

**Statement**  
**of**  
**Thomas L. Garthwaite, M.D.**  
**Under Secretary for Health**  
**Department of Veterans Affairs**  
**on**  
**Protection of Human Subjects of Research in the**  
**Veterans Health Administration**  
**before the**  
**Subcommittee on Oversight and Investigations**  
**of the**  
**Committee on Veterans' Affairs**  
**U.S. House of Representatives**  
**September 28, 2000**

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Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to appear before you to discuss the VA Medical and Prosthetic Research and Development program and, in particular, protection of human subjects of research in the Veterans Health Administration (VHA).

VHA's Research and Development program is focused upon the high priority health care needs of veterans. A special advantage of the VA research program is that it is nested within a health care system that serves more than 3 million veterans, creating a unique national laboratory for the discovery and application of new medical knowledge. VA research is conducted by VA scientists and clinicians who also have responsibility for providing care for our patients and for training future health care providers for the nation. Unlike NIH, VA does not make research grants to colleges and universities, cities or states, or any other non-VA entity. Many advances in health care that benefit veterans and the nation have emerged from VA research – from the first treatments for tuberculosis and some of the first successful organ transplants, to the discovery of a gene for schizophrenia and improved treatments for Post-Traumatic Stress Disorder.

Given the importance of clinical research in VA, it is essential that our research program be committed to protect the safety of patients and research subjects. VA is one of the 17 federal agencies that are signatories to the Common Rule for the Protection of Human Subjects of Research (38 CFR 16) and also has a separate regulation (38CFR 17.85) that guarantees needed medical care for any patient injured in a VA research project. All VA scientists are expected to abide by stringent ethical principles and rigorous regulatory requirements to ensure the protection of their research subjects.

VA considers all research conducted at a VA facility to be VA research, even if direct funding costs do not derive from federal funds. Therefore, the provisions of the Common Rule and the requirements of VA regulations apply equally to all VA research, regardless of sponsor or funding source. Much of the research conducted in VA facilities is also subject to the regulations of other federal agencies. For example, human studies funded by pharmaceutical companies and conducted at VA facilities in support of a new drug or device application are subject to FDA as well as VA regulations and oversight. Similarly, studies funded by NIH and conducted in VA facilities are subject to Department of Health and Human Services as well as VA regulations and oversight. Thus the framework for a strong human subjects protection program has long been in place in the VA.

During the past two or more years, VHA has taken several aggressive steps to further enhance and strengthen protections for human subjects of research. In April 1999, the former Under Secretary for Health announced that VHA would establish a separate Office of Research Compliance and Assurance (ORCA) to assure compliance with VA and other federal research policies and regulations and, in addition, would engage an external contractor to inspect and certify the human subjects protection program of every VA facility conducting research involving human subjects. Within weeks of that announcement, VHA had initiated a search for a Chief Officer to direct ORCA and had issued an RFP for an external contractor to certify VA research programs. Both of these initiatives have now come to fruition:

- ORCA has been assigned a full scope of assurance and compliance responsibilities and is currently recruiting to a level of 8 staff in headquarters and is staffing four regional offices in Washington, DC, Atlanta, Chicago, and West Los Angeles for an initial staff of 24 persons.
- VHA has issued a contract for external accreditation of human subjects programs to the National Committee for Quality Assurance (NCQA), an independent, not-for-profit accrediting organization that is nationally renowned for its objective evaluations of health care organizations, and the pilot phase of that program has been initiated. NCQA will soon commence a series of on-site inspections of human subjects programs at VAMCs and will be accompanied by observers from ORCA. VA is the first and, so far, the only public or private organization in the nation to mandate external certification of its human subjects protection programs.

VHA has implemented many other initiatives to further enhance human subjects protections. Let me highlight a few examples for you:

- In the summer of 1999, a VA Multiple Project Assurance Contract (VA MPA Contract) was issued to require each VA facility conducting research involving human subjects to provide documentation of its human subjects protection program and assurances that it would abide

by all VA regulations and federal policies governing such research. (See Attachment 1)  
Issuance of VA MPA Contracts to more than 100 VA facilities was completed late last winter.

