

Version Number: 2	Research & Development Policy 151-24	Supersedes Document Dated: 02/01/2011
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PURPOSE

This policy describes the various VA Research Education requirements that are mandatory of staff associated with research activities at the Syracuse, Canandaigua, and Bath VA Medical Centers.

BACKGROUND

The VA R&D program has seen consistent and continuous increases in procedural requirements directed from VA Central Office and other regulatory bodies, many of which are related to training. Each new individual is required to complete a specific set of trainings on an ongoing basis in order to work on approved research protocols, or to perform the review and oversight of research activities. Evidence of completion of these trainings must be tracked for reporting and notification purposes. The Syracuse R&D Office has responded by creating data tracking tools and practices in order to best meet the requirements in this area.

POLICY

It is the responsibility of all VA employees associated with VA research to uphold the standards of research education as established by the VA. This policy requires that all individuals reviewing, conducting or supporting VA research demonstrate and maintain sufficient knowledge of the ethical principles and standards, federal regulations, applicable law, professional standards and institutional policies and procedures governing human subject research, animal subject research, laboratory research safety, and research data security.

DEFINITIONS

Please refer to SOP151-01, Appendix B for Definitions.

ACTION

The Medical Center Director is responsible for:

- (1) Assurance that R&D Committee (R&DC) members, R&DC subcommittee members (Institutional Review Board/Subcommittee for Animal Studies/Subcommittee on Research Safety-IRB/SAS/SRS), investigators, and research staff are appropriately knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- (2) Ensuring the development and implementation of an educational plan for R&D Committee members, IRB/SAS/SRS members, investigators and staff;
- (3) Ensuring that the VA Research Office maintains accurate, up-to-date records regarding the mandatory VA Research training of investigators and other appropriate research staff;
- (4) Fulfilling all educational requirements mandated by the VA Office of Research and Development, the facility's federal wide assurance, the facility's Animal Welfare Assurance, accreditation agencies, funding institutions, and OHRP.

The R&D Committee is responsible for:

- (1) Evaluating on an annual basis whether IRB/SAS/SRS members and staff and investigators and their research staff have the requisite knowledge, understanding and experience relevant to their roles. The R&D Committee will verify if all investigators and research staff have fulfilled the educational training requirements set forth in this policy.

Subcommittees of the R&D Committee (IRB/SAS/SRS) are responsible for:

- (1) Determining that the principal investigator, all other investigators and staff of a proposed research activity have met all current educational requirements mandated by the VA Office of Research and Development, the facility's federal wide assurance, the facility's Animal Welfare Assurance, accreditation agencies, funding institutions, and OHRP.
- (2) Determining that the investigator(s) is qualified through education, training and experience to conduct the research.

The Research Compliance Officer is responsible for:

- (1) Serving as a consultant to investigators, research staff, committee members, and IRB/SAS/SRS members and staff on issues that may include ethical research principles and standards, federal regulations, applicable law and institutional policies and procedures governing VA research.

TRAINING REQUIREMENTS

Requirements are outlined by role. Individuals may need to complete more than one category due to overlap of roles and proposed research activities. One training course may also fulfill requirements for multiple roles (e.g., Information Security 201). All training completion and anniversary dates are tracked by calendar year for fulfillment and compliance. Training completion certificates are to be submitted to the Syracuse VAMC R&D Office for tracking purposes. The R&D Office will maintain a centralized spreadsheet for documentation of the training listed below. Human Subject Researchers, research staff; IRB members, IRB chairs, and others involved in human subject research must complete the initial education prior to their R&D approval to participate in any part of the human subject research program.

Institutional Official signing FWA must complete:

- (1) OHRP's Human Subject Assurance Training modules found on OHRP website: <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>. In order to qualify for an Assurance, the OHRP strongly recommends that the Institutional Official complete Module 1. The Human Protections Administrator (Primary Contact) and IRB Chair should complete all three modules. These modules are completed at the time of initial FWA submission or at the 3-year renewal.

