TITLE: Definitions Used in VA Central IRB SOPs

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide a reference for definitions of words and terms used in the VA Central IRB SOPs.

2.0 REVISION HISTORY

Date of Initial Approval	March 30, 2010
Revision Dates	September 21, 2010 February 14, 2011 August 11, 2011

3.0 SCOPE

This SOP applies to all personnel who reference the VA Central IRB SOPs. This can include VA Central IRB staff, VA Central IRB members, investigators, local site liaisons and other institutional officials, oversight agencies, and the general public since the VA Central IRB SOPs are available on a public website.

4.0 POLICY

It is the policy of the VA Central IRB that standard definitions used in VHA Handbooks are used as the primary reference source for definitions if available. If not available, other sources, such as the FDA and PHS may be used. All definitions will reference the source document for the definition unless one does not exist and is a local definition.

5.0 DEFINITIONS

5.1	Ad hoc Consultant	An individual with select competence in special areas invited by the VA Central IRB to review certain protocols based on a specific or unique expertise and to render an opinion or make recommendations to the VA Central IRB. These individuals may not vote on the project.
5.2	Adverse Event (AE)	An AE is defined as any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article. An AE does not necessarily have to have a causal relationship with the research. (VHA Handbook 1200.05). In the context of a multi-center study, local or

		internal AEs are those AEs experienced by subjects, research staff, or others at the reporting individual's own VA facility or VA-approved research site.
5.3	Alternate IRB Member	A person officially appointed to serve in the absence of a specific primary voting member and authorized to deliberate and vote in the primary member's absence. The alternate member's specialty, qualifications and experience must be comparable to that of the primary member being replaced. An alternate can also be appointed for a non-voting member and can provide the same advice and guidance as the primary member in the primary member's absence.
5.4	Approval Period	The period of time the VA Central IRB determines the protocol may be approved prior to a requirement for another review. The VA Central IRB may approve a study for a period of up to one full calendar year, i.e., May 1, 2007 through April 30, 2008. The approval period would expire April 30th at midnight. If the approval period is for a shorter period of time, such as six months, the approval period would encompass the full six months, i.e., May 1, 2007 through October 31st 2007. The approval period would expire on October 31st at midnight.
5.5	Assent	A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent (45 CFR 46.402(a)). In VA research, assent is also used in context with adults with impaired decision making capacity.
5.6	Assurance	A written commitment by the institution to protect human subjects participating in research and to comply with the requirements of 38 CFR Part 16 (VHA Handbook 1058.03). For the purposes of these SOPs, "assurance" and a "Federalwide Assurance" (FWA) are synonymous.
5.7	Children	Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (45 CFR 46.402(a)).
5.8	Clinical Investigation	Any experiment that involves a test article and one or more human subjects, and that either (1) must meet the requirements for prior submission to the Food and Drug

		Administration (FDA) under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or (2) need 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 later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations 21 CFR 50.3(c) and 21 CFR 56.102(c).
5.9	Cognitively Impaired	Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia), or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and patients and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests (Office of Human Research Protections (OHRP) Guidebook, chapter 6, section D). For the purposes of this SOP, the phrase “impaired decision-making capacity,” is synonymous with “cognitively impaired.” Cognitive impairment may be temporary, permanent, or may fluctuate over time.
5.10	Confirmed Report	Noncompliance that is supported by incontrovertible factual information.
5.11	Conflict of Interest (COI)	Any situation in which financial or personal obligations or interests may compromise or present the appearance of compromising an individual’s or group’s professional judgment in conducting, reviewing, or reporting research. An appearance of COI is when the circumstances would cause a reasonable person with knowledge of the relevant facts to question an employee’s impartiality in the review and conduct of human research protocols.
5.12	Continuing Noncompliance	Persistent failure to adhere to the laws, regulations, or policies governing human research (VHA Handbook 1058.01).