- ORCA has continuing responsibility for the MPA contracts and will be completing a comprehensive validation of all of these contracts at 120 VAMCs this fall.
- Last spring, ORCA launched the Training, Education, and Development (TED) Initiative, a program designed to develop and disseminate information on a wide spectrum of training and education activities, including those offered by public and private agencies, for investigators and research administrators. ORCA is currently developing a strategic plan for education and training for all VHA personnel involved in the protection of human subjects in research.
- Earlier this year VHA established a requirement that all VA investigators must provide documentation that they have participated in educational programs on human subjects protections before their research projects can be approved, and I am announcing today that, effective January 1, 2001, VA investigators will be required to be certified on human subjects protection regulations in order to be eligible for VA research funding.
- A complete revision of the Research and Development Policy Manual is currently underway to ensure that VHA's research policies are as complete and up-to-date as possible. The first drafts of the revised policy directive and research handbooks are currently under review within VHA. Copies of the draft directive and the draft handbook on protection of human subjects in research were provided to the committee earlier this week. We intend to finalize and publish these documents, which include informed consent requirements, before the end of this calendar year.
- Compliance with research requirements is included in VISN Director performance agreements for 2001.

ORCA and the VHA Office of Research and Development (ORD) have, over the past year and a half, provided extensive guidance and information to field facilities in the form of satellite conferences, monthly Hotline conference calls, surveys, information letters, formal conferences, site visits, self-study materials, and many, many ad hoc informal consultations.

ORCA has recently assumed responsibility for two additional oversight functions. ORCA is now the headquarters component that receives reports of adverse events involving research protocols from VA field facilities. The development of an improved process for the submission of these reports and the systematic collection of data has been initiated in coordination with VHA's National Center for Patient Safety. ORCA is also responsible for liaison and coordination of enforcement activities with other federal research regulatory agencies, including the Food and Drug Administration (FDA) and the Department of Health and Human Services' Office of Human Research Protections (OHRP). As an example of this collaboration, the FDA has recognized the need to revise its reporting procedures for serious adverse events and has involved ORCA in the

development of a clearer set of procedures and guidelines. Also, ORCA officials have met with their counterparts in these other agencies and are working collaboratively to develop educational initiatives for investigators and research administrators in the field.

GAO's recent report acknowledges that VHA has in place strong policies for the protection of human subjects who volunteer to participate in VA research projects. The report also recognizes that VA has taken many steps to strengthen human subjects protections. GAO's review of research that was being conducted in the 1997-1999 timeframe documents variability across the VA system in the implementation of VA's policies for the protection of human subjects. VHA concurs with GAO's recommendations and believes that the initiatives currently underway will significantly strengthen processes for the protection of human research participants. We view GAO's report as validating the need for the strong actions that we are taking. We intend to continue these oversight efforts so that our patients who participate in research projects will have confidence that their rights, dignity and safety are of paramount importance to VA. Attachment 2 provides a more detailed description of the steps VA has already taken or will initiate that will implement GAO's recommendations.

## **CONCLUSION**

The Department of Veterans Affairs intends to be leader in the nation in assuring that its scientists follow the highest standards for assuring respect of the rights, dignity, and safety of research participants. We believe the approach VA is taking, with its continued emphasis on training and education, independent oversight and external accreditation will result in a system-wide human subjects protections program that will place VA at the forefront of protecting human research subjects. I appreciate your invitation to discuss these important issues with you, and my colleagues and I will be pleased to try to answer any questions you may have.

## ATTACHMENT 1

### VA Multiple Project Assurance Contract Assurance of Compliance For Protection of Human Research Subjects

The \_\_\_\_\_, hereinafter known as the "institution" (see Appendix A), hereby gives assurance, as specified below, that it will comply with the Department of Veterans Affairs (VA) regulations for the protection of human research subjects, 38 CFR Part 16 and Part 17, as amended to include provisions of the Federal Policy for the Protection of Human Subjects (56FR28003), also known as the Common Rule, and as described in VA Manual M3, Part I, Chapter 9 and as may be further amended during the approval period for this Assurance. Where applicable it will also comply with FDA regulations 21 CFR 50 and 56.

#### PART 1 -PRINCIPLES, POLICIES, AND APPLICABILITY

##### I. Ethical Principles

- A. This institution is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the "Belmont Report"]), regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e., sponsorship).
- B. All institutional and non-institutional performance sites for this institution, domestic or foreign, will be obligated by this institution to conform to ethical principles which are at least equivalent to those of this institution, as cited in the previous paragraph or as may be determined by the Department of Veterans Affairs Undersecretary for Health.

