VA NEBRASKA-WESTERN IOWA
HEALTH CARE SYSTEM (VA NWIHCS)
Omaha, NE (636)

HUMAN RESEARCH PROTECTION PLAN
STANDARD OPERATING PROCEDURES

A MANUAL

for

IRB/R&D Committee Members,
Principal Investigators,
& Staff

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[Signature]
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Date
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A. DESCRIPTION OF INSTITUTION

The NWIHCS is committed to fostering a strong research community with the highest levels of ethical standards. Over the past several years, we have focused attention on increasing the resources necessary to support the research endeavor, developing a comprehensive Human Research Protection Program (HRPP) and requiring ongoing education for all involved in research.

The Omaha VA Medical Center Research Service has been serving veterans in both rural and urban settings for over 60 years in the following types of research:

- Clinical research (we have a designated Clinical Research Unit for clinical research purposes)
- Behavior and Social Sciences
- Epidemiological
- Repository
- Quality improvement
- Patient Records
- Genetic

There are three major focus areas of research at NWIHCS that involve:

- Alcohol and Addictive Disorders
- Obesity and Type II Diabetes Mellitus
- Rheumatology and Immunology

Additional areas of research include work in Mental Health, Substance Abuse, Liver Disease, Immunology, Endocrine/Diabetes/Obesity, Pulmonary Airway Inflammation and COPD, Rheumatology Arthritis, Infectious Disease, Orthopedic Rehabilitation, GI Physiology (obesity emphasis), Surgical Wound Healing, Cancer Treatment Trials, Reproductive Endocrinology, Videolaryngoscopy and Virtual Perioperative Care, Vascular Diseases/gait, Dental Prosthetics, Quality of Care and Patient Safety. Conducting research on each of these areas which impact on the health and care of veterans is consistent with the NWIHCS and VA mission.

There are currently approximately 130 studies being conducted at NWIHCS and the affiliate University of Nebraska Medical Center (UNMC) by about 60 principal investigators and over 300 research personnel within the VA and our academic affiliates. The research done at NWIHCS is supported by a variety of funding sources including the following:

- Department of Veteran Affairs
  - VA Merit Review
  - VA Cooperative Studies program
  - VA Health Services R&D
  - VA Rehabilitation R&D
- National Alliance for Research on Schizophrenia and Depression
- National Cancer Institute
- Pharmaceutical companies
- Henry Jackson Foundation
B. GOAL OF NWIHCS HUMAN RESEARCH PROTECTION PROGRAM

The Human Research Protection Program (HRPP) at the NWIHCS is an integrated and comprehensive program involving senior management of the institution to include: The Research Administrative Office (RAO), Institutional Review Board (IRB), Research and Development (R&D) Committee, Subcommittee for Research Safety (SRS), and all investigators who conduct research involving humans. It is supported with dedicated resources allocated by the Institutional Official. The goal of the Human Research Protection Program is to protect the human rights, safety and well-being of any individual who may serve as a subject/participant of a research project at the VANWIHCS. This includes Veterans and non-Veterans, patients and non-patients, volunteers, students and employees. The outcome criteria upon which success of the program is judged are:

1. Human research activities occur throughout the NWIHCS medical center and the human subjects protection program is integrated into the overall operations of the medical center
2. Subjects are provided protections when they take part in studies conducted or overseen at NWIHCS
3. Individuals involved in human research understand the organization's goals to protect subjects.
4. All levels of the organization make human research protection a priority.
5. Research procedures do not commence until the research protocol has received all approvals required by the organization.
6. Investigators and research staff are trained in human protections and the specific procedures of their approved research.

C. DESCRIPTION OF GOVERNING REGULATIONS AND GUIDANCE

The Human Research Protection Program (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 VA facility Director, Associate
Chief of Staff for Research and Development (ACOS/R&D), the Administrative Officer (AO) for R&D, the R&D Committee, the IRB, other committees or subcommittees addressing human subjects protection (e.g., Biosafety, Radiation Safety, Conflict of Interest, investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer), research compliance officers (RCOs), Information System Security Officers (ISSOs), privacy officers (POs), 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. A diagram of the [name of institution] program may be found at Appendix 5.

This HRPP program operates under a Federal-wide Assurance (FWA0000556) with a VA Addendum issued by ORO. The program is governed by the VA regulations at 38 CFR parts 16 and 17; the Food and Drug Administration (FDA) regulations (21 CFR), and the Department of Health and Human Services (DHHS) 45 CFR Part 46 subparts. These regulations apply to all research conducted at NWIHCS, both VA funded and externally funded when applicable to the study. HIPAA and Privacy rules apply to the majority of our studies. When FDA regulations apply, the activities subject to the human research protection program will include "clinical investigations" as defined by the FDA regulations. Investigators receiving support from other Federal agencies (e.g. DoD, DoE or DHHS) must meet requirements for the protection of human subjects of the funding source in addition to those of the VA. Research activities subject to the HRPP include all research involving humans as subjects as defined by the VA regulations. The HRPP also oversees the process of making determinations as to whether a project meets the regulatory definition of human subject's research.

The operation of the HRPP is governed by the principles outlined in the Belmont Report, the document of ethical principles underlying modern concepts of human subject protection. The three key principles governing the use of humans in research at the NWIHCS are respect for persons, beneficence, and justice. It is imperative that human research subjects receive the highest level of protection possible and that any questions or any legal or ethical ambiguities that arise always be resolved in favor of the human research subject. The principals of the HRPP apply to all research involving human subjects, and all other activities which even in part involve such research, regardless of whether the research is otherwise subject to VA regulations, if:

A. The research is sponsored/funded by the VA or receives a direct HHS award, or;

B. Any full-time, part-time, consultant or without compensation (WOC) employee of NWIHCS, or an individual supported by an on-station fee-basis, on-station contract, or on-station sharing agreement basis who intervenes or interacts with living individuals for research purposes or obtains individually identifiable private information for research purposes or is otherwise known as “engaged” in the research, or;

C. The research is conducted using any property or facility owned or
managed by NWIHCS or;

D. The research recruits subjects at NWIHCS, thus implying endorsement by this institution or;

E. The research involves the use of the NWIHCS nonpublic information to identify or contact human research subjects or prospective subjects or to use such data for research purposes.

All research to be performed on human subjects in NWIHCS requires the prior approval of the R&D Committee. The R&D Committee will approve non-exempt research studies involving human research only after approval by the IRB and all other appropriate subcommittees. The R&D committee may approve “research not involving human subjects” and “exempt” studies after a research determination is made and any institutional requirements for approval are met.

Exempt research determinations may be made through a VA approved electronic determination platform or by an individual trained in making research determinations. That person may or may not be a member of the IRB, however for exempt studies determined to require limited IRB review, an IRB member must conduct the limited IRB review in accordance with the IRB SOP.

Research funded through a VA Non-Profit Corporation (NPC) is considered VA research and the NPC must use the IRB(s) of Record and the R&D Committee of the VA facility that will conduct the research (see VHA Handbook 1200.17). Neither the VA facility nor the investigator may engage the services of another IRB for the purposes of avoiding the requirements or determinations of the IRB of Record.

Individual investigator conflicts of interest (COI) documents are centrally collected and processed. Where an institutional conflict of interest is suspected, the conflict may be reviewed and managed by the VISN Director. (see Appendix 16)

The documents required to submit a research protocol are located: https://www.nebraska.va.gov/services/Research/irb_home.asp

If this facility is contacted by a research participant with a concern about the research study, the concern will be forwarded within 1 business day to the Administrative Officer at 402-995-3541 who will adjudicate the concern to the appropriate committee(s). (see IRB SOP chapter research complaints)

This program is committed to returning incidental finding results to research participants when the information is deemed by the study team to be potentially actionable.

This use of a non-affiliated IRB is not allowed at NWIHCS.
E. HRPP PROGRAM DESIGN

The NWIHCS Director serves as the Institutional Official (IO)

The Institutional Official (IO) is the individual legally authorized as Signatory Official to commit an institution to an FWA. The Signatory Official assures that human subjects research to which the FWA applies is conducted in accordance with the terms of the assurance (see VHA Handbook 1058.03). The IO is ultimately responsible for overseeing the protection of human subjects within the facility. As such, the IO provides oversight of both the IRB and R&D committees, and all VA investigators (compensated, WOC, contractors, or those appointed under an Intergovernmental Personnel Agreement). The Institutional Official has approved a HRPP program that consists of a) oversight, b) implementation, and c) quality assurance and improvement subunits.

The IO undergoes training regarding his/her responsibilities as the IO within approximately 30 days of assuming this position. If there is to be a transition in IO leadership, every effort is made to ensure that there is overlap in IO coverage. When not possible, a senior member of the staff with appropriate authority may be trained as the IO and serve in this capacity until a new IO is named.

The IO delegates the day to day oversight of the program to the Associate Chief of Staff of Research, and Institutional Review Board. Quality Assurance is overseen by the Research Compliance Officer who reports to the Director. Quality assurance of the Research Pharmacy is overseen by the Chief of Pharmacy and Clinical Services.

The RCO is assigned to the Medical Center Director and operates independently of the Research Service.

The CRADO (delegated to the Director, ORPP&E) will approve any changes to the IRB(s) of Record for the institution.

F. DESCRIPTION OF THE HRPP IMPLEMENTATION

The Director of the NWIHCS has delegated the responsibility for the implementation of the HRPP to the Associate Chief of Staff for Research and Development (ACOS R&D). The implementation subunit consists of the Research Administrative Office.

The Research Office includes the Associate Chief of Staff for Research and
Development (ACOS/R&D), Administrative Officer (AO), R&D Coordinator and IRB Coordinator. These staff are located in Research Administrative in building 1. The office suite includes offices equipped with computers linked to both the VA intranet and internet, printers and telephone access, conference rooms, a photocopy room and file space. All active and archived research files are located within the Research Administrative Office. Meetings of the IRB and R&D Committee and all other committees and subcommittees occur in the main research conference room.

Research Administrative Offices, through the IRB/HRPP, oversees investigators involved in over 65 studies with human subjects. NWIHCS has a wide variety of studies ranging from health services research; investigator initiated merit review studies; VA Cooperative Studies; and pharmaceutical company sponsored clinical trials. These studies address a wide variety of health issues (cancer, HIV, GI disorders, cardiology treatments, pulmonary medications, health services research, mental illness, etc.)

The types of subjects covered by the HRPP are NWIHCSVA Veteran patients, non-Veterans from the community and employees.

G. STRUCTURAL ELEMENTS OF THE HRPP

The HRPP at the Institution consists of 2 main components.

1. Research Office Operations
   d. Administration: The IO has delegated the responsibility for ensuring day-to-day operation of the HRPP to the ACOS/R&D. The ACOS/R&D relies on the R&D Administrative Officer and other staff to assist with the operational functions. The Credentialing Coordinator will be responsible for assuring that anyone who is involved in conducting human subjects research have an appropriate employment status and that their professional credentials and licenses (if applicable) have been reviewed and they are trained to be involved with human research activities at the Institution.
   e. Budget: The AO, and ACOS/R&D in coordination with the budget technician annually prepare a budget reflecting the required costs for the management of the HRPP. The budget is discussed at an R&D Committee meeting as part of the annual HRPP report. The R&D Committee evaluates the budget in relation to the current research activities and forwards their recommendations to the Institutional Official through the Chief of Staff (COS). Should unexpected costs arise or the research program undergoes a rapid expansion, a special review is scheduled by the R&D Committee. Any deficits are addressed by the R&D Committee and recommendations forwarded to the IO through the COS. The budget includes personnel, supplies, equipment, educational expenses (TDY), space, and capital equipment.
f. **Education:** The IRB/HRPP incorporates an ongoing training and education program for investigators, research staff, IRB and R&D Committee members and other individuals with responsibility for human subject protection, which is described in detail in the separate Educational Plan. (Appendix 6). Instructional methods and materials include web based tutorials and information, VA manuals; handbooks and policy documents, ongoing educational conferences and internal and external training activities. The R&D Committee annually reviews the training needs of committee members and committee support staff. The ACOS/R&D, with input from the IRB Coordinator, annually reviews the training needs of investigators and their staff. The IRB Coordinator tracks compliance with required training. The NWIHCS also takes advantage of educational sessions offered through the cyberseminars of ORPP&E.

g. **Quality Management:** The RCO is responsible for research quality management at NWIHCS. There is an ongoing quality assurance(QA)/quality improvement(QI) HRPP program review for evaluating HRPP effectiveness and for reporting QI activities. Evaluation and improvement include measuring, assessing and improving compliance with the Institution’s HRPP policies, and assurances and other requirements for the protection of human subjects in research. The Research Compliance Officer (RCO) is responsible for conducting these reviews and reports findings and recommendations monthly report to the Subcommittees and R&D Committee. The R&D Committee reviews and may endorse any necessary changes, and empowers the service to implement any needed changes.

h. **Institutional Policy Development:** The IRB Coordinator is responsible for identifying any external guidance that affects the Institution’s IRB policies, or gaps in IRB policies and procedures. They will develop any necessary changes to the Institution’s policies with input from the IRB and present revised policies or procedures to R&D Committee for review.

i. **Communications Coordination.** The IRB Coordinator in collaboration with R&D Coordinator integrates information from all the components of the HRPP, including assessing the need for additional resources, new committee members, and policy revision. In addition, the IRB Coordinator serves as the focal point for communication, monitoring the flow of information concerning all elements of the HRPP, including project approval to the investigator and when appropriate to the Pharmacy, reviewing compliance reports.