Research Integrity Officer (RIO) must complete:

VHA Handbook 1058.2, Paragraph 7.b.(3), states that RIOs are responsible for "receiving initial and continuing education and training in the handling of research misconduct allegations." The most important step for a newly appointed RIO is to become familiar with all of the provisions of Handbook 1058.2. Secondly, RIOs should review VA Handbook 0700 (Administrative

Investigations). Beyond that, ORO will send out periodic announcements about further training opportunities. Examples of possible training include:

- (1) Review "How to Interpret and Use Handbook 1058.2 in Handling Allegations of Research Misconduct"; PowerPoint slides available at:
http://vawww.appc1.va.gov/oro/docs/07_13_05.ppt;
- (2) Attendance at conferences/meetings at which Handbook 1058.2 is presented by ORO staff;
- (3) Review of RIO materials found on <http://ori.hhs.gov/rio/>
- (4) Review of ORO RIO FAQs which will be updated periodically;
- (5) Individual consultation with ORO staff in particular research misconduct cases;
- (6) Local SOP 151-07 "Misconduct in Scientific Research".

R&D Committee Members must complete:

- (1) VA Human Subjects Protection and Good Clinical Practices: Basic Course needs to be completed once. The VA Human Subjects Protection and Good Clinical Practices Refresher Course is required bi-annually thereafter. Course found on www.citiprogram.org. (Bi-annually is defined as within the second full calendar year after the previous training.)
- (2) Information Security 201 for R&D, found on LMS website: www.lms.va.gov. This is completed once.

SAS Members must complete:

- (1) New SAS members receive orientation in areas of protocol review and SAS responsibilities.
- (2) All SAS members must complete the VA web based training course and exam entitled "Essentials for IACUC Members" found on the CITI website: www.citiprogram.org. This training must be completed biannually.
- (3) Specific OLAW training must be completed biannually; website provided by SAS Administrator.
- (4) Information Security 201 for R&D, found on LMS website: www.lms.va.gov. This is completed once.

Personnel that work with animals must complete:

- (1) Personnel that utilize laboratory animals and are listed on the ACORP must pass the "Working with the VA IACUC" web course, in addition to any species-specific course that covers the species proposed for use. This training is found on the CITI website: www.citiprogram.org and is completed on a biannual basis.
- (2) Information Security 201 for R&D, found on LMS website: www.lms.va.gov. This is completed once.
- (3) Research Specific Safety Training: Annual training must be completed. No set training at this time. This training is selected annually by the SRS Chair.

- (4) VA ORD Biosecurity Training is completed once and found on CITI website at www.citiprogram.org.
- (5) VA Biosafety/Biosecurity Training is completed once and found on CITI website at www.citiprogram.org. (*Different training modules from (4) above*).
- (6) Chemical Hygiene Training (*if applicable*): Conducted with each new employee once by the Medical Center's Environmental Engineer through the Occupational Safety Office. Contact the Occupational Safety Office at ext. 52423, to coordinate this training.
- (7) Each PI is responsible for providing protocol specific training for his / her staff working with animal subjects.
- (8) Husbandry Staff : Husbandry staff may access web-based training developed by AALAS at www.aalas.org
- (9) Personnel working with non-human primates are required to complete the web-based training entitled, **Working with Non-Human Primates in Research Settings** at www.citiprogram.org, and to watch the DVD entitled, **Primates, Protection and Personnel**. This DVD is available in room D106.
- (10) Radiation Safety Training (*if applicable*): mandatory requirement for all employees prior to working with radioactive materials to view the Radiation Safety Video. This is completed once. Please contact the Occupational Safety Office at ext. 53594, to coordinate this training.

SRS members must complete:

- (1) New SRS members receive orientation in areas of protocol review and SRS responsibilities.
- (2) Information Security 201 for R&D, found on LMS website: www.lms.va.gov . This is completed once.
- (3) Research Specific Safety Training: Annual training must be completed. No set training at this time. This training is selected annually by the SRS Chair
- (4) VA ORD Biosecurity Training is completed once and found on CITI website at www.citiprogram.org.
- (5) VA Biosafety/Biosecurity Training is completed once and found on CITI website at www.citiprogram.org (*Different training modules from (4) above*).

Personnel working in research laboratories must complete:

- (1) Research Specific Safety Training: Annual training must be completed. No set training at this time. This training is selected annually by the SRS Chair.
- (2) VA ORD Biosecurity Training is completed once and found on CITI website at www.citiprogram.org.