##### II. Institutional Policy

- A. All requirements of Title 38, Part 16 and Part 17, of the Code of Federal Regulations (38 CFR 16) will be met for all *federally-sponsored* research, and all other human subject research regardless of sponsorship, except as otherwise noted in this Assurance. Federal (all departments and agencies bound by the Federal Policy) funds for which this Assurance applies may not be expended for research involving human subjects unless the requirements of this Assurance have been satisfied.
- B. Except for those categories specifically exempted or waived under 38 CFR 16 Section 101(b) (1-6) or 101(i), all research covered by this Assurance will be reviewed and approved by an Institutional Review Board (IRB) which has been established under this Multiple Project Assurance Contract (MPA Contract) with VA Headquarters (VAHQ), or as may otherwise be agreed to by VAHQ (see Part I, II, G). The involvement of human subjects in research covered by this Assurance will not be permitted until an appropriate IRB has reviewed and approved the research protocol and informed consent has been obtained from the subject or the subject's legal representative (see M3 Part I Chapter 9, Sections 9.09, 9.10, 9.119.12 and appendix 9c), unless properly waived by the IRB under Section 9.11 b (3) or by any applicable waiver under 38 CFR 16 Section 101(i). The referenced VA manual sections include and amplify on 38 CFR 16 Sections 111, 116 and 117.
- C. This institution assures that before human subjects are involved in nonexempt research covered by this Assurance, the IRB(s) will give proper consideration to:

1. The risks to the subjects
  2. The anticipated benefits to the subjects and others,
  3. The importance of the knowledge that may reasonably expected to result, and
  4. The informed consent process to be employed.
- D. Certification of IRB review and approval for all non-HHS sponsored research involving human subjects will be submitted to the Office of Research Administration (ORA) for forwarding to the appropriate Federal department or agency or other funding source. Compliance will occur within the time and in the manner prescribed for forwarding certifications of IRB review to VAHQ or other Federal departments or agencies for which this Assurance applies.

As provided for under 38 CFR 16 Section 118, applications and proposals lacking definite plans for involvement of human subjects will not require IRB review and approval prior to award. However, except for research exempted or waived under section 38 CFR 16 Section 101 (b) or (i), no human subjects may be involved in any project supported by such awards until IRB review and approval has been certified to the appropriate Federal Department or agency.

As required under 38 CFR 16 Section 119, the IRB will review proposed involvement of human subjects in Federal research activities undertaken without prior intent for such involvement, but will not permit such involvement until certification of IRBs review and approval is received by the appropriate Federal department or agency

- E. Institutions that are not signatories to this Assurance are not authorized to cite this Assurance. This institution will ensure that such other institutions and investigators not bound by the provisions of this Assurance will satisfactorily assure compliance with 38 CFR 16, as required (see Part 2, 1, D and II, K), as a prior condition for involvement in any human subject research which is under the auspices of this institution (see part 1, IIIA). Institutions that have entered into an Inter-Institutional Amendment (IIA) to this Assurance must submit a Single Project Assurance (SPA) to the Office for Protection from Research Risks (OPRR) for DHHS-sponsored research, or to VAHQ for other research when that research is not conducted under the auspices of a signatory institution to this Assurance.
- F. This institution will ensure that any collaborating entities (i.e., those entities engaged in human subject research by virtue of subject accrual, transfer of identifiable information, and/or in exchange of something of value, such as material support (e.g., money, drugs, or identifiable specimens), co-authorship, intellectual property, or credits) materially engaged in the conduct of non-federal sponsored research involving human subjects will possess mechanisms to protect human research subjects that are at least equivalent to those procedures provided for in the ethical principles to which this institution is committed (see Part 1, 1).
- G. This institution will exercise administrative overview to ensure that the institution's policies and procedures designed for protecting the rights and welfare of human subjects are being effectively applied in compliance with this Assurance.
- H. Descriptions of this institution's policy for the protection of human subjects is contained in its internal written procedures which are available to VAHQ and other Federal departments or agencies, upon request.

### III. Applicability

- A. Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under 38 CFR 16, Sections 101 (b) (1 -6) or 101 (i) and M3 Part 1, Section 9, appendix A, this Assurance applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:
  - 1. The research is sponsored by this institution, or
  - 2. The research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
  - 3. The research is conducted by or under the direction of any employee or agent of this institution, or
  - 4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.
  