2. **HRPP Committee Structure and Other Related Resources**

**R&D Committee:** The R&D Committee is responsible to the IO (with notification to the COS) for ensuring high research standards throughout the Institution and ensuring that projects proposed for the Institution are appropriate for the Institution if approved. The R&D considers other projects occurring within the Institution to ensure that a targeted population is not oversaturated with research. Additional considerations
include those concerning scientific quality of research projects and the impact of the research on the facility. In addition to reviewing IRB minutes (specifically looking at: the controverted issues that might affect other committees or the institution as a whole; corrective plans taken by the IRB for noncompliance) and RCO’s QA/QI monthly reports regarding human research, the R&D Committee requires an annual report on the status of the HRPP. The IRB may recommend to the R&D Committee that additional sanctions be considered that are outside of its immediate purview, e.g., suspending overall research privileges for a period, recommending that a Service Chief take disciplinary action, etc. The R&D Committee will make recommendations to the Institutional Official through the Chief of Staff for any remediation proposals or change in research privileges. This includes an assessment of the composition of the IRB to ensure it is appropriately constituted and has the scientific and medical expertise to evaluate research currently being reviewed.

The R&D Committee reviews a list of all IRB approved human subject’s research to ensure that the circumstances at the facility have not changed that might affect the ability for the study to be conducted. Additional prerequisites for R&D Committee approval include approval from IRB, Biosafety Subcommittee, and Radiation Safety Committee (if applicable) along with information concerning resources that demonstrates that there are adequate resources for compensation of subjects, information about the relevance of the project to the overall VA mission, etc. The R&D Committee cannot approve a study in which all applicable subcommittees approvals have been obtained. The R&D Committee may never approve a study that has not been approved by the IRB; however, IRB approved research may be disapproved by the R&D Committee, the Medical Center Director or the Office of Research and Development (ORD) central office.

d. **Institutional Review Board (IRB):** The IRB is a board established in accordance with and for the purposes expressed in the Common Rule (38 CFR §16.102(g)). As stipulated in the Belmont Report and based upon the principles respect for persons, beneficence, and justice, the primary responsibility of the IRB is to ensure: (1) the sum of the benefits to the subject and the importance of the knowledge to be gained so outweigh the risks to the subjects as to warrant a decision to allow the subject to accept these risks, (2) legally effective informed consent is obtained, unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations, and (3) the selection of subjects is equitable and is representative of the group that will benefit from the research. There is a separate IRB SOP that outlines the responsibilities and functions of the IRB. The IRB will review all non-exempt research at an interval appropriate to the degree of risk, but not less than once per year except where continuing review is not required. The institution requires an annual status report on all human
subjects studies not subject to continuing review, this includes exempt research. The annual status report is listed at Appendix 2. Although designated as a subcommittee of the R&D Committee by VA regulations, the IRB functions independently, free of undue influence and oversight of its decisions. The Institution’s IRB cannot serve as an IRB of Record for any non-VA entity except for a federal agency (e.g., DoD, DOE) or VA NPC. At this Institution, the NPC is Nebraska Educational Biomedical Research Association. On NEBRA FWA# 00011257 must list the NWIHCs IRB.

**AND/OR:**

**Institutional Review Board (IRB):** The NWIHCs has (an) agreement(s) in place and registered with ORO to use the services of the following IRB(s):

- VA Central IRB

Prior to a protocol being submitted to the IRB the following cases must be specifically addressed:

- If the study involves an intervention with a pregnant woman, the facility Director must certify that the study will be allowed to occur.

- If the study involves neonates (up to 28 days of life outside the womb) in any way, the facility director must certify the research.

- If the study involves prisoners, the CRADO (delegated to the Director, ORPP&E) must grant a waiver. See Appendix 4 for waiver application.

- If the study involves an interaction or intervention with children, the facility Director must certify that the study will be allowed to occur.

- Any study involving the medical records related to alcohol use or treatment, illegal drug use or treatment, sickle cell anemia, or HIV are reviewed under the privacy considerations of 38 CFR 7332.

- If the study involves treatment in a VA facility (inpatient or outpatient) only veterans eligible for care in a VHA facility may be enrolled, unless there are insufficient eligible veterans available to conduct the study. in accordance with 38 CFR 17.45 and 38 CFR 17.92. All regulations pertaining to the inclusion of Veterans pertain to non-Veteran subjects enrolled in VA approved research. For studies conducted that target families or care around the veteran, the VA will allow enrollment of non-veteran populations.

- If the study is a multisite study and requires reliance on a non-VA IRB, the facility director (or designee) must seek approval from the
The IRB(s) of Record does serve as a privacy board for the institution ensuring compliance with the Health Insurance Portability and Accountability Act (HIPAA) and Privacy requirements when applicable and granting HIPAA authorization waivers as applicable.

The IRB has the authority to approve, require modifications to secure approval, and disapprove all research activities under their purview. The IRB has the authority to suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that had been associated with unexpected serious harm to participants. The IRB has the authority to observe, or have a third party observe, the consent process and the conduct of the research. The Institution does not allow any officials of the Institution to approve non-exempt research that has not been approved by the IRB.

Investigators may only use the IRB(s) of Record listed in this HRPP. The investigator may not decide which institutional IRB is used for a given study. That determination will be made by the research office staff.

e. **Other Committees and Subcommittees**
   i. SRS review is required for any study that may expose staff to risk and a Safety Application is required. Research projects that do not expose staff to risk do not require reporting or approval by the SRS. The checklist at Appendix 3 must be completed and included with protocol documents.
   ii. Research in which human subjects are subjected to exposure to ionizing radiation must be reviewed by and approved by the Radiation Safety Committee.

f. **Compliance:** The Research Compliance Officer (RCO) performs compliance assessment of the investigators, the IRB, the R&D committee, and the HRPP on an on-going basis. This involves reviewing study documents to ensure appropriate enrollment and consent procedures, appropriate adherence to the protocol, any identified serious deviations are reported immediately and that the investigator continues to have adequate resources to protect the subjects enrolled in the research. Results are shared with the IRB, R&D Committee and Administrative Officer monthly.

g. **Legal support:** The VA Office of Regional Counsel (STAR – Specialty Team Advising Research) is available for consultation concerning the interpretation of any laws or any issues of misconduct involving research. Guidance is available for the IO as well as researchers.

h. **NON-PROFIT Corporation:** The NPC administers non-VA grants for the Institution’s investigators. The NPC has its own FWA and interacts with the IRB Coordinator, R&D Coordinator, and the Administrator Officer ensuring that projects do not commence without R&D Committee approval.
i. **Principal Investigator** is the individual who conducts a research investigation and is responsible for the safety of all subjects enrolled in the research. In the event the research is conducted by a team, the Principal Investigator (PI) is the responsible leader of that team. A Co-PI assumes the same responsibilities as a PI. Co-investigators work under the direction of the PI and may be involved in some or all aspects of the research project, including the design of the study, conduct of the study, analysis and interpretation of collected data, and writing of resulting manuscripts. Any VA investigator must be either compensated by the VA, be appointed to work without compensation (WOC) or may be assigned to the VA through the Intergovernmental Personnel Act (IPA).

j. **Research Pharmacist.** The research pharmacist is responsible for the control and dispensing of all investigational drugs utilized in research. This person provides technical advice to investigators about drugs, ensures that only authorized prescribers prescribe the study medications, and ensures the properly executed informed consent documents are present prior to dispensing medication. In addition, the research pharmacist can be an ex-officio voting member of the R&D Committee.

k. **Sponsors:** Sponsors can be investigators, industry, federal partners, VA programs, and other types of organizations (university or Non-profit). The usual role is the overall management of the project and there specific reporting requirements of sponsors, depending on the type of study.

H. **SPECIFIC POLICY ISSUES AND CERTIFICATION REQUIREMENTS**

1. **Signatures:** Signatures may either be made with ink or collected electronically.

2. **Broad consent:** This institution does not allow the use of broad consent for data and specimens collected solely for research.

3. **In Vitro fertilization research:** This institution does not allow research involving the provision of invitro fertilization services.

4. **In Vitro Fertilization research:** This institution does not allow research involving prospective or retrospective studies that enroll or include pregnant subjects conceived through invitro fertilization are permitted.

5. **Stem cell research:** This institution does not allow the use of adult stem cells in research.

6. **Embryonic stem cells:** This institution does not allow research involving embryonic stem cells IAW NIH Policy. If it advised that VISN notification occur prior to the approval of such a study.

7. **Interventional Research with children:** This institution does not allow research with children. If allowed, the research is not more than minimal risk and facility director certification is required.

8. **International Research:** This institution does allow international research. If allowed, facility director certification is required. (Appendix 13)

9. **Interventional research with Pregnant Women:** This institution does not allow interventional research with pregnant women.

10. **Neonate:** This institution does not allow interventional research with neonates; however observational studies may be permitted.
11. **Expanded Access**: When access to a drug is required under the FDA expanded access regulations, notification of the COS is required.

12. **Interventional Fetal research**: This facility does not allow any interventional research where the focus is the fetus.

13. **Other than Interventional veteran research participation**: This facility does allow veterans who are not eligible for care to participate in non-interventional research such as surveys with appropriate justification.

14. **Veterans not eligible for care in interventional research and non-veterans**: This facility (choose one) does allow veterans who are not eligible for care or others who are not eligible for care in VHA system to participate in interventional research studies. An exception may be requested through the facility director.
I. GENERAL RESPONSIBILITIES (see Responsibility Matrix Appendix 11)

Institutional Official:

(1) Overseeing the facility’s research program. The IO is responsible for the creation and implementation of an HRPP for research involving human subjects. The IO’s responsibilities for the facility’s IRB/HRPP include, but are not limited to:

(a) Ensuring that the institution’s IRB/HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects;

(b) Overseeing the R&D Committee, IRB, and other applicable subcommittees of the R&D Committee, facility research office, and all VA investigators and VA research staff who conduct human subjects research at that facility;

(c) Delegating authority in writing for respective roles and responsibilities for the IRB/HRPP. This delegation of authority must provide the organizational structure and ensure leadership for oversight activities for all human subjects research conducted at or by the facility;

   i. May not delegate the responsibility of signing the Assurance, signing certification letters, or conducting human research training.

   ii. May delegate all other responsibilities.

(d) Ensuring provision of adequate resources to support the operations of the IRB/HRPP;

(e) Ensuring independence of the IRB;

(f) Appointing the facility’s IRB voting members in writing when the VA facility operates its own IRB;

(g) Appointing the Chair and, when applicable, Co-chair(s) or Vice Chair(s) for a term of up to 3 years when the VA facility operates its own IRB;

(2) Serving as the official representative of the institution to external agencies and oversight bodies, and providing all written communication with external departments, agencies, and oversight bodies;

(3) Ensuring that a procedure is in place to review and approve recruiting media, including documents, flyers, and advertisements for research that is not VA research prior to being posted or distributed in any form within or on the premises of a VA facility. Posting or distributing may include announcing, distributing, publishing, or advertising the study either electronically, by hard copy, or other means to anyone, including Veterans, clinicians, or other staff (see ORD guidance at http://www.research.va.gov/resources/policies/default.cfm);
(4) Ensuring that a documented procedure is in place for determining when a research activity approved by the IRB, prior to January 21, 2019, can transition to the 2018 Requirements, if applicable. The documented procedure must list what individuals or groups are designated to make the determinations. **NOTE:** Investigators may not unilaterally decide that their studies can be transitioned to the 2018 Requirements;

(5) Ensuring appropriate documentation of required actions and responsibilities pertaining to review, approval, conduct and oversight of research conducted at that facility set forth in this directive;

(6) Ensuring all research subject to this directive is reviewed and approved by an IRB and will be subject to oversight by the IRB. **NOTE:** Research that meets the exempt categories is not subject to IRB review unless it is determined to meet one of the exempt categories requiring limited IRB review. All exempt research must be reviewed and approved by the R&D Committee (see Appendices A and B);

(7) Ensuring that any IRB operated by the VA facility is established in accordance with the requirements of this directive and registered through ORO with the HHS OHRP (see VHA Handbook 1058.03);

(a) The facility’s IRB(s) of Record may include the facility’s own IRB(s), VHA Central Office IRB (VA Central IRB), an IRB of another VA facility, the IRB(s) of an affiliated medical or dental school, or the IRB of another Federal agency. A facility may also use for multi-site protocols an IRB from a non-affiliated medical or dental school if that IRB has been specifically designated by ORD as an IRB that may serve as a multi-site IRB for VA facilities. **NOTE:** A VA facility may not use a commercial IRB as an IRB of Record;

(b) A VA facility’s own IRB, also known as an internal IRB, and the VA Central IRB, cannot serve as an IRB of Record for any non-VA entity except a Department of Defense (DoD) facility, Department of Energy laboratory, or a VA NPC;

(c) When the facility engages the services of another entity’s IRB as its IRB of Record, the IO is responsible for:

1. Establishing and signing a Memorandum of Understanding (MOU) or Authorizing Agreement with other VA facilities or external organization(s) providing IRB services (see VHA Handbook 1058.03 and MOU Checklist: http://www.va.gov/ORO/orochecklists.asp);

2. Ensuring that external IRBs of Record used by the VA facility hold current IRB registrations with FDA/OHRP and provide updates to membership as required by VHA Handbook 1058.03;

(8) Requesting CRADO approval when the VA facility wants to establish a new HRPP, change its IRB(s) of Record, or wants its internal IRB to serve as an IRB of Record for a non-VA entity. **NOTE:** All IRBs overseeing VA human subjects research regardless of the type described above must meet all the IRB requirements described in 38 CFR Part 16;
(9) Submitting waiver requests electronically to the CRADO for approval of research involving prisoners conducted by VA investigators while on official VA duty, in accordance with the process outlined in section 20 below; and

(10) Approving VA participation in proposed research that includes pregnant women, neonates, or children as described in this directive (see sections 19 and 21).

