type 1 contingency following a Joint Commission on Accreditation of Healthcare Organizations site visit related to research safety.

### **D. Research Misconduct:**

#### **Report to ORO CO directly:**

1. All initiations of inquiries and investigations of research misconduct as defined in 65 Federal Register 76260 (December 6, 2000), i.e., fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting results.
2. Copies of inquiry and investigation reports.
3. All adjudications (both finding of research misconduct and no findings of research misconduct).

Attachment B

**Office of Research Oversight (ORO) (10R)**

Internet Address: <http://www.va.gov/orca/>

VA Intranet Address: <http://vaww.va.gov/orca/>  
(new ORO website is under construction)

**CENTRAL OFFICE**

811 Vermont Avenue, N.W., Suite 574 (10R)  
Washington, D.C. 20420  
FAX: (202) 565-9194

<b>Acting Chief Officer, David A. Weber</b>	<b>RM 574</b>	<b>10R</b>	<b>202-565-5179</b>
Associate Director, Joan P. Porter	<b>RM 574</b>	<b>10R</b>	<b>202-565-7191</b>
Health Science Specialist, Priscilla A. Craig	<b>RM 574</b>	<b>10R</b>	<b>202-565-8162</b>
Health Science Specialist, Peter Poon	<b>RM 574</b>	<b>10R</b>	<b>202-565-8107</b>
Program Analyst, Paula Squire Waterman	<b>RM 574</b>	<b>10R</b>	<b>202-565-6188</b>
Management Analyst, Shannon B. Williams	<b>RM 574</b>	<b>10R</b>	<b>202-565-6621</b>
<b>Program Support Assistant, Lisa L. Franklin</b>	<b>RM 574</b>	<b>10R</b>	<b>202-565-4835*</b>

\*MAIN CONTACT NUMBER

**MID-ATLANTIC REGIONAL OFFICE**

50 Irving Street, N.W., (10R)  
Washington, D.C. 20422  
FAX: (202) 745-8538

<b>Director, Min-Fu Tsan</b>	<b>10R</b>	<b>202-745-8544</b>
Deputy Director, Anna C. Alt-White	<b>10R</b>	<b>202-745-8687</b>
Health Science Specialist, Kenneth Sung	<b>10R</b>	<b>202-745-8549</b>
<b>Program Support Assistant, Sanitra McKenzie</b>	<b>10R</b>	<b>202-745-8110</b>

**MID-WESTERN REGIONAL OFFICE**

Building 1 (10R), Room B-103  
5<sup>th</sup> & Roosevelt Avenues  
Hines, IL 60141  
FAX: (708) 202-7250

<b>Director, Karen M. Smith</b>	<b>10R</b>	<b>708-202-7256</b>
Deputy Director, Cindy Paulsen	<b>10R</b>	<b>708-202-7251</b>
Health Science Specialist, David Semlow	<b>10R</b>	<b>708-202-7266</b>
<b>Program Support Assistant, Kimberly Griffin</b>	<b>10R</b>	<b>708-202-7254</b>

Attachment B

**Office of Research Oversight (ORO) (10R)**

Internet Address: <http://www.va.gov/orca/>

VA Intranet Address: <http://vaww.va.gov/orca/>  
(new ORO website is under construction)

**NORTHEASTERN REGIONAL OFFICE**

VAMC Bedford  
200 Springs Road  
Bedford, MA 01730  
**FAX: (781) 687-3858**

<b>Director, Richard D'Augusta</b>	<b>10R</b>	<b>781-687-3854</b>
Health Science Specialist, Leslie Ann Cahill	<b>10R</b>	<b>781-687-3852</b>
<b>Program Support Assistant, Ovidia Dragoli</b>	<b>10R</b>	<b>781-687-3850</b>

**SOUTHERN REGIONAL OFFICE**

1670 Clairmont Road (10R)  
Decatur, GA 30033  
**FAX: (404) 417-2935**

<b>Director, David J. Miller</b>	<b>10R</b>	<b>404-417-2933</b>
Deputy Director, Dale Conaway	<b>10R</b>	<b>404-417-2934</b>
Health Science Specialist, Edward Cannady	<b>10R</b>	<b>404-417-2931</b>
<b>Program Support Assistant, Jane Roberts</b>	<b>10R</b>	<b>404-417-2929</b>

**WESTERN REGIONAL OFFICE**

P.O. Box 7360  
Moreno Valley, CA 92552-7360

***Federal Express Address:***

ORO, Western Region (10R)  
March ARB  
5029 4th Street, Bldg. 2641  
March ARB, CA 92518

**FAX: (909) 801-5176**

<b>Director, Paul Hammond</b>	<b>10R</b>	<b>909-801-5167</b>
Deputy Director, Alain Fymat	<b>10R</b>	<b>909-801-5168</b>
Health Science Specialist, Lynn Willis	<b>10R</b>	<b>909-801-5169</b>
<b>Program Support Assistant, Susan Seiss</b>	<b>10R</b>	<b>909-801-5164</b>