- B. All human subject research which is exempt under M3 Part 1, Appendix 9A will be conducted in accordance with: (1) the Belmont Report, (2) this institution's administrative procedures to ensure valid claims of exemption, and (3) orderly accounting for such activities.
  
- C. This Assurance may be accepted by other Federal departments or agencies that are bound by the Federal Policy for the Protection of Human Subjects with the exception of the Department of Health and Human Services, when appropriate for the research in question and therefore applies to all human subject research so sponsored.

## PART 2 - RESPONSIBILITIES

### I. Institution

- A. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this Assurance, including complying with Federal, state, or local laws as they may relate to such research.
- B. This institution will require appropriate safeguards in research that involves the cognitively impaired or other potentially vulnerable groups as provided in M3, Part 1, Section 9.12.
- C. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects in research covered by this Assurance.
- D. This institution is responsible for ensuring that no performance site cooperating in the conduct of federally sponsored research for which this Assurance applies does so without Federal department or agency approval of an appropriate assurance of compliance, in whatever appropriate form, and satisfaction of IRB certification requirements.
- E. In accordance with the compositional requirements of M3, Part 1, Sections 9.08, and 38 CFR 16 Section 107, this institution has established the IRB(s) listed in the attached roster(s) (See Appendix A). Certain research supported by the U.S. Department of Education will be reviewed in accordance with the requirements of Title 34 CFR Parts 350 and 356 which require that the IRB(s) include at least one person who is primarily concerned with the welfare of handicapped children or mentally disabled persons.
- F. This institution will provide both meeting space and sufficient staff to support the IRB's review and record-keeping duties.
- G. This institution is responsible for ensuring that it and all its affiliates comply fully with all applicable Federal policies and guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV).
- H. The Institution shall provide appropriate medical care to a subject injured in connection with participation in VA research under provisions of 38 CFR 17.

### II. Office of Research Administration (ORA) Responsibilities

- A. The institution's ORA will receive from investigators, through their supervisors, all research protocols that involve human subjects, keep investigators informed of decisions and administrative processing, and return all disapproved protocols to them.
- B. The ORA is responsible for reviewing the preliminary determination of exemption by investigators and supervisors and for making the final determination based on 38 CFR 16 Section 101 and M3, Part 1, 9.06 and 9A of the regulations. Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigator; such research may not commence until written concurrence is issued. All nonexempt research will be forwarded to the appropriate IRB.
- C. The ORA will make the preliminary determination of eligibility of expedited review procedures (see 38 CFR 16 Section 110, and 63FR60364). Expedited review of research activities will not be permitted where full board review is required.

- D. The Research and Development Committee (R&D) assisted by the ORA will review all research (whether exempt or not) and recommend to the CEO whether the institution will permit the research. If approved by the IRB, but not permitted by the CEO, the ORA will promptly convey notice to the investigator and the IRB Chair. Neither the ORA nor any other office or official of the institution may approve a research activity that has been disapproved by the appropriate IRB.
- E. The ORA will forward certification of IRB approval of proposed research to the appropriate Federal department or agency only after all IRB-required modifications have been incorporated to the satisfaction of the IRB.
- F. The ORA will designate procedures for the retention of signed consent documents for at least three years past completion of the research activity.
- G. The ORA will maintain and arrange access for inspection of IRB records as provided for in 38 CFR 16 Section 115 and VA M3, Part I section 9.14.
- H. The ORA is responsible for ensuring constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.
- I. The ORA will arrange for and document in its records that each individual who conducts or reviews human subject research has first been provided with a copy of this Assurance, as well as with ready access to copies of 38 CFR 16, regulations of other federal departments or agencies as may apply, the Belmont Report, and all other pertinent federal policies and guidelines related to the involvement of human subjects in research.
- J. The ORA will report promptly to the IRB(s), appropriate institutional officials, the VAHQ, and any other sponsoring federal department or agency head:
  - 1. Any injuries to human subjects or other unanticipated problems involving risks to subjects or others,
  - 2. Any serious or continuing noncompliance with the regulations or requirements of the IRB, and
  - 3. Any suspension or termination of IRB approval for research.
- K. The ORA will ensure (a) solicitation (or confirmation where applicable assurances to comply already exist), receipt, and management of all assurances of compliance (whatever the appropriate format), and (b) certifications of IRB review (where appropriate) for all performance sites to this institution (including those listed in Appendix B) and subsequent submission of new documents to the proper federal department of agency authorities (e.g., VAHQ for VA) or any other Federal department or agency for which this Assurance applies.
- L. The ORA will ensure that all affiliated performance sites that are not otherwise required to submit assurances of compliance with Federal regulations for the protection of research subjects at least document mechanisms to implement the equivalent of ethical principles to which this institution is committed (see Part 1,I). The ORA is responsible for assuring adequate numbers and training of staff to support IRB functions.
- M. The ORA will be responsible for procedural and record-keeping audits not less than once every year for the purpose of detecting, correcting, and reporting (as required) administrative and/or material breaches in uniformly protecting the rights and welfare of human subjects as required at least by the regulations and as may otherwise be additionally required by this institution(s)