1. The Associate Chief of Staff for Research and Development (ACOS/R&D)
   d. Serves as the primary point of contact for internal and external research integrity inquiries and complaints.
   e. Reviews and evaluates the reports and results of compliance assessment and quality improvement activities.
   f. Implements needed improvements and follow-up on actions as appropriate.
   g. Evaluates the implementation and progress of the HRPP to ensure its compliance with acceptable ethical principles.
   h. Is responsible for the implementation subunit of the HRPP
   i. Obtains from the entity administering the study funds an annual accounting of the total amount of direct costs of industry-funded studies conducted at the NWIHCS as well as the amount of funds that were made available for support of HRPP costs. This accounting will be compared to records maintained by the Research Office.
   j. Ensures that all clinical and academic activities of NWIHCS, including research, are conducted ethically.
   k. Monitors reports provided by the Research Compliance Officer
   l. Ensures oversight mechanisms are implemented

2. The Administrative Officer for Research and Development
   d. Submits RDIS reports for all VA research projects regardless of funding source to the Director of Finance, and ORD.
   e. Is responsible for the oversight of the Human Research Protection Program and directly supervises all IRB support staff
   f. Serves as an ex-officio, non-voting member of the IRB
   g. Assists in establishing new IRB members
   h. Reviews IRB SOP at least annually
   i. Completes and submits reports to the facility Privacy Officer, via email or telephone, of any unauthorized use, loss, or disclosure of individually-identifiable patient information immediately or no later than 60 minutes after notification of the breach/suspected breach.
   j. Completes and submits reports to the facility Information Security Officer via email or telephone, immediately or no later than 60 minutes after notification of the breach/suspected breach.
   k. Communicates with outside institutions participating in multi-site and collaborative research regarding local IRB
determinations

I. Provides notifications/reports to Medical Center Director and other outside agencies.

m. Assists ACOS in the implementation of a Quality Improvement Plan and required corrective actions.

n. Functions as an institutional contact person for human research protection activities with administrative responsibility for the Human Research Protection Program. As such, provides sufficient oversight to ensure that the research being approved and conducted meets the agreed upon ethical standards.

o. Understand policies, procedures and regulations regarding human subjects research and IRB operations.

3. IRB Coordinator

d. Understand policies, procedures and regulations regarding human subjects research and IRB operations.

e. Serves as the contact person for IRB related to human research protection activities with administrative responsibility. As such, provides sufficient oversight to ensure that the research being approved and conducted meets the agreed upon ethical standards.

f. Serves as an ex-officio, non-voting member of the IRB and does not have to be appointed by the Institutional Official since membership is based on the position rather than the individual.

g. Provides a copy of any ORO compliance reports regarding the research program to the Associate Chief of Staff for Research, Research. & Development Committee, any relevant research review committee(s), and the Research Compliance Officer in a timely manner.

h. Oversees education/training for IRB, staff, and investigators related to IRB/Human Research Protection Program.

i. Develops quality improvement activities for the IRB related to Human Research Protection Program.

j. Assists the AO with all regulatory inspections, site visits and accreditation visits pertaining to the IRB related to Human Research Protection Program.

k. Compiles the minutes of IRB meetings in compliance with regulatory requirements.

l. Assists the IRB Chair with scheduling IRB meetings.

m. Updates the IRB on any guidance related to the IRB/HRPP.

n. Maintains the official roster of current IRB members and all previous membership rosters.

o. Reviews all human research study forms such as the application for IRB packets other related documentation pertaining to new and continuing review of all human research projects.
p. Assigns reviewers, with the assistance of the IRB Chair, as required by the IRB
q. Provides guidance on compliance-related educational activities and incorporates into the day-to-day operation of the Research Administrative Office as well as to committee members and all other research staffs working with human subjects
r. Prepares IRB policies for programs pertinent for human subject research protections.
s. Ensures regulatory and policy updates are disseminated to investigators and research staff in a timely manner
t. Updates the IRB standard operating procedures (SOPs) in accordance with VHA Handbook changes or revisions
u. Orients new IRB members in completing orientation procedures and meeting required education standards.
v. Serves in an advisory role for IRB/HRPP related issues, policies and procedures to the IRB Community.
w. Maintains training documentation and reference materials related to human subject protection requirement.
x. Drafts reports and correspondence to research investigators on behalf of the IRB or IRB Chairperson regarding the status of the research, including conditions for approval of research and cases of adverse events or unanticipated problems.
cc. Attends and participates in the Human Studies Subcommittee (IRB).
dd. Tracks program goals and objectives and identifies results indicative of successful program accomplishments in
ee. Assists the IRB in determining the need for additional ad hoc review/representation from scientific and medical practice specialties
ff. Writes the IRB discussion for various items and ensures all criteria are met in accordance to applicable regulation.
cc. Understand policies, procedures and regulations regarding human subjects research and IRB operations.
ii. Prepare and distribute review materials to members and consultants
mm. Maintains regulatory files

oo. Liaison for all departments reviewing submissions and confirms approvals are obtained in a timely fashion.
pp. Database protocol management (protocols, agendas, minutes, correspondence, reports, etc.) ensuring all criteria are met in accordance to applicable regulation.
qq. Facilitates discussion between PI/Study Staff and IRB Reviewer
rr. Ensures that all stipulations have been met prior to scheduling for re-review
ss. Assists investigators with organizing and presenting data for review board
consideration.
tt. Consults with IRB Chair and ACOS/AO R&D regarding requests
for exemption, expedited review and other unusual requests.
ww. Facilitates communication with sub-committees and the R&D Committee.
xx. Ensures scientific quality, safety and appropriateness of all research
involving human subjects relative to the Belmont Report and applicable
government regulations.
 yy. Evaluates at least annually the risk/benefit ratio of all ongoing research
studies involving human subjects.
zz. Evaluates composition of IRB and adequacy of its policies.

7. HRPP Administrator/ Research and Development Coordinator, Committee, and its
Subcommittees
a. Coordinates, prepares and submits all compliance related correspondence to various
governmental agencies including, the Office of Research Oversight (ORO) and Federal
Wide Assurance (FWA)s needed.
    b. Prepares policies for programs pertinent for human subject
research protections.
    c. Assists the AO with all regulatory inspections, site visits and
accreditation visits pertaining to the Human Research Protection
Program
    y. Promptly reports changes in IRB membership to ORO. Once
ORO has reviewed it, ORO will forward this documentation to
OHRP.
    z. Updates, ACOS/AO R&D on the standard operating procedures
(SOPs) in accordance with VHA Handbook changes or revisions
aa. Maintains OHRP training documentation and reference
materials related to human subject protection requirement.
bb. Drafts reports and correspondence directed to research facility
officials, federal officials, and others on behalf of the Human
Research Protection Program.
cc. Coordinates, prepares and submits all compliance related
correspondence to various governmental agencies including Office
of Human Research Protection (OHRP), the Office of Research
Oversight (ORO), the Department of Health and Human Services
(DHHS), National Institutes of Health (NIH), Food and Drug
Administration (FDA), Federal-Wide Assurance (FWA), and Office
of Inspector General (OIG) as needed.
dd.

y institutional contact for the Human Research Protection Program
    b. Serves as the HRPP Administrator for updating and maintain FWA for
internal/external IRBs, maintaining MOUs related to the FWAs. Serves as contact person for human research protection (i.e. FWA, MOUs). As such, provides sufficient oversight to ensure that the research being approved and conducted meets the agreed upon ethical standards.

c. Serves as HRPP external IRB Coordinator/Liaison maintaining all protocols, SOPs, FWAs, and MOUs, related to cIRB.

6. Verifies that reports required by facility research procedures are complete and submitted within required timeframes

a. Maintains external IRB HRPP regulatory files
   Database protocol management (protocols, agendas, minutes, correspondence, reports, etc.) ensuring all criteria are met in accordance to applicable regulation.

b. Prepares, copies, and distributes packets for to R&D Committee for external IRB projects.

7. Reviews all human research study forms such as the application for external IRB packets other related documentation pertaining to new and continuing review of all external IRB human research projects or exempt IRB research projects.

a. Evaluates composition of IRB and adequacy of its policies.

b. Evaluates quality improvement activities and supports implementation of needed changes.

c. Provides oversight of the implementation of NWIHCS HRPP policies and program ensuring that they are always current.

d. May strengthen requirements and conditions, or add other modifications to secure R&D Committee approval or approval by a higher authority within the VA.

e. Reviews and acts upon all IRB minutes. Minutes and access to protocol files serve as an important oversight tool.

f. Evaluates the results of review by the following committees and subcommittees when appropriate:
   - Biosafety
   - Radiation Committee
   - Conflict of Interest

g. Reviews all subcommittee reports and once all concerns have been satisfied, grants approval to conduct the proposed research at NWIHCS. No human study may be approved without a thorough ethical review by the IRB.

h. Reviews projects that have been determined to be exempt from IRB review prior to their initiation.

i. Reviews major human research policies and procedures

Additional information on committee procedures can be found within their respective SOP Manuals.

8. IRB Members (See IRB SOP)
a. Conducts thorough reviews of all new policies to ensure that they are scientifically sound and ethically acceptable.
b. Identifies any personal conflicts of interest and recuses from discussion and vote.
c. Reviews all research that involves the use of human subjects at least on a yearly basis and ensures that the research is compliant with all federal regulations and all state and local laws.
d. Reviews the risks and benefits of research to participants on a continuing basis and takes appropriate action to ensure that risks are minimized and that benefits are maximized.

9. The Research Compliance Officer (see required responsibilities in matrix)
a. Conducts the QA/QI activities and reports results to the R&D Committee, ACOS R/D, Administrative Officer, and the Chief of Staff or Director as appropriate.
b. Keeps abreast of changing federal policies and recommends changes to local policies and procedures.
c. Audits investigators to assure compliance with all regulations and policies.

10. The Principal Investigator (see matrix)
a. Ensures the safety and welfare of research subjects.
b. Ensures that the design of studies is scientifically sound, and minimizes risks to subjects while maximizing research benefits.
c. Assures that the research is conducted ethically and in accordance with the IRB requirements.
d. Ensures that s/he has adequate resources to protect human subjects in the research.
e. Carefully delegates authority to subordinates and assures that research personnel are adequately trained and supervised to perform the tasks that are assigned.
f. Reports adverse events for a subject of the experiment to the appropriate authorities as required by the IRB.
g. Ensures that informed consent from research subjects or their legally authorized representatives is obtained and documented prior to involving them in research.
h. Secures initial and ongoing approval for the research.
i. Meets education requirements for self and assure that research staff meets educational requirements.
j. Ensures that all records of the research are maintained in such a form that the subject’s privacy is protected.
k. Discloses to the IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research and complies with all applicable VA and other Federal requirements regarding conflict of interest.
l. Ensures research staff are qualified, (e.g., including but not limited to appropriate training, education, expertise, credentials, and, when relevant, privileges) to perform procedures assigned to them during
the study. In a protocol, study team members are generally identified by name or by title:

I. Promptly reports any changes in PI, Local Site Investigator (LSI) to the IRB. Changes in other key research staff, if any, must be reported at the time of continuing review or as soon as the change is needed. These changes include, but are not limited to, additions to or loss of staff. Changes in the PI, LSI, or Co-LSI of an IRB-approved project must be evaluated and approved by the IRB to ensure the new individual meets the criteria described in 38 CFR 16.111.

m. Oversees research staff under the PI's direction to ensure compliance with all applicable requirements including, but not limited to, implementing the research study in accordance with the approved protocol.

n. Ensures the research protocol contains all required information.

o. Obtains written approval(s) before initiating research. Before initiating the research study, IRB approval must be obtained in writing from the IRB Chair or other voting member of the IRB, and all other committees (e.g., R&D Committee), subcommittees, and other approvals according to local, VA and other Federal requirements.

p. Ensures the study is implemented as approved by the IRB and in accordance with other required approvals and with all applicable local, VA, and other Federal requirements including, when applicable, those for research involving investigational drugs or investigational devices.

q. Will comply with all document requests related to audits, inspections or other requirements by the research office.

