

**VA RESEARCH
AND HUMAN SUBJECTS, VERSION 1.2
RESEARCH SERVICE
VA MEDICAL CENTER 581, HUNTINGTON WV**

All **research** involving the use of **human subjects** subject to the Huntington VAMC Human Research Protection Program **must** be submitted to the Research Service for review **prior** to transmittal to the Marshall University Institutional Review Board #1 (MU IRB#1) for review and approval.

All potential studies involving human subjects must be submitted to the Research Service as an abstract, if there is any doubt whether the study is **human subject research**. The Research Service will make an initial determination and if necessary will submit the abstract to MU Office of Research Integrity for the MU IRB#1 Chair to review and make a determination. This abstract should be written in lay terms and should include the following information:

- The Purpose of the Research
- The Scientific or Scholarly Rationale
- The Procedures to be Performed
- A Description of What Procedures Were Being Performed Already for Diagnostic or Treatment Purposes
- The Risks and Potential Benefits of the Research
- Complete Inclusion/Exclusion Criteria

The abstract can be mailed, hand delivered, or e-mailed to the Administrative Officer for Research (mailstop 151, x2792) or the Research Service Program Support Assistant (mailstop 151, x2791). Once a determination is made, the Research Office will contact the investigator.

Research, human subject, and human subject research definitions vary depending on the Federal agency.

Research:

Under VHA (Veterans Health Administration) policy (VHA Handbook 1200.05 par. 3 kkk) is defined as: *Research means a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy whether or not they are conducted or supported under a program which is considered research for other purposes.*

Under DHHS (Department of Health and Human Services) regulations (45 CFR §46.102(d)) is defined as: *A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.*

Under FDA (Food and Drug Administration) regulations (21 CFR §50.3(c)) is defined as: *Any experiment that involves a test article and one or more human subjects, and that either is subject to requirements for prior submission to the Food and Drug Administration.*

Human Subject:

Under VHA policy (VHA Handbook 1200.05 par. 3 ff) is defined as: *This definition of human subject includes investigators, technicians, and others assisting investigators, when they serve in a "subject" role by being observed, manipulated, or sampled.*

(1) 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:

(a) Data through intervention or interaction with the individual; interaction includes communication or interpersonal contact between the researchers and the subject; or

(b) Identifiable private information (38 CFR 16.102 (f)).

(2) For research covered by Food and Drug Administration (FDA) regulations, human subjects means 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), 21 CFR 66.102(c)).

(3) 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)).

Under DHHS Regulations (45 CFR §46.102(f)) is defined as: *Living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.*

Under FDA regulations (21 CFR §50.3(g)) a human subject is defined as:

- *An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A participant may be either a healthy human or a patient.*
- *Or in the case of a medical device: 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 participant may be in normal health or may have a medical condition or disease.*

Human Subject Research:

Under VHA policy (VHA Handbook 1200.05 par. 3 ff) is defined as: *Human research is research involving human subjects as defined in this Handbook or one or more identifiable human biological specimens.*

Activities are human subject research under DHHS regulations when they meet the DHHS definition of “**research**” (45 CFR §46.102(d)) and involve a “**subject**” as defined in DHHS regulations (45 CFR §46.102(f)).

Activities are human subject research under FDA regulations when they meet the FDA definition of “**research**” (21 CFR §50.3(c), 21 CFR §56.103(c), 21 CFR §312.3(b), or 21 CFR §812.3(h)) and involve a “**subject**” as defined in FDA regulations (21 CFR §50.3(g), 21 CFR §56.103(e), 21 CFR §312.3(b), or 21 CFR §812.3(p))

Human Research Protection Program (HRPP):

Under VHA policy (VHA Handbook 1200.05 par. 3 ee): 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 for R&D or Research Coordinator, Administrative Officer for Research, Research Compliance Officer, R&D Committee, 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 in research.

What is NOT Human Subject Research? (courtesy MU ORI website)

Data collection for internal departmental, school, or other institutional administrative purposes. (i.e. teaching evaluations, customer service surveys)

Information-gathering interviews where questions focus on things, products, or policies rather than about people or their thoughts. (i.e. canvassing librarians about inter-library loan policies or rising journal costs)

Publicly available data does not require IRB approval. (i.e. for internal departmental, school, or other institutional administrative purposes. (i.e. teaching evaluations, customer service surveys)

Coded data that were not collected for the currently proposed projects as long as the investigator receiving the data cannot link the data back to the individual.

Case Studies which are published and/or presented at national or regional meetings are often **not** considered human subject research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge. (for example: the comparison of case studies would qualify as human subject research)

Note: When there is any doubt as to whether or not a study could qualify as human subject research, you must submit an abstract to Research Service to review and make a determination (as outlined above).

Decision Charts:

The Office for Human Research Protections has developed helpful decision charts for determinations of research involving human subjects under DHHS regulations.

Chart 1 is reproduced below (<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1>):

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

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