### III. Institutional Review Board (IRB)

- A. The IRB(s) will review, and have the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research. For approved research, the IRB will determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.
- B. IRB decisions and requirements for modifications will be promptly conveyed to investigators and the ORA, in writing. Written notification of decisions to disapprove will be accompanied by reasons for the decision with provision of an opportunity for reply by the investigator, in person or writing.
- C. Initial and continuing convened IRB reviews and approvals will occur in compliance with 38 CFR 16 and provisions of this Assurance for each project unless properly found to be exempt (Section 101(b) or (i) and M3 Part 1, Sections 9.06 and Appendix 9A by the Office of Research Administration. Continuing reviews will be preceded by IRB receipt of appropriate progress reports from the investigator, including any available study-wide findings.
- D. The IRB(s) will observe the quorum requirements of 38 CFR 16 Section 108(b). This institution's IRB(s) must have effective knowledge of subject populations, institutional constraints, differing legal requirements, and other factors which can foreseeably contribute to a determination of risks and benefits to subjects and subjects' informed consent and can properly judge the adequacy of information to be presented to subjects in accordance with requirements of 38 CFR 16 Sections 103(d), 107(a), 111, and 116.
- E. The IRB(s) will determine, in accordance with the criteria found at 38 CFR 16 Section 111 and Federal policies and guidelines for involvement of human subjects in HIV research, that protections for human research subjects are adequate.
- F. The IRB(s) will ensure that legally effective informed consent will be obtained and documented in a manner that meets the requirements of 38 CFR 16 Sections 116 and 117. The IRB will have the authority to observe or have a third party observe the consent process.
- G. Scheduled meetings of the IRB(s) for review of each research activity will occur not less than every 12 months and may be more frequent, if required by the IRB on the basis of degree of risk to subjects. The IRB may be called into an interim review session by the Chairperson at the request of any IRB member or institutional official to consider any matter concerned with the rights and welfare of any subject.
- H. The IRB(s) will prepare and maintain adequate documentation of its activities in accordance with 38 CFR 16 Section 115 and in conformance with ORA requirements.
- I. The IRB(s) will forward to the ORA any significant or material finding or action, at least to include the following:
  - 1. Injuries or any other unanticipated problems involving risks to subjects or others,
  - 2. Any serious or continuing noncompliance with the regulations or requirements of the IRB, and
  - 3. Any suspension or termination of IRB approval.
- J. In accordance with 38 CFR 16 Section 113, the IRB(s) will have the direct authority to suspend or terminate previously approved research that is not being conducted in

accordance with the IRB(s) requirements or that has been associated with unexpected serious harm to subjects.

- K. The IRB(s) for this institution will ensure effective input (consultants or non-voting members) for all initial and continuing reviews conducted on behalf of performance sites where there will be human research subjects. IRB minutes will document attendance of those other than regular voting members. The IRB list(s) in Appendix A includes those who are identified as knowledgeable about any affiliate institution having entered into an Inter-Institutional Amendment or other institutional performance site for which an Assurance is required when relying on one or more of the IRBs of this institution.
- L. Certifications of IRB review and approval will be forwarded through the ORA to the appropriate federal department or agency for research sponsored by such departments or agencies.