J. DEFINITIONS

a. Adverse Event. An adverse event (AE) in human subjects research is any untoward physical or psychological occurrence in a human subject participating in research. **NOTE:** AEs are further discussed in VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 15, 2015, and VHA Handbook 1004.08, Disclosure of Adverse Events to Patients, dated October 2, 2012.

b. Assurance. An assurance is a written commitment to protect human research subjects and comply with the requirements of the Common Rule. **NOTE:** Assurances are further discussed in VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research, dated November 21, 2014.

c. Beneficence: Beneficence is a Belmont principle for the conduct of research. It is understood as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

d. Broad Consent: Broad consent is a new type of informed consent provided under the 2018 requirements of the Common Rule pertaining to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Broad consent does not apply to
research that collects information or biospecimens from individuals through direct interaction or intervention specifically for the purpose of the research.

e. **Certificate of Confidentiality.** A Certificate of Confidentiality is a document issued by a component of HHS pursuant to The Public Health Service Act Section 301(d), 42 U.S.C. 241(d) amended by Section 2012 of the 21st Century Cures Act, Public Law 114-255, to protect the privacy of individuals who are subjects of certain specified research activities by authorizing investigators to withhold from all persons not connected with the conduct of such research the names or other identifying characteristics of such subjects. Persons so authorized to protect the privacy of such individuals may not disclose information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

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

g. **Classified Research:** Research that is considered restricted or secret by Federal government, sponsor, or any third party. For example, research for the Federal government that is considered sensitive or would affect National security.

h. **Clinical Investigation.** The Food and Drug Administration (FDA) considers the term clinical investigation to mean any experiment that involves a test article and one or more human subjects, and that either:

   (1) Meets the requirements for prior submission to the FDA under Sections 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. 355(i) and 360j(g) respectively; or

   (2) Does not meet the requirements for prior submission to the FDA under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit (21 CFR 56.102(c)).

i. **Clinical Trial.** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

j. **Collaborative Research:** A research project involving investigators from VA and other institutions with VA investigators having a substantive role in the design, conduct, and/or analysis of the research.

k. **Conflict Of Interest (COI):** Refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising a researcher’s professional judgment in conducting or reporting research.

l. **Consent Form:** An IRB approved explanation of the purpose, risks and benefits to the research subject for a specific protocol.
m. **Continuing Review:** Periodic review by the Institutional Review Board (IRB) of active non-exempt human subjects research for re-approving, requiring modifications, disapproving, terminating or suspending the study. CONTINUING REVIEW must occur at least annually, or as determined by the IRB. See also ONGOING MONITORING.

n. **Cooperative Research and Development Agreement (CRADA):**

o. **De-identified Information.** De-identified information is health information that is presumed not to identify an individual, and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual, because the 18 patient identifiers described in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule have been removed or a qualified biostatistician has determined that the health information has been de-identified. De-identified information is no longer covered by the Privacy Act, 38 U.S.C. 5701, 38 U.S.C. 7332, or the HIPAA Privacy Rule (see VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016).

p. **Engagement:** The interaction between researchers and research end-users (including industry, government, non-governmental organizations, communities, and community organizations), for the mutually beneficial transfer of knowledge, technologies, methods or resources.

q. **Federalwide Assurance.** A Federalwide Assurance (FWA) is an assurance approved for Federalwide use by the Office of Human Research Protections (OHRP) in accordance with Section 103(a) of the Common Rule (see 38 CFR 16.103(a)).

r. **Fetal Tissue Research:** Research involving tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth. Includes the dead fetus; or cells, material, or organs excised from a dead fetus.

s. **Fetus.** For purposes of this directive and as defined in Subpart B of the Common Rule for the Protection of Human Subjects, a fetus is the product of conception from the time of implantation until delivery.

t. **Food And Drug Administration (FDA):** The Federal agency responsible for the regulation of food, drugs and cosmetics, including the human subject research performed for FDA-regulated articles.

u. **Generalizable Knowledge:** Activities designed (with intent) to collect information about some individuals to draw general conclusions about other individuals that are predictive of future events and that can be widely applied as expressed in theories, principles, and future events and that can be widely applied as expressed in theories, principles, and statements and that enhance scientific or academic understanding.

v. **Human Research Protection Program.** The Human Research Protection Program (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 VA facility Director, Associate Chief of Staff for Research and Development (ACOS/R&D), the Administrative Officer
(AO) for R&D, 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), research compliance officers (RCOs), Information System Security Officers (ISSOs), privacy officers (POs), 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.

w. **Human Subject.** A human subject is a living individual about whom an investigator (whether professional or student) conducts research, and:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

**NOTE:** Individuals who receive test articles or who serve as controls in clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are also considered human subjects for the purposes of this directive.

x. **Human Subject Research:** Human subject research includes all research meeting the definition of "research" performed with "human subjects."

y. **Identifiable Private Information.** Identifiable private information is information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the private information.

z. **Identifiable Biospecimen.** An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimens.

aa. **Institutional Official.** The Institutional Official (IO) is the individual legally authorized as Signatory Official to commit an institution to an FWA. The Signatory Official assures that human subjects research to which the FWA applies is conducted in accordance with the terms of the assurance (see VHA Handbook 1058.03). The Principal Deputy Under Secretary for Health or designee is the IO for VHA Central Office, and VA facility Directors are the IOs for local VA facilities.

bb. **Institutional Review Board.** An IRB is a board, committee, or other group formally designated by an institution to review, approve, require modification, disapprove, and conduct continuing oversight of human subject research in accordance with the Common Rule (38 CFR Part 16) and other applicable regulations. **NOTE:** For the purposes of this directive, unless otherwise specified, references to IRB include any IRB which is responsible for approval and monitoring of a research project.

cc. **Interaction.** Interaction includes communication or interpersonal contact between investigator and subject.
dd. **Intervention.** Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

ee. **Investigational Device Exemption (IDE):** The process by which the FDA permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for conducting investigations of that device.

ff. **Investigational New Drug Application (IND):** The process by which new drugs or biologics, including the new use of an approved drug, are registered with the FDA for administration to human subjects. An IND number is assigned by the FDA to the drug or biologic for use in tracking.

gg. **Investigator.** An investigator is any individual who conducts research including, but not limited to, the Principal Investigator (PI), sub-investigator or co-investigator, and Site Investigator or Local Site Investigator (LSI). All VA investigators on a VA research study or program must hold a VA appointment.

(1) **Principal Investigator or Co-Investigator.** The Principal Investigator (PI) is a qualified person who directs a research study or program. The PI oversees scientific, technical, and day-to-day management of the research. If a study is conducted by a team of individuals, the PI is the responsible leader of that team.

(2) **Sub-Investigator or Co-Investigator.** A sub-investigator or co-investigator is a qualified person designated by the PI or LSI to perform critical research procedures and/or to make important research-related decisions. Both terms are interchangeable but are key personnel on a research study or program.

(3) **VA Investigator.** A VA investigator is any individual who conducts research while acting under a VA appointment, including full and part-time employees, without compensation (WOC) employees, or individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970 (5 U.S.C. 3371 et seq.). Individuals working under a contract with VA cannot conduct research as VA Investigators under a WOC appointment while simultaneously working as a contractor. **NOTE:** Trainees can serve as a co- or sub-investigator but must have a VA PI sufficiently experienced in the area of the trainee’s research interest to serve as the PI. Trainee research activities are further discussed in VHA Directive 1200.02(1), Research Business Operations, dated March 10, 2017.

hh. **IRB Documentation:** Any written evidence of the IRB’s consideration, evaluation, and/or assessment of proposed or active research.

ii. **Justice:** Justice is a Belmont Principle regarding the consideration of who ought to receive the benefits of research and bear its burdens, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

jj. **Legally Authorized Representative.** A legally authorized representative (LAR) is 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. If there is no applicable law addressing this issue, LAR means an individual recognized by
institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research.

kk. **Minimal Risk.** 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.

Il. **Neonate.** Neonate means a newborn within the first 4 weeks of birth.

mm. **Noncompliance:** The failure of a person or organization to act in accordance with the requirements of the law, regulation, policy or the requirements and/or determinations of a determination official or IRB.

(1) **Continuing Noncompliance.** Continuing noncompliance is a persistent failure to adhere to the laws, regulations, or policies governing human subjects research. NOTE: Continuing noncompliance is further discussed in VHA Handbook 1058.01.

(2) **Institutional Noncompliance.** Failure of an organization to adhere to the internal policies of its HRPP or the Agency policies, directives, handbooks, and regulations.

(3) **Serious Noncompliance.** Serious noncompliance is a failure to adhere to the laws, regulations, or policies governing human subjects research that may reasonably be regarded as:

(a) Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or

(b) Substantively compromising the effectiveness of a facility’s human subjects research protection or human subjects research oversight programs. **NOTE:** Serious noncompliance is further discussed in VHA Handbook 1058.01.

nn. **Memorandum Of Understanding (MOU):** A written agreement outlining the details of the relationship between organizations, including the responsibilities of each. Such an agreement is used by the VAMC to delineate the terms and conditions under which it may utilize another entity's IRB.

oo. **Nonprofit Research and Education Corporations.** VA-affiliated nonprofit research and education corporations (NPC) are authorized by Congress under 38 U.S.C. 7361-7366 to provide flexible funding mechanisms for the conduct of research and education at one or more VA facilities. Research approved by a facility R&D Committee and education approved by the facility Education Committee are considered to be a VA research project or a VA education activity respectively, regardless of the source of funding, the entity administering the funds, or the research or education site (see VHA Handbook 1200.17, Department of Veterans Affairs Nonprofit Research and Education Corporations Authorized by Title 38 U.S.C. Sections 7361 Through 7366, dated April 27, 2016 and revised May 9, 2017).

pp. **Pregnancy.** Pregnancy encompasses the period of time from implantation until delivery. A woman is assumed to be pregnant if she exhibits any of the pertinent presumptive signs of
pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

qq. **Private Information.** 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). (See 38 CFR 16.102(e)(4)).

rr. **Program Office.** A Program Office is any office within the VHA Office of the Under Secretary for Health. A Program Office includes all of its component offices and subdivisions, regardless of physical location. **NOTE:** The organization chart for the VHA Office of the Under Secretary for Health may be found on the VHA Web site.

ss. **Program Office Employee.** A Program Office employee is any individual working under a VA appointment in a VHA Program Office, regardless of duty station, including (but not limited to) full and part-time employees, WOC employees, and employees under the IPA.

tt. **Research.** Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this directive, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are considered research for purposes of this directive. For purposes of this directive, the following activities are not considered research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

uu. **Research Records.** Research records include, but are not limited to, IRB and R&D Committee records, records of all observations, subject recruitment activities, other data relevant to
the investigation, progress notes, research study forms, surveys, questionnaires, and other
documentation regarding the study (see VHA Records Control Schedule (RCS) 10-1, Chapter 8).

vv. **Research and Development Committee.** The R&D Committee is a committee responsible,
through the Chief of Staff (COS) to the VA facility Director, for oversight of the facility’s research
program and for maintenance of high standards throughout that program (see VHA Handbook
1200.01, Research and Development (R&D) Committee, dated June 16, 2009).

ww. **Research Protocol.** A research protocol details the aims and objectives of a research
study, scientific rationale, the methods used to carry out the research, and how data will be
analyzed. For human subjects research it also entails how subjects will be accessed/recruited, any
foreseeable risks, and how these risks will be mitigated. **NOTE:** The protocol for social or
behavioral research is sometimes referred to as the Research Plan or Research Purpose and
Methodology.

xx. **Respect For Persons:** Respect for persons is a Belmont Principle that incorporates at least
two ethical convictions: first, that individuals should be treated as autonomous agents, and second,
that persons with diminished autonomy are entitled to protection. The principle of respect for
persons thus divides into two separate moral requirements: the requirement to acknowledge
autonomy and the requirement to protect those with diminished autonomy.

yy. **Safety Reports** (*IND/IDE*): These are written reports from sponsors that notify the FDA and
all participating investigators of any adverse experience associated with the use of a drug that is
both serious and unexpected.

zz. **Secondary Research:** refers to research use of materials that are collected for either
research studies distinct from the current secondary research proposal, or for materials that are
collected for non-research purposes, such as materials that are left over from routine clinical
diagnosis or treatments.

aaa. **Serious Adverse Event** (*SAE*): A serious adverse event (SAE) is an AE in human subjects
research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of
hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect.
An AE is also considered serious when medical, surgical, behavioral, social, or other intervention is
needed to prevent such an outcome.

bbb. **Signatory Official.** The Signatory Official is the individual legally authorized to commit an
institution to the requirements of an FWA.

ccc. **Sponsor:** Any person or entity who takes responsibility for and initiates a clinical study. The
sponsor may be an individual, pharmaceutical company, device manufacturer, governmental
agency, academic institution, private organization, or other organization.

ddd. **Systematic Investigation:** A planned scientific or scholarly activity involving qualitative or
quantitative data collection and/or data analysis that sets forth an objective(s) and a set of
procedures intended to reach the objective(s), i.e., to acquire knowledge, develop a theory, or
answer a question.
eee. **Unanticipated or Unexpected.** The terms unanticipated and unexpected refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

fff. **Unanticipated Problem Involving Risks To Subjects Or Others (UPIRTSO):** Any incident, experience, or outcome that meets all of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized (per OHRP guidance for 45 CFR § 46.108 (a)(4)(i)).

ggg. **Veteran** Served on active duty, in the Reserves, or in the National Guard (including the Coast Guard), and Received an honorable or general discharge (under honorable conditions). Holds a veteran ID card. Not all veterans are eligible for clinical care at VHA facilities.

