	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
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HUMAN SUBJECT'S RESEARCH DETERMINATION

Purpose:

To present the definition of human subject's research applicable to UPR MSC as described under the code of federal regulations.

Sources:

45 CFR 46.102
21 CFR 56.102

Applicability:

IRB members, office staff and investigators

Background:

Activities performed by physicians outside of the clinical context may or may not meet the definition for research involving human subjects.

Policy:

It is required that all human research studies in which the UPR MSC or affiliated institutions are engaged must be reviewed and approved by the UPR MSC IRB prior to initiation.

Procedure:

The UPR MSC utilizes Code of Federal Regulations' (CFR) Human Subject's Research Definition. Under the CFR (45 CFR 46.102(d)), an activity is considered to be "research" if it involves a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Activities not systematic, not designed to contribute to general knowledge, or done only for personal or classroom use (i.e. not shared with *anyone* else, including other members of the laboratory or department) do not meet this definition.

Per 45 CFR 46.102(f), research is considered to involve "human subjects" if it entails obtaining information about living individuals, either through intervention or interaction with the individuals or if the research involves the receipt of *individually identifiable* information originally obtained in a context in which the individuals could reasonably expect privacy.

What characterizes an intervention with an individual?

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

An example of such an intervention would be an educational intervention such as randomly providing pamphlets to some patient-subjects that provide tips for sticking to medication regimens while not providing that information to a set of other patient-subjects with the intent of testing the effectiveness of such a program on increasing compliance with medication schedules. This type of project involves human subjects because there is an intervention (handing out educational pamphlets) with living individuals.

What characterizes an interaction with an individual?

Interactions include communication or interpersonal contact between investigator and subject.

An example of an interaction with a human subject could be a blood draw or finger stick for research purposes. In this case, there is an interaction with a living individual that is being done outside of the realm of regular patient care.

What is private information?

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 (e.g., medical record information).

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.

What defines a "living" individual?

Since the definition of a human subject is a "living" individual, research which only involves autopsy materials, cadavers or death records is not considered human subjects research and is not reviewed by the IRB.

FDA Definition of Human Subject

FDA regulations (21 CFR 56.102 (e)), define human subject as 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. For research involving medical devices, a human subject is also an individual on whose specimen an investigational device is used.

Some projects, such **case reports**, research on de-identified human specimens, research on deceased individuals, and quality assurance/quality improvement projects that do not involve drugs or medical devices other than the use of an approved drug or medical device in the course of medical practice or data that will be submitted to or held for inspection by the FDA are not human research as defined above.

It should be noted that other federal, state, or local laws or regulations (i.e. HIPAA), may apply to activities whether or not they meet the definition for research involving human subjects as outlined by 45 CFR 46.

Studies involving deceased individuals

The Health Insurance Portability and Accountability Act (HIPAA) Security and Privacy regulations [45 CFR 160, 164] apply to individuals both living and deceased. Thus, additional protections for subjects may be necessary before beginning a proposed activity (even if the activity does not otherwise qualify as human subjects' research) in order to comply with HIPAA.

In this case, research on decedents may or may not require IRB review. If any protected health information as defined by the HIPAA regulations is collected about deceased individuals, the investigators should submit a complete application on the IRB website. The IRB staff will then determine if further information is required.

Clinical Practice vs. Clinical Investigation

The IRB is aware that research conducted in an academic setting can often result in an overlap between clinical practice designed to take care of a specific patient's medical needs and clinical investigation designed to collect generalizable knowledge to advance standards of care. This distinction can be particularly confusing in clinic-based research where contact with patients and clinical investigators may extend over long periods of time.

The decision as to what constitutes clinical practice in a department is made by the Medical Director. However, in those grey areas where one may be unsure about whether an activity is clinical practice/patient care or research, we encourage faculty to contact the IRB in writing for an opinion. This will avoid any future confusion should the question arise in the course of an application for funding or review of a submitted manuscript for publication of case results.

QI/QA Activity

The UPR MSC has adopted the proposed description of quality improvement projects put forth by the National Bioethics Advisory Commission (NBAC) in their December 19, 2000 draft document. Activities that meet the terms explained in the following statements are considered quality improvement/quality assurance activities (QI/QA) at the UPR MSC and do not have to be reviewed by an IRB.

Some data collection and analysis activities in the health services area are not intended to generate scientific knowledge, but rather are used as a management tool to improve the provision of services to a specific health care population (IOM 2000). These activities are not intended to have any application beyond the specific organization in which they are conducted. These activities are generally referred to as program evaluation or quality improvement. But, like public health, because populations are the targets of study and because the methods used in program evaluation or quality improvement are the same as those used in research, it is often difficult to determine whether or not the activity is research that falls under the oversight system.

When the purpose of an activity is to assess the success of an established program in achieving its objectives and the information gained from the evaluation will be used to provide feedback to improve that program, the activity is not human subjects' research. The evaluation is a management tool for monitoring and improving the program. Information learned has immediate benefit for the program and/or clients receiving the program or services. When the quality improvement involving human participants is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used elsewhere, the activity is research. The systematic comparison of standard or non-standard interventions involving human participants also is research.

Public Health Research

The IRB recognizes that surveillance, emergency responses, and program evaluations do not meet the DHHS definition of research. These activities although use systematic methodology, constitute public health activities the primary intent of which is to prevent disease in a particular population, to improve a public health program, or to provide emergency disaster relief and do not meet the DHHS definition of research. Therefore, these activities do not have to be reviewed by an IRB.

In cases where it is not clear whether an activity falls into clinical practice, QA/QI, or public health research, faculty should request an IRB opinion on whether an activity is research requiring IRB review. The request for opinion should be sent by a letter addressed to an IRB chair. The final determination of the question of whether the activity is or is not a research project is the responsibility of the IRB.