#### IV. Research Investigator

- A. Research investigators acknowledge and accept the responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provision of this Assurance.
- B. Research investigators who intend to involve human research subjects will not make the final determination of exemption from applicable federal regulations or provisions of this Assurance.
- C. Research investigators are responsible for providing a copy of the IRB approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the ORA.
- D. Research investigators will promptly report proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
- E. Research investigators are responsible for reporting progress of approved research to the ORA, as often as, and in the manner prescribed by the approving IRB on the basis of risks to subjects, but no less than once per year.
- F. Research investigators will promptly report to the IRB any injuries or other unanticipated problems involving risks to subjects and others.
- G. In the event of injury to a subject, the research investigator shall seek to provide any necessary emergency and continuing medical care. Such care is authorized under 38 CFR 17.
- H. No research investigator who is obligated by the provisions of the Assurance, any associated Inter-institutional Amendment, or Non-institutional Investigator Agreement will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law (see 38 CFR 16 section 116(f)). However, such activities will not be counted as research nor the data used in support of research.
- I. Research investigators will advise the IRB, ORA and the appropriate officials of other institutions of the intent to admit human subjects who are involved in research protocols

for which this Assurance or any related Inter-institutional Amendment or Noninstitutional Investigator Agreement applies. When such admission is planned or a frequent occurrence, those institutions must possess an applicable OHRP-approved Assurance prior to involvement of such persons as human subjects in those research protocols.

Part 3 - SIGNATURES

Institutional Endorsements

The officials signing below assure that any research activity conducted, supported or otherwise subject to DVA or other Federal departments or agencies that are authorized to rely on the Assurance (Parts 1,2,3 and Appendices) or any other sources provided for in this Assurance, will be reviewed and approved by the appropriate IRBs in accordance with the requirements of all applicable subparts of Part 16 and Part 17, Title 38 Code of the Federal Regulations, with this Assurance, and the stipulations of the IRB(s).

A. Primary Signatory Institution (if any)

1. AUTHORIZED INSTITUTIONAL OFFICIAL

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Title: Chief Executive Officer \_\_\_\_\_

Institution and Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_

FAX: \_\_\_\_\_

E-mail: \_\_\_\_\_

PRIMARY CONTACT

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Title: ACOS/Research & Development \_\_\_\_\_

Institution and Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_

FAX: \_\_\_\_\_

E-mail: \_\_\_\_\_

VHA Office of Research Compliance and Assurance

Approval A.

VHA Recommending Official

AUTHORIZED INSTITUTIONAL OFFICIAL

Signature: \_\_\_\_\_

Name: JOAN P. PORTER, DPA, MPH

Title: Associate Director, Office of Research Compliance & Assurance

Institution and Address: Veterans Health Administration  
Office of Research Compliance & Assurance  
811 Vermont Ave., N.W., Room 574 (10R)  
Washington, D.C. 20005  
Phone: (202) 565-7191  
FAX: (202) 565-9194  
E-mail: [joan.porter@mail.va.gov](mailto:joan.porter@mail.va.gov)

EFFECTIVE DATE OF ASSURANCE:

EXPIRATION DATE OF ASSURANCE:

B. VHA APPROVAL OFFICIAL

AUTHORIZED INSTITUTIONAL OFFICIAL

Signature: \_\_\_\_\_

Name: JOHN H. MATHER, M.D.

Title: Chief Officer, Office of Research Compliance & Assurance

Institution and Address: Veterans Health Administration  
Office of Research Compliance & Assurance  
811 Vermont Ave., N.W., Room 574 (10R)  
Washington, D.C. 20005  
Phone: (202) 565-9080  
FAX: (202) 565-9194  
E-mail: [john.mather@hq.med.va.gov](mailto:john.mather@hq.med.va.gov)

VA Multiple Project Assurance Contract  
Assurance of Compliance  
For Protection of Human Research Subjects

**Contract Number:**

**AMENDMENT 1**

The purpose of this amendment is to include the VA \_\_\_\_\_  
in this Assurance. Name and Location

The first paragraph on the first page of the Assurance should be amended to include: \_\_\_\_\_, her

Part 3, *Signatures*, should be amended to include, after A, *Primary Signatory Institution*:

B. Secondary Signatory Institution (if any)

1. AUTHORIZED INSTITUTIONAL OFFICIAL

Signature: \_\_\_\_\_

Name:

Title:

Institution and Address:

PRIMARY CONTACT

Signature: \_\_\_\_\_

Name:

Title:

Institution and Address:

Part 3—SIGNATURES

Contract Number:

**AMENDMENT 1**

Institutional Endorsements

The officials signing below assure that any research activity conducted, supported, or otherwise subject to DVA or other Federal departments or agencies that are authorized to rely on the Assurance (Parts 1,2,3, and Appendices) or any other sources provided for in this Assurance, will be reviewed and approved by appropriate IRBs in accordance with the requirements of all applicable subparts of Part 16 and Part 17, Title 38 Code of the Federal Regulations, with this Assurance, and the stipulations on the IRB(s).