hhh. **VA Data or VA Information:** Data or information owned, in the possession of, under the control of, or collected by VA or any entity acting for or on behalf of VA. The data may be identifiable, deidentified, sensitive, or non-sensitive.

iii. **VA Investigator.** A VA investigator is an individual who conducts research approved by the R&D Committee while acting under a VA appointment on VA time, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970 (5 U.S.C. 3371 et seq.). As a VA investigator, that individual represents the interests of the VA in conducting the study. **NOTE:** Individuals working under a contract with VA cannot be given a WOC appointment to conduct research on their contract time. Contractors can provide clinical services or other activities in support of VA research in accordance with their contract.

jjj. **VA Research.** VA research is research that is conducted by investigators (serving on VA compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have R&D Committee approval before it is considered VA Research and before it can be initiated. All research activities approved by the R&D Committee are considered VA Research.

kkk. **Vulnerable Subjects/Population:** Individuals whose willingness to volunteer in a research study may be unduly influenced or coerced and individuals with limited autonomy. These individuals may include, but are not limited to, children, prisoners, pregnant women, mentally disabled, or economically or educationally disadvantaged persons.
I. **RESCISSION**

Policy dated 01/10/2019

J. **FOLLOW UP RESPONSIBILITY**

Research Administrative Offices
Figure 1

Note: Information Security Officer is now Information System Security Officer
R&D Continuing Review/Status Update Form

This form can be used for both IRB annual status check in as well as for projects overseen solely by the R&D Committee

I. Project Identification

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Title of Project</td>
</tr>
<tr>
<td>2.</td>
<td>Study Number</td>
</tr>
<tr>
<td>3.</td>
<td>Project Status:</td>
</tr>
<tr>
<td></td>
<td>*update findings</td>
</tr>
<tr>
<td></td>
<td>Active ☐ Ended/Final Report ☐ (provide impact/significance)</td>
</tr>
<tr>
<td>4.</td>
<td>Principal /Co-Principal Investigator (PI)</td>
</tr>
<tr>
<td></td>
<td>If more than two Co-PIs, add additional rows.</td>
</tr>
<tr>
<td></td>
<td>PI Name:</td>
</tr>
<tr>
<td></td>
<td>VA E-mail:</td>
</tr>
<tr>
<td></td>
<td>Phone:</td>
</tr>
<tr>
<td></td>
<td>Co-PI Name:</td>
</tr>
<tr>
<td></td>
<td>VA E-mail:</td>
</tr>
<tr>
<td></td>
<td>Phone:</td>
</tr>
<tr>
<td>5.</td>
<td>Person Providing Information</td>
</tr>
<tr>
<td></td>
<td>Name:</td>
</tr>
<tr>
<td></td>
<td>Study Role:</td>
</tr>
<tr>
<td></td>
<td>Location:</td>
</tr>
<tr>
<td></td>
<td>Phone:</td>
</tr>
<tr>
<td></td>
<td>VA E-mail</td>
</tr>
</tbody>
</table>

II. Verification of Investigators/Study Coordinators

Attach a list of all study personnel and check one of the boxes below indicating accuracy of the list, along with any changes.

- ☐ The list is accurate and there are no changes.
- ☐ There have been changes and these are annotated below

List all personnel who have left the project

<table>
<thead>
<tr>
<th>Name</th>
<th>Project Role</th>
<th>Date Departed</th>
</tr>
</thead>
</table>

List all personnel who have joined the project since the last update or amendment adding them.

<table>
<thead>
<tr>
<th>Name</th>
<th>Project Role</th>
<th>Date Added</th>
<th>Obtaining IFC</th>
<th>VA E-mail</th>
</tr>
</thead>
</table>

III. Continued Review Questions:

The person completing the report needs to acknowledge and check each of the following

- ☐ yes 1. Have any possible Conflict of Interest issues, concerning this project, been identified?
- ☐ no Financial Conflict of Interest is most easily identified, but Conflict of Interest goes beyond finances - any fiduciary and/or psychological interest which may bias the judgment of an individual (e.g., an HSS or R&D member, or an Investigator), or give the appearance of bias, should be considered as a possible Conflict of Interest. Any Conflict of Interest issue that withstands the 'reasonable man or
woman test' (i.e., that a reasonable man or woman would consider as potentially significant) should be disclosed to the appropriate Subcommittees and the R&D Committee in writing.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. This Project has changed since the last report with respect to the source (or the sufficiency) of funding, the need for space, the need for equipment and supplies, and/or the personnel involved.</td>
<td>If Yes, please summarize the changes:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Has the use, storage, and security of VA data and VA sensitive information, including VA protected information, changed since your initial submission or previous continuing review?</td>
<td>If Yes, please complete Appendix NN - Checklist for Reviewing Privacy, Confidentiality and Information Security in Research. Obtain the approval of the Privacy Officer and Information Security Officer and submit with this continuing review form.</td>
</tr>
</tbody>
</table>

### IV. Current Project Status (Exempt from further Subcommittee review)

The person completing the report must check one of the following to indicate the overall status of the study:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data collection and analysis study only</td>
</tr>
<tr>
<td>2.</td>
<td>Study not yet open to enrollment</td>
</tr>
<tr>
<td>3.</td>
<td>Open to enrollment; no participants enrolled.</td>
</tr>
<tr>
<td>4.</td>
<td>Active and open to enrollment; participants are undergoing interventions per approved project.</td>
</tr>
<tr>
<td>5.</td>
<td>Closed to enrollment at all sites; participants continue to undergo interventions per protocol. <strong>Date Closed to Enrollment:</strong></td>
</tr>
<tr>
<td>6.</td>
<td>Closed to enrollment at all sites; participants are in follow-up only (e.g. survival) <strong>Date Participant Intervention Ended:</strong></td>
</tr>
<tr>
<td>7.</td>
<td>No further patient interventions or follow-up at any sites; data analysis of private identifiable information only ongoing. <strong>Date Follow-up Ended:</strong></td>
</tr>
</tbody>
</table>

### V. Reminders

The person completing the report needs to acknowledge and check each of the following:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>All amendments have been reviewed and approved by the IRB/R&amp;DC before implementation (or none submitted)</td>
<td></td>
</tr>
<tr>
<td>All reportable events have been reported, reviewed and acknowledged by the IRB/R&amp;DC</td>
<td></td>
</tr>
<tr>
<td>All PI, LSI, and Investigator additions have been submitted to the IRB/R&amp;DC and received IRB/R&amp;DC approval</td>
<td></td>
</tr>
</tbody>
</table>

Signature: ___________________________ Date: ____________

(ONLY THE PRINCIPAL INVESTIGATOR IS AUTHORIZED TO SIGN)

APPROVED / DISAPPROVED Meeting Date: ____________

Signature: ___________________________ Date: ____________

Chairperson, Research & Development Committee
Date: INSERT DATE

From: VA Medical Facility Director

Subj: Facility Director Support Letter for Prisoner Research (INSERT NAME OF APPROVED VA RESEARCH STUDY INVOLVING PRISONERS OR THE TITLE OF AN APPROVED STUDY WHERE A SUBJECT OF THAT STUDY IS NOW A PRISONER)

To: INSERT NAME OF VA PRINCIPAL INVESTIGATOR

1. As required by VHA Handbook 1200.05, Paragraph 20.a(1), I support the conduct of this research study that involves a prisoner(s). This research will: state rationale for conducting the study and why the prisoner population is needed. Consider one of the following sentences:

   The approval is being requested because prisoners are part or all of the subjects to be asked to participate in the study.

   OR

   The approval is being requested because the VA Principal Investigator conducting the study has been informed that a subject who was previously consented into the study is now a prisoner. Include a rationale why the VA Principal Investigator and/or IRB supports the position that it is in the best interest of the subject’s safety and welfare to continue participating in the study

2. The prisoner(s) in this study will be afforded extra protections to ensure that participation in the research is voluntary by insert description here.

3. This investigator and his/her team is/are uniquely qualified to conduct a study with prisoners because state reason here. His/Her CV/biosketch is attached along with a roster of the study team members.

4. The research will take place at insert location(s) here.

5. The following documents are provided for your review as required:

   - A copy of the IRB approval letter documenting its review determinations for the study approving inclusion of prisoners according to 45 CFR 46.305(a);

   - A copy of the IRB minutes documenting the review determinations for the study approving inclusion of prisoners according to 45 CFR 45.305(a); (The IRB minutes may be draft minutes but must also include documentation that at least one prisoner representative or prisoner was present for the discussion and vote of the IRB’s actions for the study.)

   - A copy of the IRB approved research study
• The IRB approved informed consent document (If the IRB approved a waiver of documentation of informed consent, please state it and include whether or not an information sheet or script, such as a telephone script, was approved by the IRB. Include a copy of the information sheet or script if applicable.)

• A copy of the HIPAA authorization or waiver of HIPAA authorization (if applicable)

6. Please contact [insert POC] with questions regarding this study. Contact information for the appropriate person.

____________________________________  _________________________
Name of VA Facility Director                      Date

cc: VA Facility ACOS/R&D
    VA Facility AO/R&D
    VA Facility Research and Development Committee Chair
Research Service Education Plan

June 2015

Highlights of Required education:

1) Collaborative Institutional Training Initiative - [WWW.CITIPROGRAM.ORG](http://WWW.CITIPROGRAM.ORG) for human subject protection and good clinical practice training for investigators/study team members and committee members tracked by the CITI website and the IRB Coordinator required every three years.

2) Collaborative Institutional Training Initiative - [WWW.CITIPROGRAM.ORG](http://WWW.CITIPROGRAM.ORG) for laboratory animal welfare courses for investigators/study team members and committee members tracked by the CITI website and the IACUC Coordinator every two years.

3) VA Talent Management System (TMS) for privacy awareness, cyber security awareness, data security, and many other mandatory training courses of the NWIHCS.

4) Annual Research Safety Training

5) VISTA CAI for Mandatory AIS Security Awareness Training

6) Radiation Safety Training

Highlights of additional education:

6) Rollout as needed of SOP changes and forms for all research personnel and committee members involved in human, animal and basic science research.

7) “Human Research Report” publication is sponsored by NEBRA and mailed to PI’s and committee members for awareness of current HRPP issues being discussed.

8) Central Office notifications and updates are distributed from the Research Administrative Office via e-mail and the PI monthly meetings.

9) The Research Week and weekly seminars coordinated by the Research Education Enhancement Committee.

10) An Educational Component (as needed) is part of all of the committee agendas which includes a Coordinator update for local training or internal issues.

11) VA and national conferences are attended by Research Administrative Office staff and committee members.

