

Version Number: 1	Research & Development Policy 151-31	Supersedes Document Dated: NONE
Effective Date: 05/13/2013	PROCESS ADDRESSING HUMAN SUBJECTS RESEARCH CONDUCTED BY STUDENTS AT THE SYRACUSE, CANANDAIGUA OR BATH VA MEDICAL CENTERS	Expiration Date: 05/13/2017

I. PURPOSE:

This guidance document reflects the commitment of the Bath, Canandaigua and Syracuse VAMCs to accommodate and encourage human subjects research that is conducted by students in compliance with VA regulations. This document differentiates research activities from student projects.

II. DEFINITION:

- a. **Research:** a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge.
- b. **Generalizable knowledge:** information that expands the knowledge base of a scientific discipline or other scholarly field of study. Systematic investigations designed to produce information to expand the knowledge base of a scientific discipline or other scholarly field of study constitute research.
- c. **Student Research:** research conducted by VA staff members (those with part- or full-time appointments, IPAs or WOCs) to fulfill an academic requirement from an accredited educational institution.
- d. **Student Project:** an activity designed specifically for educational or teaching purposes, where data are collected from or about human subjects as part of a class exercise or assignment, but are not intended for use outside of the classroom or the local VAMC.

III. SCOPE:

This guidance applies to Bath, Canandaigua and Syracuse VAMC appointees who wish to conduct human subjects research within the VA to fulfill an academic requirement from an accredited educational institution.

IV. AUTHORITY:

Authority resides with the Chiefs of Staff of the VA facilities, as delegated by the Facility Directors.

V. REGULATORY DOCUMENTATION:

VHA Handbook 1200.05.63.a (1-4): Student and Other Trainee Research

- a. **Research Conducted by Students and Other Trainees to Fulfill Academic Requirements:** Only students and other trainees (including residents and fellows), including VA employees, from schools with an academic affiliation agreement consistent with current VHA policy, may serve as investigators within a VA facility, or use data, or human biological specimens that have been collected within VA for clinical, administrative, or research purposes. *Note: a waiver may be obtained from the CRADO under special circumstances.*

- (1) A VA investigator sufficiently experienced in the area of the trainee's research interest must serve as PI or co-PI and is responsible for oversight of the research and the trainee. The PI or co-PI is responsible for ensuring the trainee complies with all applicable local, VA, and other Federal requirements.
- (2) In conducting the research, the trainee must comply with all VA and other Federal and local institutional requirements, including those related to research, information security, and privacy.
- (3) If the trainee does not complete all aspects of the research prior to leaving VA, the VA employee serving as the PI or co-PI must ensure the protocol is completed or terminated in an orderly fashion, and in accordance with all applicable local, VA, and other Federal requirements.
- (4) When the trainee leaves VA, the VA employee serving as the PI or co-PI is responsible for ensuring all research records are retained by VA.

VI. APPLICATIONS:

- a. All human subject research conducted by students at the Bath and Canandaigua VAMCs will comply with VHA Handbook 1200.05.
- b. Students who wish to conduct **research** at the Bath, Canandaigua and Syracuse VAMCs:
 - (1) Must have a part- or full-time, IPA or WOC appointment at their respective VAMC.
 - (2) Must be attending an accredited educational institution that has a current academic affiliation agreement with either their respective VAMC.
 - (3) Must ensure that there are no regulatory restrictions on their proposed research activities.
 - (4) May serve as principal investigators of their research studies, if they are experienced VA researchers. For those students without research experience, a VA researcher with expertise in their area of research must serve as the study principal investigator; the student may serve as a co-investigator.
 - (5) Must successfully complete all human research protection program (HRPP) education required by the Syracuse VAMC research office.
 - (6) Must be properly credentialed or privileged and have fully executed a research scope of practice.
 - (7) Must obtain the review and approval by the Syracuse VAMC IRB prior to initiating research.
- c. The following criteria describe **student projects**, which do not meet the definition of research and do not require Syracuse VAMC IRB review and approval:
 - (1) There are no regulatory restrictions on the data to be collected; the student has routine access to these data as part of his or her VAMC appointment.
 - (2) Only de-identified data (excluding the 18 HIPAA identifiers [Appendix A]) will be recorded.
 - (3) Findings will be shared only within the student's classroom, or among his or her colleagues at the respective VAMC.
 - (4) Surveys of Veterans will not be conducted.
 - (5) The student will obtain written approval to conduct the activity from the appropriate supervisory official.

- d. A determination regarding whether a particular activity is defined as research or a student project will be made in compliance with VHA Handbook 1058.05: VHA Operations Activities that May Constitute Research. Written concurrence with each determination will be provided by the Chair of the SVAMC IRB. Students will receive written documentation of this determination.
- e. The AOs for Research at the Bath, Canandaigua and Syracuse VAMCs will serve as points of contact for questions regarding this procedure.

VII. REFERENCES:

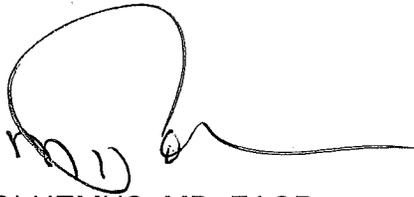
- a. VHA Handbook 1058.05: VHA Operations Activities that May Constitute Research (October 28, 2011).
- b. VHA Handbook 1200.05: Requirements for the Protection of Human Subjects in Research (May 2, 2012).

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

IX. IMPLEMENTATION: May 2013

X. RESCISSION: NONE

XI. RECERTIFICATION: May 2017



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APPENDIX A

The 18 HIPAA Identifiers

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

There are also additional standards and criteria to protect an individual's privacy from re-identification. Any code used to replace the identifiers in datasets cannot be derived from any information related to the individual and the master codes, nor can the method to derive the codes be disclosed. For example, the unique code cannot include the last four digits (in sequence) of the Social Security number. Additionally, the researcher must not have actual knowledge that the research subject could be re-identified from the remaining identifiers in the PHI used in the research study. In other words, the information would still be considered identifiable if there was a way to identify the individual even though all of the 18 identifiers were removed.