Title: What is Research Involving Human Subjects?
SOP # 10
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Subject: Definition of Research Involving Human Subjects

Policy:
This section provides guidance to Investigators to distinguish human subjects research requiring IRB review, from activities not requiring review. A working definition of human subjects research is any systematic investigation that is designed with the intent to develop or contribute scholarly knowledge and which uses living humans, or collects or uses identifiable information about living humans. Contributing to scholarly knowledge includes, but is not limited to, activities such as publication in a scientific journal and submittal of an abstract or paper to a conference.

Procedures:
A. Definition of Human Subjects Research
HHS regulations define "research" as: 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. UC Merced defines "generalizable knowledge" as results shared at conferences, included in abstracts, or published in journals or other literature, outside the institution.

Heath and Human Services (HHS) regulations define *human subject* as: a living individual about whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, or

- 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. *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.

B. Data Gathering Activities That May Not Be Research

Quality Assessment (QA) - The purpose of the activity is to assess the success of an established program. The activity is a management tool used for monitoring and improving the program. Information learned has immediate benefit for the program and/or clients receiving the program or services.

Quality Improvement (QI) - Quality Improvement is assessing and redesigning processes to improve the processes. The emphasis is on continuous improvement in the processes.

- QA/QI activities typically do not meet the federal definition of "human subjects research" because the intent of the activity is not to add to generalizable knowledge. However, some QA/QI activities may transition into research during the course of the activity. See Section D in such cases.

Single Case Report – A detailed report of the diagnosis, treatment, and follow-up of an individual patient. Case reports contain some demographic information about the patient (for example, age, gender, ethnic origin). Single Case Reports are typically a medical/educational activity, reported through publication, poster or verbal presentation, which report an interesting treatment situation or medical condition as a result of a clinical experience.

- A Single Case Report typically does not meet the federal definition of "human subjects research" because the activity was not a systematic investigation.

Student Classroom Activities – Normal educational activities, conducted as a part of a regular course and in a normal classroom setting, including activities designed to train students in research technique methods.

- Simulations of human experimentation and course-assigned data collection typically do not constitute human subjects research if the activities are designed for educational purposes only and do not add to generalizable knowledge.

C. Non-Research Activities that Transition into Human Subjects Research

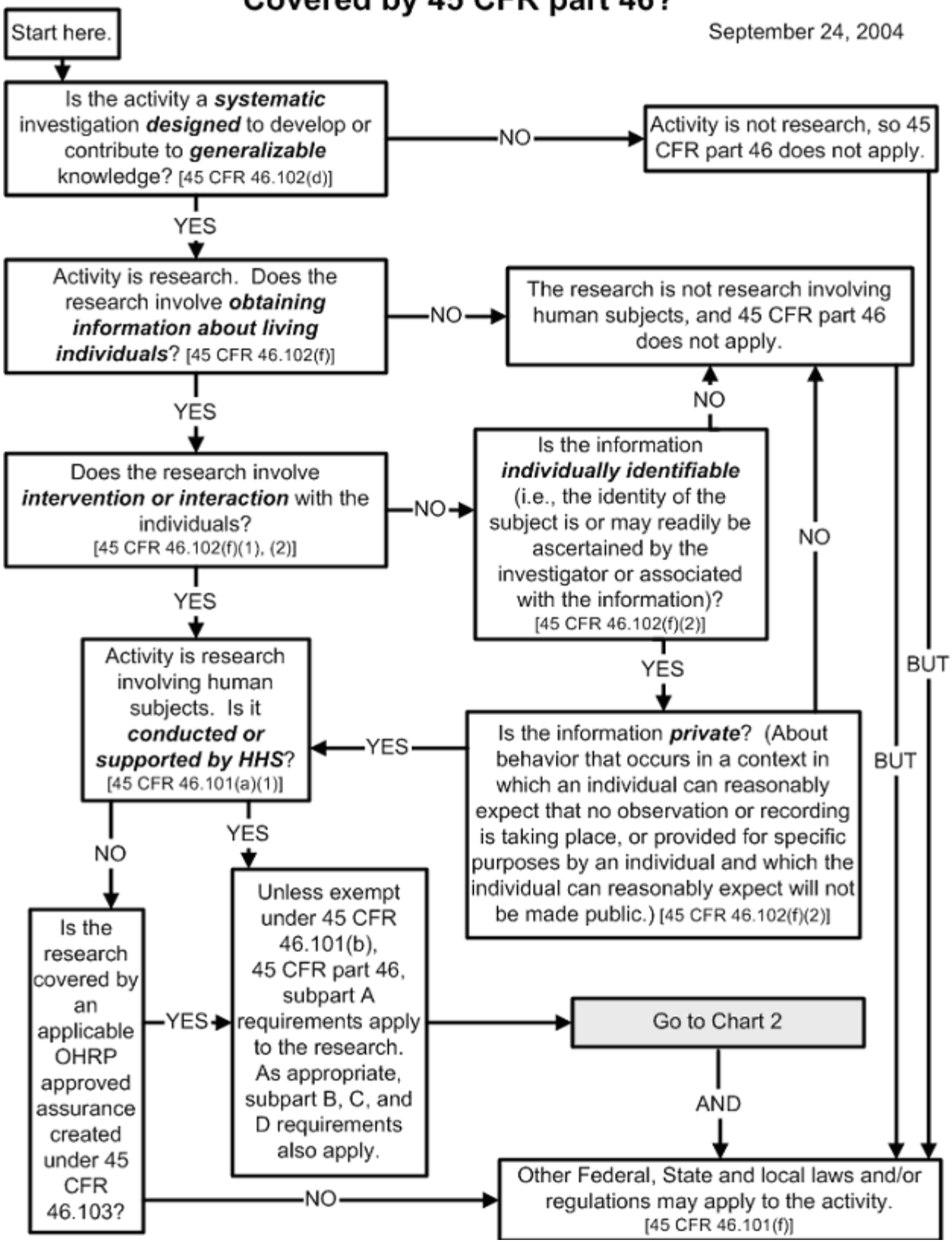
If an activity begins in a manner that it does not meet the definition of human subjects research under the federal regulations, such as the conduct of a QA/QI activity, but in the process of conducting the activity a decision is made to use the data or results of the activity to develop or contribute to generalizable knowledge (results shared at conferences, included in abstracts, or published in journals or other literature, outside the institution), the activity becomes research and requires IRB review and approval.

D. How To Determine Whether or Not An Activity is Human Subjects Research

The following graphic aid describes how to determine if an activity is research involving human subjects:

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

September 24, 2004



References:

45 CFR 46.102(d)

45 CFR 46.102(f)

OHRP Decision Chart: “Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?”

DHHS Guidance on Research Involving Coded Private Information or Biological Specimens, August 10, 2004

Institutional Review Board, Management and Function, Robert Amdur and Marjorie A. Speers, Identifying Research Intent, Chapter 4-3

National Bioethics Advisory Commission, “Ethical and Policy Issues in Research Involving Human Participants”, Chapter 2: A Proposal for Oversight, December 19, 2000, Draft, p.33