5.13	Controverted issues	Issues that involved some controversy, disagreement, argument, opposition, or concern among the VA Central IRB members during the meeting.
5.14	Cooperative Studies Program Coordinating Center (CSPCC)	One of five centers established by the CSP to ensure that large clinical trials are scientifically sound, cost effective, and run efficiently and in accordance with all established regulations. These include Hines, Palo Alto, Perry Point, West Haven, and Boston. A sixth center is the Clinical Research Pharmacy located in Albuquerque, which provides input into the study design if the study involves drugs or medical devices and it is responsible for all drug-related activities, such as developing the drug handling protocol, negotiating with pharmaceutical companies, and packaging, distributing, and accounting for study drugs.
5.15	De-identified Data	Health information that does not 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 (VHA Handbook 1605.1, paragraph 4l.) De-identified data are data that have been de-identified in accordance with both the HIPAA Privacy Rule (45 CFR 164.51) (see VHA Handbook 1605.01) and the Common Rule provision that the identity of the subject cannot be readily ascertained by the investigator or be associated with the information. (VHA Handbook 1200.05)
5.16	Designated Reviewer	A VA Central IRB voting member who has been appointed in writing by the VA Central IRB Co-Chairs to review requests for exemption from 38 CFR 16 on behalf of the VA Central IRB.
5.17	Employee	Refers to any employee of the Department of Veterans Affairs to include Without Compensation (WOC) employees or appointment through an Intergovernmental Personnel Act (IPA) appointment. Status as an employee is unaffected by pay or leave status.
5.18	Epidemiological Research and Information Center (ERIC)	One of four centers that enhance VA health care delivery by promoting VA based population research and converting those results into a format that VHA providers and administrators can apply to improve patient care.

		These centers are located at Boston, Durham, Seattle, and West Haven.
5.19	Exempt Research	Includes research activities in which the only involvement of human subjects is in one or more of the categories listed in 38 CFR 16.101(b). The exempt status must be determined by the IRB Chair or an IRB voting member designated by the Chair. (VHA Handbook 1200.05).
5.20	Expedited Review Procedures for Research	In contrast to a convened IRB review process, the expedited review process consists of a review carried out by the IRB Chair or by one or more experienced voting members of the IRB designated by the IRB Chair in accordance with 38 CFR 16.110(b). (VHA Handbook 1200.05).
5.21	Federalwide Assurance (FWA)	See "Assurance."
5.22	Fee-Basis VA Employees	VA employees who are working for the VA on an individual contract and not through a company or corporation.
5.23	Fetus	The product of conception from the time of implantation until delivery (VHA Handbook 1200.05).
5.24	Financial Interest	Financial interests are limited to those owned by the employee or by the employee's spouse or minor children. It includes any current or contingent ownership, equity, or security interest in real or personal property or a business and may include an indebtedness or compensated employment relationship. It includes interests in the nature of stocks, bonds, partnership interests, fee and leasehold interests, mineral and other property rights, deeds of trust, and liens. It extends to any right to purchase or acquire any such interests, such as a stock option or commodity future. It does not include a future interest created by someone other than the employee, the employee's spouse, or dependent child or any right as a beneficiary of an estate that has not been settled. It does include service, with or without compensation, as an officer, director, trustee, general partner, or employee of any person, including a nonprofit entity, whose financial interests are imputed to the employee (5 CFR 2635.403(c)).

5.25	Gift	Any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item having monetary value. This includes services as well as gifts of training, transportation, local travel, lodgings and meals, whether provided in-kind, by purchase of a ticket, payment in advance, or reimbursement after the expense has been incurred. It does not include: • Modest items of food and refreshments • Greeting cards and other items of little intrinsic value • Loans from banks or other financial institutions on terms generally available to the public • Opportunities and benefits available to the public or to a class consisting of all government employees, whether or not restricted on the basis of geographic considerations • Rewards and prizes given to competitors in contests or events open to the public unless the employee's entry into the contest or event is required as part of their official duties • Pension or other benefits resulting from continued participation in an employee welfare and benefits plan maintained by a former employer • Anything which is paid for by the government or secured by the government under contract • Anything for which market value is paid for by the employee (5 CFR 2635.203(b))
5.26	Health Information	Any information created or received by a health care provider or health plan that relates to: the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or payment for the provision of health care to an individual. This encompasses information pertaining to examination, medical history, diagnosis, and findings or treatment, including such information as: laboratory examinations, X-rays, microscopic slides, photographs, prescriptions, etc. (VHA Handbook 1605.1).
5.27	Human Protections Administrator (HPA)	The individual named in an FWA as a primary contact responsible for directing, or having in-depth knowledge of, the daily operations of an Institution's program for protecting human research subjects (VHA Handbook

1058.03).