12) Training is required for various roles with Research Service (i.e., animal procedures, fiscal, ADPAC, FWA and shipping of specimens).
<table>
<thead>
<tr>
<th>Responsibility:</th>
<th>Action:</th>
<th>Delegated to:</th>
<th>Others who share responsibility:</th>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL</td>
<td>Prioritizes protecting human subjects in research</td>
<td>ALL Research Personnel</td>
<td>ACOS/AO R&amp;D, IRB Committee</td>
<td>There are no “research credentials”. Credentials refer to medical credentials for providers to include Scope of Practice.</td>
</tr>
<tr>
<td>ALL</td>
<td>Uphold professional and ethical standards</td>
<td>ALL Research Personnel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALL</td>
<td>Complete appropriate training and education</td>
<td>ALL Research Personnel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALL</td>
<td>Comply with 2018 Common Rule requirements for all human research studies approved after 21 Jan 2019</td>
<td>ALL Research Personnel</td>
<td>ACOS/AO R&amp;D, IRB/R&amp;D Committee</td>
<td></td>
</tr>
<tr>
<td>ALL</td>
<td>Comply with 2018 common rule requirements for all studies transitioned to the 2018 requirements and all studies that implemented the burden reducing provisions</td>
<td>ALL Research Personnel</td>
<td>ACOS/AO R&amp;D, IRB/R&amp;D Committee</td>
<td></td>
</tr>
<tr>
<td>USH</td>
<td>Responsible for ensuring compliance with 1200.05 and 1200.01</td>
<td>IRB/R&amp;D</td>
<td>ACOS/AO R&amp;D</td>
<td>Is there a VHA HRPP?</td>
</tr>
<tr>
<td>PDUSH</td>
<td>Serve as the IO for the VHA Central Office</td>
<td></td>
<td></td>
<td>Detailed in separate HRPP</td>
</tr>
<tr>
<td>DUSH O&amp;M</td>
<td>Ensures that VISN Directors have</td>
<td></td>
<td></td>
<td>How is this determined?</td>
</tr>
<tr>
<td>Role</td>
<td>Responsibility</td>
<td>Responsible Party</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>----------------</td>
<td>-------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DUSH O&amp;M</td>
<td>Communicate responsibilities of 1200.01 to VISN Directors</td>
<td>CRADO, ORPP&amp;E</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DUSH O&amp;M</td>
<td>Oversight of VISNs to assure compliance</td>
<td>ORO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRADO</td>
<td>Develops policies for human research protection</td>
<td>Dir, ORPP&amp;E</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VISN Director</td>
<td>Ensure compliance of this regulation within the VISN</td>
<td>Visn Director</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VISN Director</td>
<td>Certifies research with embryonic stem cells</td>
<td>Guidance not required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VISN Director</td>
<td>Certifies research with fetal tissue</td>
<td>Guidance not required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dir, ORO</td>
<td>Review VA facility SOPs to ensure compliance</td>
<td>Coordinators/Committees, ACOS/AO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Director</td>
<td>Serves as the IO for the medical facility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Director</td>
<td>Signs the Federal Assurance</td>
<td>R&amp;D Coordinator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Director</td>
<td>Establishes a facility Human research protection plan (HRPP)</td>
<td>IRB, ACOS/AO R&amp;D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Director</td>
<td>Ensures necessary resources are provided for functioning of the</td>
<td>R&amp;D Coordinator, ACOS/AO R&amp;D</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>Facility Director</th>
<th>Action</th>
<th>HRPP</th>
<th>ACOS R&amp;D</th>
<th>R&amp;D Coordinator/Committee, AO R&amp;D</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oversee all committees related to the HRPP</strong></td>
<td></td>
<td><strong>Facility Director</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Delegates HRPP authority in writing</strong></td>
<td></td>
<td><strong>Facility Director</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ensures independence of the IRB</strong></td>
<td></td>
<td><strong>Facility Director</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>If facility has an internal IRB, Appoint an IRB, co-chairs, or vice chair for a period of up to 3 years, renewable</strong></td>
<td></td>
<td><strong>Facility Director</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Appoints IRB members in writing for up to 3-year renewable term</strong></td>
<td></td>
<td><strong>Facility Director</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Communicates with external agencies and oversight agencies and oversight bodies</strong></td>
<td></td>
<td><strong>Facility Director</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Establishes a procedure to review and approve recruiting materials for non-VA studies</strong></td>
<td></td>
<td><strong>Facility Director</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ensures a transition plan and a way to document it is in place for studies transitioning to the 2018 requirements</strong></td>
<td></td>
<td><strong>Facility Director</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ensures that all nonexempt human</strong></td>
<td></td>
<td><strong>Facility Director</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>Task Description</th>
<th>Responsible Role(s)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and all exempt research requiring limited IRB review is reviewed by an IRB</td>
<td>IRB Coordinator/Committee</td>
<td>IAW Directive 1200.05 and VHA Handbook 1058.03</td>
</tr>
<tr>
<td>Documents all required actions and responsibilities related to human research review, approval, conduct and oversight</td>
<td>IRB Coordinator/Committee</td>
<td></td>
</tr>
<tr>
<td>Establishes the IRB or establishes an agreement (MOU) with another IRB</td>
<td>R&amp;D Coordinator</td>
<td>ACOS R&amp;D/AO R&amp;D</td>
</tr>
<tr>
<td>Requests Dir, ORPP&amp;E approval for new HRPP, change in IRB(s) of record or reliance on a non-VA IRB</td>
<td>R&amp;D Coordinator</td>
<td>ACOS R&amp;D/AO R&amp;D</td>
</tr>
<tr>
<td>Certifies research involving interaction or intervention with children</td>
<td>IRB Coordinator/Committee</td>
<td>ACOS R&amp;D/AO R&amp;D</td>
</tr>
<tr>
<td>Ensures that no institution rely on the internal IRB</td>
<td>ACOS R&amp;D/AO R&amp;D</td>
<td>IRB Coordinator/Committee</td>
</tr>
<tr>
<td>Establish the R&amp;D Committee or sign agreement (MOU) for use of another VA facility R&amp;D committee</td>
<td>ACOS R&amp;D</td>
<td>R&amp;D Committee</td>
</tr>
<tr>
<td>Appoint at least 5 voting members to the R&amp;D Committee in</td>
<td>R&amp;D Coordinator/Committee, ACOS R&amp;D, AO R&amp;D</td>
<td>At least 2 members with patient care or management responsibilities; At least 2 members engaged in R&amp;D programs or activities; if investigation drug research is conducted regularly,</td>
</tr>
</tbody>
</table>
## Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>Description</th>
<th>Committee Member</th>
<th>Appointment Authority</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appoint alternate R&amp;D voting members</td>
<td>Director</td>
<td>R&amp;D Coordinator/Committee, ACOS R&amp;D, AO R&amp;D</td>
<td>The alternate must be designated on the roster who they are an alternate for and can only vote in the absence of the primary member.</td>
</tr>
<tr>
<td>Appoint an elected R&amp;D committee chair in writing for a period of 1-2 years (renewable)</td>
<td>Director</td>
<td>R&amp;D Coordinator/Committee, ACOS R&amp;D, AO R&amp;D</td>
<td>The chair is not permitted to chair a subcommittee.</td>
</tr>
<tr>
<td>Ensure all human research for the institution has been approved by the R&amp;D committee and all appropriate subcommittees</td>
<td>ACOS R&amp;D</td>
<td>AO/R&amp;D, R&amp;D Coordinator/Committee</td>
<td></td>
</tr>
<tr>
<td>Suspending or terminating research after approval by the R&amp;D where substantiated concerns are found in the conduct of the study</td>
<td>ACOS R&amp;D</td>
<td>AO R&amp;D, IRB Coordinator/Committee, R&amp;D Coordinator/Committee</td>
<td></td>
</tr>
<tr>
<td>Suspends or terminates investigator privileges</td>
<td>ACOS R&amp;D</td>
<td>R&amp;D Committee</td>
<td>For cause</td>
</tr>
<tr>
<td>Review allegations of inappropriate research conduct</td>
<td>ACOS R&amp;D/AO R&amp;D, IRB Coordinator/Committee</td>
<td>R&amp;D Coordinator/Committee</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>Position</th>
<th>Responsibility</th>
<th>CRMO/Flagship R&amp;D Committee</th>
<th>ACOS R&amp;D/AO R&amp;D</th>
<th>R&amp;D Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility Director</td>
<td>Ensure all committees supporting the human research program have adequate resources to fulfill their duties</td>
<td>ACOS R&amp;D/AO R&amp;D</td>
<td>R&amp;D Committee</td>
<td></td>
</tr>
<tr>
<td>Facility Director</td>
<td>Disapprove a study even if approved by all subcommittees</td>
<td>R&amp;D Committee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Director</td>
<td>When relying on an external IRB must establish and MOU or authorizing Agreement</td>
<td>R&amp;D Coordinator</td>
<td>ACOS R&amp;D/AO R&amp;D, R&amp;D Committee</td>
<td>See 1058.03 MOU Checklist <a href="www.va.gov/ORO/orochecklists">www.va.gov/ORO/orochecklists</a></td>
</tr>
<tr>
<td>Facility Director</td>
<td>When relying on an external IRB ensure the IRB holds an IRB registration</td>
<td>R&amp;D Coordinator</td>
<td>ACOS R&amp;D/AO R&amp;D</td>
<td>With FDA/OHRP, (e.g. cIRB)</td>
</tr>
<tr>
<td>Facility Director</td>
<td>Submits support letters and waiver requests for prisoner research</td>
<td>ACOS/AO R&amp;D</td>
<td>IRB Coordinator/Committee</td>
<td></td>
</tr>
<tr>
<td>Facility Director</td>
<td>Certifies research with pregnant women, neonates or children</td>
<td>IRB Coordinator/IRB</td>
<td>ACOS R&amp;D/AO</td>
<td>Only interventional research with pregnant women and children need certification. Neonatal research must be certified by it cannot be interventional.</td>
</tr>
<tr>
<td>Facility Director</td>
<td>Oversee the operation of the R&amp;D Committee</td>
<td>R&amp;D Committee, ACOS/AO R&amp;D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACOS (R&amp;D) or Coordinator for R&amp;D at smaller sites</td>
<td>Serves as the Executive Secretary of the R&amp;D committee and provides administrative support to the committee</td>
<td></td>
<td></td>
<td>Correspondence, scheduling meetings, responding to questions</td>
</tr>
<tr>
<td>ACOS (R&amp;D) or Coordinator for R&amp;D at smaller sites</td>
<td>Notifies investigators in writing of project approval</td>
<td>R&amp;D Coordinator/Committee</td>
<td>This approval letter may be combined with the R&amp;D Committee approval letter. May be signed by the ACOS(R&amp;D) alone or jointly signed with the R&amp;D Chair</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-------------------------------------------------</td>
<td>---------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Review and Approve, require modifications to secure approval, or disapprove the research.</td>
<td>All appropriate subcommittees</td>
<td>All appropriate subcommittees</td>
<td></td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Oversees the research portfolio and all R&amp;D subcommittees.</td>
<td>R&amp;D Coordinator ACOS/AO R&amp;D</td>
<td>ACOS/AO R&amp;D</td>
<td></td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Ensures that all research at the facility is consistent with VA mission and all statutory and regulatory requirements are met.</td>
<td>R&amp;D Coordinator ACOS/AO R&amp;D</td>
<td>All appropriate subcommittees; investigators</td>
<td></td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Establishes subcommittees to review and oversee human research.</td>
<td>Facility Director</td>
<td>R&amp;D Committee ACOS/AO R&amp;D</td>
<td>Where a protocol does not need a subcommittee approval (e.g. exempt research without limited IRB review) the R&amp;D committee is the approving committee; -external subcommittees established by MOU or other agreement are not considered facility subcommittees</td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Develops an SOP that details how ex officio members are included in the committee.</td>
<td>R&amp;D Coordinator</td>
<td>ACOS/AO R&amp;D</td>
<td></td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Ensures ISSO and Privacy review is complete before final approval.</td>
<td>R&amp;D Coordinator</td>
<td>ACOS/AO R&amp;D</td>
<td>R&amp;D can approve contingent on securing ISSO and privacy review</td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Determining whether the facility should participate in a study (e.g. right subject mix, competing)</td>
<td></td>
<td>ACOS/AO R&amp;D</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>R&amp;D Committee</th>
<th>ACOS/AO R&amp;D</th>
<th>ACOS/AO R&amp;D; Investigators</th>
</tr>
</thead>
<tbody>
<tr>
<td>If relying on an external IRB, ensure that appropriate IRB agreements are in place</td>
<td>R&amp;D Coordinator</td>
<td></td>
</tr>
<tr>
<td>Establish procedures to ensure that all approved research has high scientific quality, protects human subjects and staff, and security of VA data and sensitive information.</td>
<td>ACOS/AO R&amp;D, Investigators</td>
<td></td>
</tr>
<tr>
<td>Establishes a COI committee</td>
<td>ACOS/AO R&amp;D</td>
<td></td>
</tr>
<tr>
<td>Ensures classified research is not conducted</td>
<td>ACOS/AO R&amp;D</td>
<td></td>
</tr>
<tr>
<td>Reviewing the operations of all research-related subcommittees.</td>
<td>ACOS/AO R&amp;D</td>
<td>R&amp;D Committee ACOS/AO R&amp;D</td>
</tr>
<tr>
<td>Reviews minutes within 60 days of finalization of subcommittee minutes</td>
<td>ACOS/AO R&amp;D</td>
<td></td>
</tr>
<tr>
<td>Fulfills other functions as designated by the medical facility director</td>
<td>ACOS/AO R&amp;D</td>
<td></td>
</tr>
<tr>
<td>Official business must be completed at a</td>
<td>R&amp;D Coordinator</td>
<td>ACOS/AO R&amp;D</td>
</tr>
</tbody>
</table>

*Studies, impact on the facility support for clinical care.*

External IRBs are IRBs of another federal agency, non-VA IRB.

As written in 1200.01 this committee focuses on financial COI. Any criminal conflicts are referred to the DAEO. Other conflict (personal, professional beside financial should also be considered).