A. Primary Signatory Institution (if any)

1. AUTHORIZED INSTITUTIONAL OFFICIAL

Signature: \_\_\_\_\_

Name:

Title:

Institution and Address:

PRIMARY CONTACT

Signature: \_\_\_\_\_

Name:

Title:

Institution and Address:

B. Secondary Signatory Institution (if any)

1. AUTHORIZED INSTITUTIONAL OFFICIAL

Signature: \_\_\_\_\_

Name:

Title:

Institution and Address:

PRIMARY CONTACT

Signature: \_\_\_\_\_

Name:

Title:

Institution and Address:

All other terms of the Assurance are hereby incorporated by reference and will apply to \_\_\_\_\_.

[List all institutions signing.]

Concurrence: VISN Director

Signature: \_\_\_\_\_

Name:

Address:

Date: \_\_\_\_\_

VA MPA Contract Number:

Amendment 1

VHA Office of Research Compliance and Assurance

Approval A

VHA Recommending Official

AUTHORIZED INSTITUTIONAL OFFICIAL

Signature: \_\_\_\_\_

Name: JOAN P. PORTER, DPA, MPH

Title: Associate Director, ORCA

Institution and Address: 811 Vermont Ave., NW (10R) Ph.: (202) 565-7191  
Room 574 Fax: (202) 565-9194  
Washington, DC 20005

EFFECTIVE DATE OF ASSURANCE:

EXPIRATION DATE OF ASSURANCE: February 2003

B. VHA APPROVAL OFFICIAL

AUTHORIZED INSTITUTIONAL OFFICIAL

Signature: \_\_\_\_\_

Name: JOHN H. MATHER, M.D.

Title: Chief Officer, ORCA

Institution and Address: 811 Vermont Ave., NW (10R) Ph.: (202) 565-9080  
Room 574 Fax: (202) 565-9194  
Washington, DC 20005

## ATTACHMENT 2

### VHA Actions to Respond to GAO Recommendations To Strengthen Human Research Protections

**GAO Recommendation 1:** Provide research staff with current, comprehensive, and clear guidance regarding protections for the rights and welfare of human research subjects.

**Response 1:**

The statement mentions the policy update being undertaken by the Office of Research and Development and the TED initiative launched earlier this year by ORCA. ORCA has also established a Field Advisory Committee to assure broad input from – and broad outreach to – our field facilities on how to make protection of human research subjects increasingly evident in the VA system. Additional guidance has been provided by both ORCA and ORD in the form of information letters, satellite conferences, presentations at our National Leadership Board meetings, monthly national Hotline conference calls, surveys, and distribution of self-study materials. These efforts will continue.

**GAO Recommendation 2:** Provide periodic training to investigators, IRB (Institutional Review Board) members, and IRB staff about research ethics and standards for protecting human subjects.

**Response 2:**

ORD has established a training requirement for investigators, similar to the educational requirements recently announced by NIH. Beginning in January, we will require investigators to be certified in human subjects protections to be eligible for VA research funding. The primary responsibility to ensure adequate training of investigators and IRB members rests with the management of local facilities. ORD provides self-study materials to every research office in the field and posts research policies, guidance, and training opportunities on its web site. National opportunities for training are provided by ORD through the Society of Research Administrators annual meeting, the annual meetings of each of the divisions of the VA Research Service, and the Office of Research and Development biennial national meeting. ORD is also planning a State of the Art conference on informed consent, in collaboration with the VA National Ethics Center and the Hastings Center.

ORCA is proceeding, in conjunction with the Employee Education System and other VA offices and with organizations with like responsibilities outside of VA, to develop and promote training,

education, and development activities in conjunction with the Veterans Integrated Systems Networks (VISNs) and other internal and external stakeholders. ORCA is accomplishing this, in part, through coordination with its VA-wide TED Focus Group. ORCA now participates as a full partner with the Department of Health and Human Services' Office of Human Subjects Protections and the Food and Drug Administration in sponsoring several regional workshops on human subject protections annually. ORCA will also sponsor a one-day symposium on VA-specific issues at the Public Responsibility in Medicine and Research annual meeting in October 2000.