- (3) VA Biosafety/Biosecurity Training is completed once and found on CITI website at www.citiprogram.org (*Different training modules from (2) above*).
- (4) Information Security 201 for R&D, found on the LMS website: www.lms.va.gov .
- (5) Chemical Hygiene Training: Conducted with each new employee once by the Medical Center's Environmental Engineer through the Occupational Safety Office. Contact the Occupational Safety Office at ext. 52423, to coordinate this training.
- (6) If working in a laboratory that is licensed to use radiation, it is a mandatory requirement for all new laboratory employees to view the Radiation Safety Video. This is completed once. Please contact the Occupational Safety Office at ext. 53594, to coordinate this training.
- (7) It is a mandatory requirement for all new laboratory employees to read the Research Service Safety Manual. This is completed once and upon each revision of the manual.
- (8) Each PI is responsible for providing laboratory / project specific training for his / her lab staff.

IRB members must complete:

- (1) New IRB members receive orientation in areas of protocol review and IRB responsibilities, including a copy of the "IRB Member's Handbook" for ready reference.
- (2) VA Human Subjects Protection and Good Clinical Practices: Basic Course must be completed once. The VA Human Subjects Protection and Good Clinical Practices Refresher Course is required bi-annually. www.citiprogram.org. (Bi-annually is defined as within the second full calendar year after the previous training.)
- (3) HRPP Training: This course is required once for all committee members and scientific reviewers. This course is available in PowerPoint format. Sign the Verification Form HRPP document and submit it to the IRB Office for credit.
- (4) Information Security 201 for R&D, found on the LMS website: www.lms.va.gov

Personnel working with human subjects/human data must complete:

- (1) VA Human Subjects Protection and Good Clinical Practices: Basic Course must be completed once. The VA Human Subjects Protection and Good Clinical Practices Refresher Course is required bi-annually. www.citiprogram.org. (Bi-annually is defined as within the second full calendar year after the previous training.)
- (2) HRPP Training: This course is required once for staff who have contact directly with patients or personally identifiable data. This course is available in PowerPoint format. Sign the Verification Form HRPP document and submit it to the IRB Office for credit.
- (3) Information Security 201 for R&D, found on the LMS website: www.lms.va.gov
- (4) Each PI is responsible for providing protocol specific training for his / her staff working with human subjects.

Special Note for all VA Employees:

Effective January 2011, the General VA Privacy and Information Security Awareness and Rules of Behavior courses were combined into **VA LMS Item Number VA 10176**. This must be completed by all VA employees (paid, WOC, IPA, students) as part of their VA appointment and to maintain access to VA IT resources. VA employees who have access to Protected Health Information (PHI) for administrative and clinical purposes have an additional requirement that will be met by completing **VHA Privacy Course LMS Item Number VA 10203**. These trainings are tracked and maintained by the individual and their immediate supervisor.

RESEARCH TRAINING NON-COMPLIANCE

R&DC and IRB/SAS/SRS Members: Members who do not comply with training requirements will be placed in a non-voting status until completed. The ACOS/R&D and R&DC will be notified by the R&DC Administrator of training deficiencies in the R&DC agenda, and further actions for significant deficiencies will be determined by the R&DC.

Principal Investigators: PIs will receive training reminders and notifications via e-mail from the R&D Office to complete their mandatory training requirements. If the training is not completed and falls out of compliance, the appropriate IRB/SRS/SAS Chair and the ACOS/R&D will be notified of the principal investigator(s) with active research protocol(s) who failed to complete mandatory refresher trainings. The IRB/SRS/SAS and R&DC will review and take appropriate action(s), which may include suspension of research activities and/or termination of research protocol approval. A new PI will not receive final protocol approval notification until training is complete for them and any personnel listed as working on the protocol. It is the PI's responsibility to ensure that staff working on their research protocol(s) remain compliant with required research training.

REFERENCES

- VA Handbook 1200.01 Research and Development (R&D) Committee, 2009.
- VA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research, 2010.
- VA Handbook 1200.07 Use of Animals in Research, 2005.
- VA Handbook 1200.08 Safety of Personnel Engaged in Research, 2009.

RESPONSIBILITY Syracuse VAMC Research and Development Service will be responsible for the content, update, and recertification of this SOP.

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