Designated review/expedited review procedures not requiring a convened meeting are allowable for both committees as outlined in 1200.01/1200.05.
### Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action Description</th>
<th>Responsible Party</th>
<th>ACOS/AO R&amp;D</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D Committee</td>
<td>Ensures ISSO and PO reviews are complete prior to final approval</td>
<td>R&amp;D Coordinator</td>
<td>ACOS/AO R&amp;D</td>
<td>May approve contingent on these approvals</td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Official business must be completed at a convened meeting with quorum</td>
<td>R&amp;D Coordinator</td>
<td>ACOS/AO R&amp;D</td>
<td>Designated review/expedited review procedures not requiring a convened meeting are allowable for both committees as outlined in 1200.01/1200.05</td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Develop SOPs or other written procedures for recurring processes</td>
<td>IRB/R&amp;D Coordinator</td>
<td>ACOS/AO R&amp;D</td>
<td></td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Establish a subcommittee on research safety and security (SRSS)</td>
<td>ACOS/AO R&amp;D</td>
<td>Safety Committee</td>
<td>Any institution with research involving chemical, biological, physical or radiation hazards (1200.08)</td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Suspend a researcher or research staff member’s privilege to conduct research pending an investigation and review by the Facility Director</td>
<td>ACOS/AO R&amp;D</td>
<td>Facility Director/Subcommittees</td>
<td></td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Require additional safeguards related to the wellbeing of human subjects, employees or the facility environment</td>
<td>IRB Coordinator/Committee</td>
<td>ACOS/AO R&amp;D</td>
<td>Related to an investigation by the facility director</td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Review and approve all subcommittee SOPs</td>
<td>R&amp;D Coordinator</td>
<td>ACOS/AO R&amp;D</td>
<td></td>
</tr>
<tr>
<td>R&amp;D Committee</td>
<td>Disapprove a study even if</td>
<td>R&amp;D Committee</td>
<td>ACOS/AO R&amp;D</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>R&amp;D Committee</th>
<th>Document the following information about the research:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- it supports the VA mission</td>
</tr>
<tr>
<td></td>
<td>- it is scientifically meritorious</td>
</tr>
<tr>
<td></td>
<td>- ensures the security of VA data, storage of data and specimens</td>
</tr>
<tr>
<td>R&amp;D Coordinator</td>
<td>Only required for VA research overseen by an external IRB</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>R&amp;D Committee</th>
<th>Conduct continuing review of each approved human research protocol at least every 364 days.</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB/R&amp;D Coordinator/Committees</td>
<td>ACOS/AO R&amp;D</td>
</tr>
<tr>
<td>R&amp;D Coordinator</td>
<td>This applies to all human research including exemptions. Continuing review focuses on: scientific progress; budget requirements; other support change requirements (space, personnel, etc.); summary and impact of unanticipated problems; Any serious or continuing noncompliance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>R&amp;D Committee</th>
<th>Notify investigators in writing of initial approval or disapproval</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACOS R&amp;D</td>
<td>R&amp;D Coordinator IRB and all other subcommittees,</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>R&amp;D Committee</th>
<th>Approval of amendments to approved research</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D Coordinator</td>
<td>IRB and all other subcommittees</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>R&amp;D Committee</th>
<th>Maintain records (minutes, correspondence, membership lists, SOPs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D Coordinator</td>
<td>IRB and all other subcommittees</td>
</tr>
<tr>
<td>Retain IAW VHA RCS 10-1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>R&amp;D Committee</th>
<th>For research overseen by an external IRB Determine and document</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D Coordinator</td>
<td>IRB Committee as deemed necessary</td>
</tr>
<tr>
<td>Research supports the VA mission; is scientifically meritorious; data security plan is consistent with VHA Directive 1605.01 and VHA Handbook 6500</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>R&amp;D Committee</th>
<th>For any research where the R&amp;D is the only</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D Coordinator</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>Committee</th>
<th>Responsibilities</th>
<th>Approvals/Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>R&amp;D Committee</strong></td>
<td>Follow VHA handbook 1605.04 if non-veteran subjects are enrolled</td>
<td>IRB Committee</td>
</tr>
<tr>
<td><strong>R&amp;D Committee</strong></td>
<td>Scientific review</td>
<td>IRB and Subcommittees</td>
</tr>
<tr>
<td><strong>IRB Committee</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>R&amp;D Committee Members</strong></td>
<td>Elect an R&amp;D Committee chair</td>
<td>Director ACOS/AO R&amp;D</td>
</tr>
<tr>
<td><strong>Designated Reviewer</strong></td>
<td>Review with enough documentation from the R&amp;D committee responses from an investigator to modifications</td>
<td>R&amp;D Coordinator/Chair ACOS/AO R&amp;D Designated reviewer approval must be noted in the minutes of the next R&amp;D committee convened meeting</td>
</tr>
<tr>
<td><strong>Designated Reviewer</strong></td>
<td>Communicate required modifications to secure approval to the investigator</td>
<td>R&amp;D Coordinator ACOS/AO R&amp;D Designated reviewer approval must be noted in the minutes of the next R&amp;D committee convened meeting</td>
</tr>
<tr>
<td><strong>Chair</strong></td>
<td>Appoint a Chair Pro Tempore or Vice Chair</td>
<td>Director ACOS/AO R&amp;D</td>
</tr>
<tr>
<td><strong>Conflict of Interest Committee</strong></td>
<td>Reviews completed, signed, and dated OGE form 450 Alternative - VA</td>
<td>ACOS/AO R&amp;D</td>
</tr>
<tr>
<td><strong>IRB</strong></td>
<td>Official business must be completed at a convened meeting</td>
<td>IRB Coordinator ACOS/AO R&amp;D Designated review/expedited review procedures not requiring a convened meeting are allowable for both committees as outlined in 1200.01/1200.05</td>
</tr>
</tbody>
</table>
## Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>Role</th>
<th>Task Description</th>
<th>Responsible Party</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB</td>
<td>Develop SOPs or other written procedures for recurring processes</td>
<td>IRB Coordinator</td>
</tr>
<tr>
<td>All subcommittees (incl IRB)</td>
<td>Report recorded findings and recommendations to the R&amp;D committee</td>
<td></td>
</tr>
<tr>
<td>All subcommittees (incl IRB)</td>
<td>Follow VHA handbook 1605.04 if non-veteran subjects are enrolled</td>
<td></td>
</tr>
<tr>
<td>All subcommittees (incl IRB)</td>
<td>Maintain records (minutes, correspondence, membership lists, SOPs)</td>
<td>Retain IAW VHA RCS 10-1</td>
</tr>
<tr>
<td>Other Subcommittees</td>
<td>Develop SOPs or other written procedures for recurring processes</td>
<td>All Committees/Coordinators, ACOS/AO R&amp;D</td>
</tr>
<tr>
<td>ISSO</td>
<td>Ensures the proposed research complies with Information security requirements for VA sensitive information</td>
<td>All Committees/Coordinators, ACOS/AO R&amp;D</td>
</tr>
<tr>
<td>Privacy Officer</td>
<td>Ensures the proposed research complies with VA privacy requirements and that the HIPAA authorization contains all required elements</td>
<td>All Committees/Coordinators, ACOS/AO R&amp;D</td>
</tr>
<tr>
<td>Principal</td>
<td>Ensure all study</td>
<td>All Committees/Coordinators,</td>
</tr>
</tbody>
</table>
### Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Study Personnel</th>
<th>ACOS/AO R&amp;D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop a scientifically valid research plan that minimizes risk to subjects, and describes the research in the detail required for review by all applicable committees.</td>
<td>Study Personnel</td>
<td>Submitting plans for data use, storage, and security to the PO and ISSO consistent with VHA Directive 1605.01 and 6500.</td>
</tr>
<tr>
<td>When necessary include safety measure information about a protocol.</td>
<td>Study Personnel</td>
<td>Type of safety information to be collected; frequency of the safety data collection, review plan for the safety data, statistical tests to detect harm, conditions to trigger suspension of the study.</td>
</tr>
<tr>
<td>Obtain all required approvals and written notification of approval prior to initiating the conduct of the study.</td>
<td>Study Personnel, IRB Committee/R&amp;D Committee ACOS/AO R&amp;D</td>
<td></td>
</tr>
<tr>
<td>Prepare and submit at least annually (or as otherwise required) on all research projects to all appropriate subcommittees or the R&amp;D committee for continuing review.</td>
<td>Investigator and Study Personnel</td>
<td>IRB Committee/R&amp;D Committee</td>
</tr>
<tr>
<td>Hold a current VA appointment to conduct research.</td>
<td>Investigator and Study Personnel</td>
<td>Credentialing Coordinator, ACOS/AO R&amp;D</td>
</tr>
<tr>
<td>Complete, sign, date and submit an OGE 450.</td>
<td>Investigator and Study Personnel</td>
<td>IRB Committee/R&amp;D Committee</td>
</tr>
</tbody>
</table>
## Appendix 11: Responsibility Matrix

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibility</th>
<th>Responsible Party</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator</td>
<td>Be identified on protocol applications</td>
<td>Investigator and Study Personnel</td>
<td></td>
</tr>
<tr>
<td>Investigator</td>
<td>Ensure that recruitment plans include initial contact by letter or in person prior to telephone contact</td>
<td>Investigator and Study Personnel, IRB; determination official</td>
<td>No cold calling</td>
</tr>
<tr>
<td>Investigator</td>
<td>Sign the recruitment letter</td>
<td>Investigator and Study Personnel</td>
<td>Cannot be signed by a contractor</td>
</tr>
<tr>
<td>Investigator</td>
<td>Maintain all study files</td>
<td>Investigator and Study Personnel</td>
<td></td>
</tr>
<tr>
<td>Investigator</td>
<td>Follow VHA handbook 1605.04 if non-veteran subjects are enrolled</td>
<td>Investigator and Study Personnel</td>
<td>IRB Coordinator/Committee</td>
</tr>
</tbody>
</table>
APPENDIX 6: HRPP Continuous Quality Improvement

A. Monitoring Study Conduct and Informed Consent:

One full-time Research Compliance Officer (RCO) is assigned VAMC roles and report to the VAMC Facility Director. RCOs are non-voting members of the R&D Committee, IRB, IACUC, and SRS. In addition to after the fact auditing of projects the RCOs are critical matter experts and inform/advise Committee members as appropriate about regulatory and agency requirements and guidance.

B. IRB Performance Evaluation

The R&D Committee reviews RCO audits reports as completed and Director Certification Checklist annually for performance evaluation of the IRB.

C. Pharmacy Service Compliance Evaluation:

Quarterly reviews are conducted

The R&D Committee has developed procedures to evaluate compliance with policies and procedures governing the investigational pharmacy including review of the following broad areas:

(1) Receipt.
(2) Storage.
(3) Security.
(4) Dispensing.
(5) Disposition.

The Investigational Pharmacy Assessment Instrument includes assessment of all five factors. A project is selected, and a compliance review is conducted quarterly. The completed review instrument is submitted to the R&D Committee for review.

D. R&D Committee IRB Oversight - Annual Review of IRB Membership, Workload, Performance and Budget

The R&D Committee has developed and implemented a multifaceted and comprehensive annual review of the IRB. The review considers:

- IRB Membership (appointed by VAMC Facility Director)
- IRB Member information on file
- IRB Member meeting attendance
- Annual performance reviews - Chairperson (by ACOS/R) and members (by IRB Chairperson)
- Types of studies
- Frequency of meetings
- Conflicts of Interest
- Reports to regulatory authorities
- HRPP components
• Research Compliance Officers
• Research Participant Outreach Program – Research Day
• Review of SOPs
• IRB Data Management System – MIRB
• Training
• Credentialing and privileging and scopes of practice
• Investigational Pharmacy workload – trends
• R&D reviews of Investigational Pharmacy
• R&D review of IRB performance
• R&D review of CRADAs
• R&D review of WOCs
• R&D review of Scopes of Practice
• HRPP space utilization and plans
• Record storage
• HRPP budget (salaries, training, supplies, services, research participant outreach program, capital expenditures, trends)
• IRB workload and trends
• IRB staffing
• HRPP budget projections for next year
• R&D expectations of HRPP

E. R&D Committee Annual Self-Review

The R&D has developed a multifaceted and comprehensive annual self-review. The review considers:

• Review Research Organization Chart
• R&D Membership (appointed by VAMC Facility Director)
• R&D member meeting attendance
• IRB, IACUC, Safety sub-committee membership rosters
• Review of IRB, IACUC, Safety sub-committee workload and review statistics
• Review of resources required and impact on research and medical center
• Quality, design, desirability, ethics and feasibility of research projects is being evaluated
• Review of sub-committee “Items Reviewed” overview of non-protocol specific items
• Review of research personnel
• Review of funding needs and funding availability
• Review of research space
• Review of research budget
• Review of capital expenditures and needs
• Review of training and education
• Status of active projects – human, animal science
• Review of investigator funding issues that will impact research workload and funding
• Review of CRADAs
• Review of publications
• Review of WOC appointments
• Review of Scopes of Practice
• Review of HRPP
F. **IRB and R&D Annual Review of Research Participant Outreach Program**

The R&D Committee developed a research participant survey that is mailed annually with a stamped, addressed envelope for mailing the survey back to the VA Research Service. Summary of results and open ended comments submitted by research participants are submitted for review to convened meetings of the R&D and IRB. The surveys are anonymous. Current survey questions are:

1. Did you understand that participating was voluntary and that you could quit at any time?
2. Did you understand there could be side effects and risks related to research treatment?
3. Did you understand the purpose of the research study?
4. Did you have a chance to ask questions before signing the consent form?
5. Did you get a copy of your signed consent form?
6. Would you participate in another research study?

G. **Self-Evaluation of IRB Process**

*Annual review is conducted. (IRB Coordinator)*

The IRB has developed an annual member survey to evaluate the effectiveness of the IRB process. Members are surveyed and the results are reviewed at a convened IRB meeting. The following are considered in the survey:

1. Established time lines for receipt and distribution of protocol materials.
2. The system for primary presenter assignment.
3. Information considered at initial review.
4. Information considered while monitoring ongoing research.
5. Information considered at continuing review.
DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date: INSERT DATE
From: VA Medical Facility Director
Subj: Facility Director Certification of Research Project Involving Pregnant women, Research titled: (INSERT NAME OF APPROVED VA RESEARCH INVOLVING PREGNANT WOMEN, FETUSES, OR NEONATES)
To: INSERT NAME OF VA PRINCIPAL INVESTIGATOR

1. As required by VHA Handbook 1200.05, Paragraph 19.g, this memorandum is my certification that the above-named VA approved research study involving pregnant women, fetuses, or neonates may be conducted at this VA Facility by (insert name of VA Principal Investigator(s) approved by the VA Facility’s Research and Development Committee for the research study).

2. The (insert name of VA Facility) has sufficient expertise in women’s health to conduct the research study as approved by the VA Research and Development Committee and any applicable review committees.

3. This certification does not replace the approvals required by the VA Research and Development Committee and any applicable review committees for oversight of the research study. This certification also does not grant authority or approval to replace or supercede any laws, regulations, or VA and VHA policies applicable to the research.