5.28	Human Research Protection Program (HRPP)	A HRPP is a comprehensive system to ensure the protection of human subjects participating in research. At a local VA facility the HRPP consists of a variety of individuals and committees including but not limited to, the VA Facility Director, Associate Chief of Staff (ACOS) for Research and Development (R&D), the Administrative Officer (AO) for R&D, Research Compliance Officer (RCO), the R&D Committee, the Institutional Review Board (IRB), other committees or subcommittees addressing human subjects protection (e.g., Subcommittee on Research Safety, Institutional Biosafety Committee, Radiation Safety Committee, Radioactive Drug Research Committee, Conflict of Interest Committee, investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer), and research pharmacy staff. The objective of this system is to assist the Institution in meeting ethical principles and regulatory requirements for the protection of human subjects. (VHA Handbook 1200.05). The VHA Central Office HRPP is composed of the VA Central IRB, the institutional leadership (the Principal Deputy Under Secretary for Health is the Institutional Official), ORD, PRIDE, investigators of VA multi-site projects approved by the VA Central IRB, local medical center directors and Research and Development Committees at participating local facilities, ORO, and many others who are involved in human research. The VHA Central Office HRPP does not replace or duplicate the efforts of the local VA facilities' HRPPs. Instead, it serves as the HRPP for VA multi-site projects that are reviewed and approved by the VA Central IRB. The VHA Office of Research Oversight (ORO) has oversight responsibility for the VHA Central Office HRPP.
5.29	Human Subject	The definition of human subject includes investigators, technicians and others assisting investigators, when they serve in a "subject" role by being observed, manipulated, or sampled. Title 38 CFR Part 16 defines a human subject as a living individual about whom an investigator (whether

professional or student) conducting research obtains either:

- Data through intervention or interaction with the individual (interaction includes communication or interpersonal contact between the researchers and the subject or
- Identifiable private information (38 CFR 16.102(f)

For research covered by the Food and Drug Administration (FDA) regulations, human subjects mean an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control.(21 CFR 50.3(g) and 21 CFR 66.102(c))

For research covered by FDA device regulations, subject means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease (21 CFR 812.3(p))

5.30 Imputed Interests

The financial interests of the following persons are considered to the same extent as if they were the employee's own interests:

- Employee's spouse
- Employee's minor child
- Employee's general partner in a business
- An organization in which the employee serves as officer, director, trustee, general partner, or employee
- Any person with whom the employee is negotiating or has an arrangement concerning prospective employment

(5 CFR 2635.402(b)(2))

5.31 Individually-identifiable Health Information

A subset of health information, including demographic information collected from an individual, that is: (VHA Handbook 1605.1)

- Created or received by a health care provider, health plan, or health care clearinghouse;
- Relates to the past, present, or future condition of an individual and provision of or payment for health care; **and**

- Identifies the individual or a reasonable basis exists to believe the information can be used to identify the individual.

Note: Individually-identifiable health information does not have to be retrieved by name or other unique identifier to be covered by VHA Handbook 1605.1.

5.32	Informed Consent Reviewer	Any voting member of the VA Central IRB assigned by one of the VA Central IRB Co-Chairs to perform an in-depth review of the informed consent process for an assigned research project to ensure it meets all VA and other requirements for the participant population.
5.33	Institutional Conflict of Interest	An institutional COI may occur when the institution, or any of its senior management, has an external relationship or financial interest in a company or organization that itself has a financial interest in a VA investigator's research project.
5.34	Institutional Official (IO)	The IO is the individual legally authorized as Signatory Official to commit an institution to an Assurance. The IO serves as the official representative of the institution to external agencies and oversight bodies and provides all written communication with external departments, agencies, and oversight bodies. The Principal Deputy Under Secretary for Health is the IO for VHA Central Office and VA facility Directors are the IOs for local VA facilities. (VHA Handbook 1200.05).
5.35	Institutional Review Board (IRB)	A board, committee, or other group formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of human research in accordance with 38 CFR Part 16 and other applicable VA and Federal requirements. (VHA Handbook 1058.01).
5.36	Investigational Device Exemption	An investigational device is a device that is an object of an investigation. (21 CFR 812.3(g)) And Investigational Device Exemption (IDE) is an application to FDA that allows an investigational significant risk device to be used in a clinical investigation to collect safety and effectiveness data. If the device is a non-significant device, it is considered to have an approved application for IDE after IRB approval

