IRB Policy 5: Research Activities

I. Definitions:

A. **Research** is defined in the DHHS Federal regulations (45 CFR 46) as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Research is defined in the FDA federal regulations as any experiment that involves a test article and one or more human participants and that either is subject to requirements for prior submission to the Food and Drug Administration under Section 505(i), 507(d) or 520 (g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. Under FDA regulations the terms “research” and clinical investigation are synonymous. VA Handbook 1200.5 defines research as “the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data and interpreting the results in terms of the hypothesis or question. 38 CFR 16.102 states that “Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

B. **Human Subjects** are defined in the “Common Rule” as “living individuals about whom an investigator (whether professional or student) conducting research obtains either (1) data through intervention or interaction with the individual or (2) identifiable private information.” FDA regulations define subjects as an individual who is or becomes a participant in research, either as a recipient of the test article or control. FDA regulations also define subjects as an individual on whose specimen a device is used. Subjects may be either a patient or a healthy human. 38 CFR 16.102 defines a human subject as meaning “a living individual about whom an investigator (whether professional or student) conducting research obtains 1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

C. **Intervention** is defined as including both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant’s environment that are performed for research purposes. 38 CFR 16.102(f) notes that “an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes.”
D. Interaction includes communication or interpersonal contact between investigator and participant.

E. Test article is defined as 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 act or under sections 351 or 354-360F of the Public Health Service Act.

F. 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

G. Investigational New Drug (IND) means “a new drug, antibiotic drug, or biological drug that is used in a clinical investigation”

H. Systematic Investigation—means typically a predetermined method for studying a specific topic, testing a specific hypothesis(es), answering a specific question or developing theory

I. Generalizable— to develop or contribute to generalizable knowledge typically means that results or conclusions of the activity are intended to be extended beyond a single person or an internal program.

II. Summary Policy

Activities that meet the definition of “research” and “human subjects” as defined in DHHS regulations, or meet the definition of “research” and involve “human subjects” as defined in FDA regulations are subject to the ETSU or ETSU/VA IRB’s jurisdiction. Activities that constitute human subject research are determined by the ETSU and ETSU/VA IRB. The IRBs delegate this decision to the IRB Chair or Vice Chair. The Chair or Vice Chair completes Form 113 to determine whether a proposal submitted to the IRB is human research according to DHHS or FDA regulatory definitions. The Chair or Vice Chair may not make this determination if he/she has direct involvement in the activity being examined. If a protocol submitted to the IRB is determined to not be human research according to DHHS or FDA regulatory definitions, the submitter is notified in writing that the proposed activity does not fall under IRB jurisdiction. If the activity meets the FDA definition of “research” and “human subjects” as defined in FDA regulations, the IRB will adhere to all applicable FDA regulations. For drugs, the FDA regulations apply where there is any use of a drug in research except the use of a marketed drug in clinical practice. For devices, FDA regulations apply to studies where the purpose is to determine the safety or effectiveness of a device or data will be submitted to or held for inspection by FDA as part of a marketing permit.

The IRB has the sole authority to make a final determination of whether a proposed activity is human research according to DHHS or FDA regulatory
definitions. Unless you are familiar enough with these regulations to be certain that the activity does not represent human research, the activity should be brought forward to the IRB for a determination.

In response to a question as to whether a proposed activity is research, the IRB Chair or Vice Chair requires all the information pertinent to the DHHS and FDA definitions. Submission of a completed Form 129 (available on IRB website. (www.etsu.edu/irb) is required in order to make the determination of whether a proposed activity is human research. Written responses to the Form 129 will be made by the Chair or Vice Chair within one week of inquiry. For VA submissions, a determination of “not human subject research” will be forwarded to the VA R&D Office rather than the submitter. The VA R&D Office then releases the letter to the submitter after review by the Privacy Officer. IRB Coordinator notifies the submitter that the letter has been sent to VA R&D.

Classified research involving human participants cannot be approved by the ETSU/VA IRB or VA Research and Development Committee or performed at VA facilities.

III. Oral History

Oral History is a method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life. Most oral history interviewing projects are not subject to the requirements of the regulations found at 45 CFR 46.102(d) which define research as, “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”. While historians reach for meaning that goes beyond the specific subject of their inquiry, unlike researchers in the biomedical and behavioral sciences, they do not reach for generalizable principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes. The oral history interview usually provides a unique perspective on the topic at hand; a series of interviews offer up, not similar “generalizable” information, but a variety of particular perspectives on the topic.

For these reasons, oral history interviewing in general, does not meet the regulatory definition of research as articulated in 45 CFR 46. Office for Human Research Protections (OHRP) concurs with this policy, as evidenced by the OHRP draft statement, dated 8/26/03. However, the IRB has the sole authority to make a final determination of whether a proposed activity is human research according to DHHS or FDA regulatory definitions. Unless you are familiar enough with these regulations to be certain that the activity does not represent human research, the activity should be brought forward to the IRB for a determination.
IV. **Other Activities**

| Case Studies | A single subject study with clear intent, before recruiting or interacting with the participant, to use data that would not ordinarily be collected in the course of daily life. The intent is to report and publish the case study. | **YES** |
| Case Studies | Retrospective review of a patient’s medical record with the intent to report and/or publish the summary. | Retrospective review of a single patient’s medical record with the intent to report and/or publish the summary AND only clinically indicated interventions or data collection were performed AND data is de-identified = NO
Exception: If any aspect of the case is unusual enough that the patient might be identifiable even though normal patient identifiers are removed, then it should be submitted. " For case reports involving more than one patient, IRB should be consulted (by submitting a Form 129) to determine whether the case report is research. If the proposed case report activity involves 4 or more patients, it must be submitted as human subject research. |
<table>
<thead>
<tr>
<th><strong>Retrospective review of a patient’s medical records for use in an educational setting. The data will be de-identified.</strong></th>
<th><strong>NO</strong></th>
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<tbody>
<tr>
<td><strong>Thesis or Dissertation Project</strong></td>
<td><strong>Thesis or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable</strong></td>
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<td><strong>Classroom projects</strong></td>
<td><strong>Classroom activities designed solely for educational purposes</strong></td>
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**References**

45 CFR § 46.102(d)
45 CFR § 46.102(f)
21 CFR § 46.102(f)(1)
21 CFR § 46.102(f)(2)
21 CFR 312.3
21 CFR § 50.3(j)
21 CFR §56.102(l)
VA Handbook 1200.5
38 CFR 16