4. Please contact (insert name and email address of the VA R&D Committee Chair or ACOS/R&D) if you have any additional questions.

_________________________________________  _________________________
Name of VA Facility Director                     Date

cc:     VA Facility ACOS/R&D
        VA Facility AO/R&D
        VA Facility Research and Development Committee Chair
Date: INSERT DATE

From: VA Medical Facility Director

Subj: Facility Director Approval of Research Project Involving International Research titled:
(INSERT NAME OF APPROVED VA RESEARCH INVOLVING INTERNATIONAL RESEARCH)

To: INSERT NAME OF VA PRINCIPAL INVESTIGATOR

1. As required by VHA Handbook 1200.05, Paragraph 25(c), this memorandum is my approval that the above-named VA approved research study involving international research may be conducted at this VA Facility by (insert name of VA Principal Investigator(s) approved by the VA Facility’s Research and Development Committee for the research study).

2. This approval includes my concurrence that the research activities involving obtaining or sending biospecimens or data outside of the VA or the United States are necessary in order to conduct the research.

3. This certification does not replace the approvals required by the VA Research and Development Committee and any applicable review committees for oversight of the research study. This certification also does not grant authority or approval to replace or supercede any laws, regulations, or VA and VHA policies applicable to the research.

4. This study is not a Cooperative Studies Program activity.

5. Please contact (insert name and email address of the VA R&D Committee Chair or ACOS/R&D) if you have any additional questions.

____________________________________  __________
Name of VA Facility Director  Date

cc: VA Facility ACOS/R&D
    VA Facility AO/R&D
    VA Facility Research and Development Committee Chair
Date: INSERT DATE

From: VA Medical Facility Director

Subj: Facility Director Certification of Children’s Research Project titled: (INSERT NAME OF APPROVED VA RESEARCH INVOLVING CHILDREN)

To: INSERT NAME OF VA PRINCIPAL INVESTIGATOR

1. As required by VHA Handbook 1200.05, Paragraph 21(a), this memorandum is my certification that the above-named VA approved research study involving children may be conducted at this VA Facility by (insert name of VA Principal Investigator(s) approved by the VA Facility’s Research and Development Committee for the research study). This project is not more than minimal risk.

2. This certification does not replace the approvals required by the VA Research and Development Committee and any applicable review committees for oversight of the research study.

3. Insert one of the following sentences:

   If the research involves interactions with a child subject and the VA research team:

   I am also certifying that this VA Facility (or insert name of VA Facility) has the personnel and resources necessary to respond to a pediatric emergency resulting from the conduct of this research.

   Or

   If the research does not involve interactions with a child subject and the VA research team:

   This research does not involve any interactions with children at this VA Facility as part of the research study. If the research is modified to include interactions with children as part of the study, the modification must be approved as required by the applicable reviewing committees or subcommittees and a revision in this Certification must be obtained prior to initiating the modification.

4. Please contact (insert name and email address of the VA R&D Committee Chair or ACOS/R&D) if you have any additional questions.

____________________________________  _________________________
Name of VA Facility Director                  Date

cc: VA Facility ACOS/R&D
    VA Facility AO/R&D
    VA Facility Research and Development Committee Chair
Determination Checklist for Research and Research Involving Human Subjects
(Part I)

Protocol Title: 
Principal Investigator: 
Your institution IRB#

Human Subjects Research Determination. 
To be completed by qualified staff member.

Review the following questions to determine if the activity constitutes human subjects research.

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? 38 CFR 16.102(l) Generalizable knowledge consists of theories, principles, or relationships (or the accumulation of data on which they may be based) that can be corroborated by accepted scientific observation and inference that is applicable to other related situations, populations, or devices outside of the tested situation.

No → Activity is not research* 
Comment:

Yes → Activity is research. Does the research involve obtaining information about living individuals? 32 CFR 219.102(f) 

No → Activity is Research Not Involving Human Subjects.**

Yes → Does the research involve intervention or interaction with the individuals? 38 CFR 16.102(f) 

No → Is the information individually identifiable? 

Yes → Is the information private? (38 CFR 16.102(f)

This activity has been determined to be (check one):

☐ *Not Research – submit to Department Chief or Quality management 
Comment:

☐ **Research Not Involving Human Subjects - Report to R&DC 
Comment:

☐ Human Subject Research – Seek Further Determination

Reviewer Name (Print): ____________________________

Reviewer Name (Sign): ____________________________ Date: ________________

Version 1
Date:

From:

Subj: Recruitment of Non-Veteran Research Subjects

PI’s Name:

Project Title:

Project Number:

To: R&D Committee Chair

1. The purpose of this memorandum is to request permission to recruit non-Veteran research subjects for this study. The recruitment of non-Veterans is not for the sake of convenience for this study. The objective and justification for enrolling non-Veterans is: ______________ may be that the targeted population are non-Veterans, such as providers who care for veterans or the veteran’s family members; or that there are not enough veterans available to reach the sample size needed to draw meaningful conclusions, etc... ________________

Although non-Veteran subjects will be recruited, we believe the results will be generalizable to the Veteran population. The approximate number of non-Veterans to be enrolled is: ________________.

2. The study was approved by the IRB contingent on the allowance of non-Veteran inclusion on: ______________ OR the study is pending review by the IRB based on the ability to include non-Veteran subjects.

For research related injuries: For any non-Veteran injured because of participation in this study, immediate care will be provided. The protocol outlines the extent to which medical services will be provided.

For a multisite study only: In this study it is/is not anticipated that any inpatient care will be needed however, we have made arrangements with the study site(s) for the provision of care if needed. The study budget was reviewed and funding will be reserved to accommodate the enrollment of non-Veterans.

For a DOD/VA joint study: Active duty will be recruited for enrollment and agreements are in place that all research related injuries of an active duty enrolled in this protocol will be treated (either inpatient or outpatient) by the DOD. In the event...
that an active duty person is within a VA medical facility when emergent care is needed, the emergency treatment will occur within VA until the subject is stabilized and then the active duty member will be transferred to the nearest DOD medical facility that is capable of caring for the injury/problem.

3. All non-Veterans will be advised of the VA privacy notices and practices IAW VHA Handbook 1605.04, Notice of Privacy Practices,

4. Please contact me if additional information is needed. Your consideration of this request for permission to recruit non-Veterans as research subjects is greatly appreciated.

5. Thank you for your consideration.

_______________________________
Signature of PI

Attachments: (list any attachments)

_______________________________
Signature/Approval of R&DC Chair/Designee  Date
CONFLICT INTERESTS OF INVESTIGATORS IN RESEARCH

1. PURPOSE: To establish policy and procedures regarding Conflict of Interest (COI) in research which will enable investigators (i.e., principal investigators, co-principal investigators, investigators, and collaborators with five percent [5%] or more effort) and immediate family members of investigators to comply with applicable VA and other federal and state regulations regarding conflicts of interest in research.

2. DEFINITIONS:

   a. A conflict of interest is defined as any financial arrangement, situation, or action that exerts, or is perceived to exert, inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. Investigators (i.e., principal investigators, co-principal investigators, investigators, and collaborators with five percent [5%] or more effort) and/or their immediate family members are automatically considered to have a conflicting interest when they or their spouse or dependent children have:

   (1) Involvement in the design, conduct or reporting of the research.
   (2) Ownership interest, stock options, or other financial interest related to the research unless it meets four tests:
      (a) Less than $10,000 when aggregated for you and your immediate family.
      (b) Publicly traded on a stock exchange.
      (c) Value will not be affected by the outcome of the research.
      (d) Less than 5% interest in any one single entity when aggregated for you, your spouse and dependent children.
   (3) Compensation related to the research unless it meets two tests:
      (a) Less than $10,000 in the past year when aggregated for you, your spouse and dependent children.
      (b) Amount will not be affected by the outcome of the research.
   (4) Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
   (5) Board or executive relationship related to the research, regardless of compensation.
   (6) Any other reason for which the member or consultant believes that he or she cannot provide an independent review.

   b. Significant financial conflict of interest does not include:

   (1) Salary, royalties, or other remuneration from the applicant’s home institution;
   (2) Income from seminars, lectures, or teaching engagements sponsored
by public or nonprofit entities;
(3) Income from service on advisory committees or review panels for public or nonprofit entities;
(4) An equity interest that, when aggregated for the investigator and the investigator’s spouse and dependent children, meets all three of the following tests:
   (a) any amount less than $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value,
   (b) does not represent more than 5% of ownership interest in any single entity; and
   (c) will not be affected by the outcome of the research; or
(5) Salary, royalties, or other payments that when aggregated for the investigator, spouse, and dependents over twelve (12) months, meets both of the following tests:
   (a) is less than $10,000; and
   (b) will not be affected by the outcome of the research;

3. SCOPE: Investigators must comply with all laws, regulations, and policies of applicable Federal Agencies, including VA, and any applicable state regulations pertaining to conflict of interest in research. All research proposals submitted to the VA Nebraska Western Iowa Health Care System (NWIHCS) for review must contain a Conflict of Interest Statement (Appendix S) identifying conflicts of interest. This requirement applies to all research 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.

4. RESPONSIBILITIES:
   a. Medical Center Director:

      (1) The Medical Center Director is the Institutional Official responsible for the Research and Development (R&D) program, including resolution of issues related to COI in research.
      (2) The Medical Center Director has designated the Associate Chief of Staff for Research & Development (ACOS/R&D) to serve as the COI Administrator and oversee the day-to-day activities related to the COI in the research program.

   b. Conflict of Interest Administrator:

      (1) The Associate Chief of Staff for Research & Development (ACOS/R&D) is the designated Conflict of Interest Administrator. The COI Administrator is responsible for reviewing financial disclosure statements from each investigator who is planning to participate in the NWIHCS research program. The COI reviews the financial disclosure statements submitted by the PI with the initial protocol submission and/or continuing review submission when need exists and shares his/her findings with the appropriate subcommittee which is then made
available to the R&D Committee. When the financial disclosure involves the COI Administrator, the Deputy ACOS/Designee will act as the COI Administrator.

(2) For research that is carried out through collaboration, the ACOS/R&D will ensure that all investigators comply with the provisions of VHA Handbook 1200.13 and all other policies, procedures, and regulations related to COI.

c. The appropriate subcommittee must evaluate the COI Administrator’s recommendations and the submitted COI statement (disclosure of information) to determine whether any conflict of interest might adversely affect subject welfare and the integrity of the research. If so, the subcommittee must take steps to ensure that steps are taken to manage, reduce or eliminate potential or real conflicts of interest have been taken.

d. R&D Committee: The R&D Committee will review the actions taken by the appropriate subcommittee. They may approve the appropriate subcommittees’ actions, and may add stipulations or changes to the proposal, but the R&D Committee may not disallow any of the subcommittee’s stipulations or required changes regarding the COI. The Committee will determine what actions should be taken by the institution or the investigator to manage, reduce, or eliminate COI.

e. Investigator: The investigator is responsible for disclosing any COI. This disclosure must be documented through the use of the COI Statement. If a COI develops after approval of the protocol, the conflict must be immediately reported. Conflicts of interest involving the investigator's spouse or dependent children that would reasonably appear to affect the research also must be reported. Investigators should consider the potential effect that a financial relationship of any kind might have on a clinical trial, including interactions with research subjects.

5. PROCEDURES: Conflicts of Interest will be evaluated and managed as follows:

a. Compliance with NWIHCS policies related to COI will be assessed through periodic audits conducted by the institution.

b. The COI policy requires disclosure of any potential COI to appropriate officials or committees.

c. Investigators must submit the Conflict of Interest Statement as a component of the research application.

d. The COI Administrator will review the financial disclosure statement and determine if there will be a negative impact on the research.

e. Following review of the Conflict of Interest Statement, the COI Administrator will transmit to the appropriate subcommittee whether or not a COI appears to exist. If a declared financial interest is identified, the COI Administrator will (1) notify the appropriate subcommittee that the application must be tabled until an appropriate management plan has been incorporated into the protocol, and (2) notify the R&D Committee.)
Committee. Regional Counsel is alerted of significant conflicts and is involved in the development of a management plan.

f. When reviewing the protocol, the IRB must consider any matter that raises the possibility of coercion or undue influence in the consent process. If a COI is identified, the subcommittee will assess the necessary actions to minimize risks to subjects.

g. The appropriate subcommittee and R&D Committee may initiate remedies to manage or eliminate conflict of interest including, but not limited to: (a) modify the protocol, (b) change the consent to reflect the COI, (c) disclose significant financial interests; and/or (d) monitor the research by independent reviewers.

h. When a significant COI exists and is not remedied by the process described above, a non-biased third party may be authorized to obtain informed consent if a potential or actual COI could influence the tone, presentation, or type of information discussed during the consent process. Independent monitoring may be necessary in this instance.

6. REFERENCES:
   a. VHA Handbook 1200.1
   b. Draft VHA Handbook 1200.13 - Memorandum
   c. VHA Handbook 1200.5
   d. VHA Handbook 1200.7
   e. Executive Order 12674
   f. 5 CFR Part 2635

7. FOLLOW-UP RESPONSIBILITY: ACOS for Research and Development

8. RESCISSION: Memorandum No. 151-11 dated April 2004

9. REVIEW DATE: Every three years

AL WASHKO
Director

Attachment: Conflict of Interest Statement