ORCA's new web site will provide a comprehensive information resource for VA's research community by providing policies and procedures, regulatory requirements, Frequently Asked Questions, formats for documents, VA MPA contract listings, announcements of educational opportunities, links to other helpful sites and many other features.

ORCA plans additional activities to help investigators, other research staff, institutional review board (IRB) members and administrators, and other VISN and Veterans' Affairs Medical Center management understand and carry out their responsibilities in the human subjects protection system. These activities will include a series of information letters, teleconferences, on-line training modules, face to face workshops and presentations, satellite coverage of major related meetings, and on site advisory consultations. ORCA will complete the preparation of a comprehensive strategic plan for all these training and education activities for all personnel involved in human subjects research this year.

**GAO Recommendation 3:** Develop a mechanism for handling adverse event reports that ensures that IRBs have the information they need to safeguard the rights and welfare of human research participants.

**Response 3:**

This is currently an area of concern throughout the broader research and regulatory community and will require careful attention. VA will participate actively in ongoing Federal government-wide efforts to develop a more useful and coordinated system to manage adverse event reporting. As an initial step the Office of Research and Development has expanded the distribution of reports from its Data Safety Monitoring Boards to include all appropriate IRBs. As I indicated earlier, ORCA is now the headquarters component that receives from VA medical centers adverse event reports and serious adverse event (SAEs) reports involving research protocols. The development

of an improved process for the submission of these reports and the systematic collection of data has been initiated in coordination with VHA's National Center for Patient Safety.

**GAO Recommendation 4:** Expedite development of information needed to monitor local protection systems, investigators, and studies and ensure that oversight activities are implemented.

**Response 4:**

VHA has initiated the contract with NCQA for mandatory external accreditation of IRBs, the first such initiative in the country. Performance measures have been put in place for VISN Directors regarding research assurance processes and external accreditation. ORD initiated a performance plan for Associate Chiefs of Staff for Research and Development at field facilities that includes responsibility for risk management, including monitoring local human subjects protection systems, investigators, and studies. ORD has established a site monitoring and review unit to conduct on-site visits at local facilities, during the conduct of clinical trials. ORD established, and ORCA is maintaining, VA Multiple Project Assurances Contracts with all local facilities that conduct research involving human subjects. .

ORCA has developed and will continue to refine an oversight program that will involve regular routine visits and for cause visits, known as Special Inquiry Force Team (SIFT) reviews, with scheduled and unscheduled on-site visits to VA sites carrying out research. ORCA staff has already conducted five of these SIFT visits to address specific concerns at several sites and to determine where systemic problems may need to be addressed. ORCA is urging sites to contact staff for help and advice and to self-report problems identified in protection of human subjects at their sites so that those problems can be rapidly and fairly addressed and ethical research can go forward. ORCA's new Mini-Assessment Program (MAP) review Focus Group has met and is advising on the development of a Self-Assessment process for Research Services and defining the most effective procedures for conduct of on-site MAP reviews. In addition, ORCA staff will serve as participant/observers at the external accreditation site visits for human subjects to be conducted by NCQA and will also collaborate with ORD's project manager in advising on the accreditation mechanism; ORCA will provide a comprehensive overview of the findings from the accreditation visits in order to ascertain systemic problems for correction through regulatory or educational activity.

**GAO Recommendation 5:** Determine the funding levels needed to support human subject protection activities at medical centers and ensure an appropriate allocation of funds to support these activities.

**Response 5:**

VHA has established a mechanism to account for allocation of VERA funds in support of the indirect costs of research, including support for assurance processes at the facility level. The Office of Research and Development already provides financial support to partially fund the assurances process, and has provided guidance to the field on the VERA allocation mechanism and on accessing additional funding streams from research that is supported by non-VA sources to fund the assurances process. VHA has asked the Director of the National Institutes of Health to add an indirect cost allocation to NIH grants for research carried out at VA facilities to partially compensate those institutions for the supplemental costs of supporting NIH research, including the costs of regulatory compliance. ORD has also provided preliminary guidance to the VISN Directors on the needed IRB staffing levels and has commissioned a formal Health Systems Research and Development study to gather real data to direct our resource allocation decisions.