DETERMINING WHETHER AN ACTIVITY IS HUMAN SUBJECTS RESEARCH AS DEFINED BY FEDERAL REGULATIONS

DESCRIPTION

It can be difficult to determine whether or not a project meets the federal definition of human subjects research that requires oversight by an Institutional Review Board (IRB). Familiarity with federal definitions and guidance is necessary to permit an accurate assessment. At the University of Cincinnati (UC), the IRB shall determine whether or not a project meets the federal definition of human subjects research and so must receive IRB approval as described in Human Research Protection Program (HRPP) Policy III.01 *Review of Human Subjects Research by the Institutional Review Board*.

RESPONSIBILITY

The IRB Chair or designee is responsible for determining whether or not a project constitutes human subjects research. This decision may not be made by the project's initiator.

DEFINITIONS

The IRB shall use the following definitions to determine whether an activity shall qualify as human subjects' research requiring IRB review and approval:

Department of Health and Human Services (DHHS) definitions:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)).

Note that "systematic investigation" typically involves a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis or developing a theory.

Note that "generalizable knowledge" is intended to expand understanding of a condition or population, or add to the body of knowledge regarding a field of study. The targeted population, data collected and analysis of those data results in knowledge that answers a research question or addresses the need for information in a scientific discipline. Most master's and doctoral level research is intended to produce generalizable knowledge. Quality assessment (QA), quality improvement (QI) or program evaluation that is intended solely to improve the care or experiences of

members of the target group does not result in generalizable knowledge. Reports of QA/QI/evaluation projects may be published or presented but would not claim to be research studies.

Human subject means 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.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Note that "interaction" includes paper and electronic surveys, online presentation of information and data collection via social media, etc., as well as in-person interaction or conversation.

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).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects (45 CFR 46.102(f)).

Food and Drug Administration (FDA) definitions:

Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient (21 CFR 56.102(e)).

Test article means 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 (21 CFR 56.102(l)).

PROCESS

A description of the proposed project shall be submitted to the IRB in sufficient detail to enable the following determinations. Both answers must be Yes for the project to be considered "human subjects research."

1. Is the activity a systematic investigation or clinical investigation, including protocol development, testing, and evaluation, designed to contribute to generalized knowledge?

2. Does the activity involve living individuals about whom the investigator obtains data through intervention or interaction[7] with the individual, or obtains identifiable private information?

In addition, for projects involving medical information, sufficient detail must be provided to enable whether or not the project will be used in support of an application for marketing of a test article. If the answer to any of the following questions is Yes, the activity must be reviewed by the IRB under FDA regulations.

1. Does the activity involve the use of a drug (including an approved drug or an over-the-counter drug), other than the use of an approved drug in the course of medical practice?

2. Does the activity involve the use of a medical device (including an approved medical device), other than the use of an approved medical device in the course of medical practice? Note that medical devices generally include devices intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, and devices intended to affect the structure or any function of the body of humans or other animals.

3. Will data be submitted to the FDA or held for their inspection?

Each determination and the basis for the decision will be documented. The researcher will be notified in writing whether the project is not considered to be human subjects research and requires no further IRB oversight, or is human subjects research that requires a standard submission for IRB review and approval.

Applicable Regulations, Document(s):
45 CFR §46.102(d, f)

UNIVERSITY OF Cincinnati

Human Research Protection Program Policy

21 CFR §56.102(e, l)
HRPP Policy III.01 *Review of Human Subjects Research by the Institutional Review Board*

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
03/2005	M. Linke	07/2007	D. Oneill	Updated IRB office terminology.
01/2014		01/2014	C. Norman	Major revision to simplify wording and be consistent with other Policies.

Date Adopted 1/24/2014 Signature signed copy on file