		is obtained. (21 CFR 812)
5.37	Investigational Drug	A chemical or biologic drug that is used in a clinical investigation. An investigational drug can be a new chemical compound, which has not been released by the FDA for general use, or an approved drug that is being studied for an approved or unapproved use, dose, dosage form, administration schedule, or under an Investigational New Drug (IND) application, in a controlled, randomized, or blinded clinical trial. Concurrent medications, comparators, or rescue medications used in the investigational trial that are not the drug(s) being studied are not defined as investigational drugs unless they are not commercially approved or not available through commercial channels. Prescription drugs, over-the-counter drugs, nutritional supplements, herbal preparations, and legend items used for diagnosis or treatment and meeting the definition for an investigational drug above, are considered investigational drugs (VHA Handbook 1108.04, paragraph 2f. and VHA Handbook 1200.05)
5.38	Investigator	An investigator is any individual who conducts research involving human subjects, including, but not limited to: the Principal Investigator (PI), Co-PI, co-investigator, and Local Site Investigator (LSI). The investigator must uphold professional and ethical standards and practices, adhere to all applicable Federal requirements, and comply with applicable local policies and procedures. (VHA Handbook 1200.05)
5.39	*In vitro* fertilization	Any fertilization of human ova, which occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means (VHA Handbook 1200.05).
5.40	IRB of Record	The IRB(s) designated under a VA facility's FWA for review and oversight of the facility's human subject research (VHA Handbook 1058.03, paragraph 4m).
5.41	Legally Authorized Representative (LAR)	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 (38 CFR 16.102c and VHA Handbook 1200.05)

5.42	Local Site Investigator (LSI) or Site Investigator	The Site Investigator or Local Site Investigator (LSI) is an investigator at a site participating in a multi-site research project. The LSI oversees scientific, technical, and day-to-day management of the research at the local site. (VHA Handbook 1200.05)
5.43	Meeting Coordinator	The individual responsible for ensuring all the logistical arrangements for a convened VA Central IRB meeting are complete. Meeting Coordinator functions may be assigned to one of the VA Central IRB Coordinators or to another administrative staff member within the Program for Research Integrity Development and Education (PRIDE).
5.44	Memorandum of Understanding (MOU)	A written agreement between two VA facilities or between a VA facility and a non-VA Institution documenting their relationship and defining their respective roles and responsibilities within that relationship (VHA Handbook 1058.03, paragraph 4n).
5.45	Minimal Risk	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 (38 CFR 16.102(i)).
5.46	Nonaffiliated IRB Members	Nonaffiliated members are not otherwise affiliated with the Department of Veterans Affairs (VA) and are not part of the immediate family of a person who is affiliated with the VA (VHA Handbook 1200.05 and 38 CFR 16.107d.) Individuals who perform occasional volunteer activities without a WOC appointment are not affiliated. Employees of academic institutional that have a formal academic affiliation agreement with VA and employees of VA nonprofit research and educational foundations are affiliated. A Veteran whose only relationship with VA is receiving care at a VA facility or receiving benefits from the Veterans Benefits Administration may be considered nonaffiliated. However, any person serving in a VA Without Compensation (WOC) appointment in another role, has an Intergovernmental Personnel Appointment (IPA), or who is retired from VA is considered to be otherwise affiliated and may not fulfill this role on the VA

		Central IRB. To be considered nonaffiliated, a WOC appointment can only be given to an otherwise nonaffiliated individual specifically for the purpose of liability protection for serving on an IRB.
5.47	Pregnancy	Encompasses the period of time from implantation until delivery. (VHA Handbook 1200.05).
5.48	Primary Reviewer	A voting member of the VA Central IRB who is assigned by one of the VA Central IRB Co-Chairs to perform an in-depth review of the research project, to include scientific methodology, to determine if the project is scientifically and ethically sound. The Primary Reviewer leads the discussion of the project at the convened meeting of the VA Central IRB and makes approval recommendations to the IRB.
5.49	Principal Investigator (PI)	The PI is a qualified person or persons designated by an applicant institution to direct a research project or program and who usually writes the grant application. The PI oversees the scientific, technical, and day-to-day management of the research. In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of the team. (VHA Handbook 1200.05) FDA considers PI and investigator to be synonymous
5.50	Prisoner	Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing (VHA Handbook 1200.05).
5.51	Protected Health Information (PHI)	Individually-identifiable health information maintained in any form or medium. *Note: PHI excludes employment records held by a covered entity in its role as an employer (VHA Handbook 1605.1, paragraph 4ss.)*
5.52	Protocol deviations	For the purposes of the VA Central IRB, a protocol deviation is any change, divergence, or departure from the design or procedures of a research project as was

		approved by the VA Central IRB. The terms *protocol violations*, *protocol exceptions*, and *protocol variances* are synonymous with *protocol deviations*.
5.53	Quorum	A majority of the voting members. In the case of the IRB, a quorum must include at least one member whose primary concerns are in non-scientific areas. At meetings of the IRB, a quorum must be established and maintained for the deliberation and vote on all matters requiring a vote. A member with a conflict of interest cannot contribute to the quorum, be present for the discussion of the issue for which they are conflicted, except to answer questions or be present for the vote on the issue. (VHA Handbook 1200.05).
5.54	Research	A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (38 CFR 16.102(d). Activities which meet this definition constitute research for the purposes of VHA Handbook 1200.05, whether or not they are conducted or supported under a program which is considered research for other purposes.
5.55	Secondary Reviewer	For the purposes of the VA Central IRB, a secondary review is a voting member of the VA Central IRB who has been assigned by one of the VA Central IRB Co-Chairs to perform an in-depth review of the project. The Secondary Reviewer supplements the comments of the Primary Reviewer during the convened meeting.
5.56	Serious Adverse Event (SAE)	An local SAE in human research is an AE that results in death, a life threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, or 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. (VHA Handbook 1200.05)
5.57	Serious Noncompliance	Failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as: (1) involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human subjects, research staff, or others; or (2)

		substantively compromising the effectiveness of a facility's research protection or human research oversight programs (VHA Handbook 1058.01).
5.58	Significant Risk (SR) Device	An investigational device that: • Is intended as an implant and presents a potential for serous risk to the health, safety, or welfare of a subject; • Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health safety, or welfare of a subject; • Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; **or** • Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. (21 CFR 812.3 (m))
5.59	Study Chair (SC)	See "Principal Investigator."
5.60	Suspension of IRB Approval	A determination by an IRB Chair, a qualified IRB voting member designated by the IRB Co-Chair, or the convened IRB to temporarily interrupt some or all previously approved research activities. The suspended activities could include, but not be limited to, recruiting of new subjects for the research. Suspended studies remain open and require continuing review. (VHA Handbook 1200.05)
5.61	Termination of IRB Approval	A termination of IRB approval is a determination by the convened IRB to permanently halt some or all previously approved research activities including, but not limited to, enrollment of new subjects in research. (VHA Handbook 1200.05)
5.62	Test Article	Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug, & Cosmetic Act or under sections 351 or 354-360F of the Public Health Service Act (21 CFR 50.3(j)).

5.63	TWX	A travel authorization signed by the Chief Research and Development Officer (CRADO) authorizing travel and reimbursement of travel costs.
5.64	Unanticipated Adverse Device Effect (UADE)	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.3(s)).
5.65	Unanticipated Problems Involving risks to Participants or others	Any event or problem that meets all of the following criteria: (1) unexpected (in terms of nature, severity, or frequency) that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents, such as the IRB-approved research protocol and informed consent document; and the characteristics of the subjects population being studied (2) related to participation in the research; and (3) suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, social, or legal harm) than was previously known or recognized.
5.66	Unexpected or Unanticipated Adverse Event (UAE)	An AE that is new or greater than previously known in terms of nature, severity, or frequency of occurrence, as documented in the protocol or other materials approved by the IRB. Such materials may include but are not limited to: the informed consent form, clinical investigators' brochure, and product labeling. (VHA handbook 1058.01 and VHA Handbook 1200.05)).
5.67	VA Institution	Any entity operated by the VA, including but not limited to: VA hospitals, medical centers, clinics, and healthcare systems; space owned, leased, or rented by VA; and

		space that is “shared” with a non-VA entity (unless the VA space is leased to a non-VA entity and specifically designated in writing not be used by VA or VA employees for research). A VA facility may include multiple campuses and satellite components. The terms “facilty” and “VA facility” are synonymous (VHA Handbook 1058.01 and VHA Handbook 1200.05).
5.68	VA Research	Research that is approved by the R&D Committee and conducted by VA investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments), utilizing VA resources (e.g., equipment), or on VA property including space leased to, and used by VA. The research may be funded by VA, by other sponsors, or be unfunded.
5.69	VA Investigator	A VA investigator is any individual who conducts research approved by VA 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. In addition, a VA investigator must comply with all applicable VA and VHA requirements and comply with applicable local VA facility policies and procedures. (VHA Handbook 1200.05)
5.70	VA Sensitive Information	All department data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about specific individuals requiring protection under various confidentiality provisions such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and information that can be withheld under the FOIA.
5.71	Without Compensation (WOC)	A category of VA employee who has been officially appointed to perform services for the Department of Veterans Affairs without any direct monetary compensation.

6. REFERENCES

References, when available, are given with the definition.

I have reviewed and approved the content of this SOP.

K. Lynn Cates, MD
Director, PRIDE

Date: 8/11/11