

I. INTRODUCTION

All activities that require the collection of data from or about individual persons must be reviewed and a determination made as to whether or not the proposed activity is research. Failure to do this prospectively may mean non-compliance with regulatory and contractual requirements. The consequences of non-compliance can include a mandatory suspension of all U.S. government funded research, harm to FHI 360's institutional reputation, and harm to research participants. In an organization like FHI 360 this is a complicated issue because we collect vast amounts of data from or about people as part of our organizational work, including both research and programs.

II. GENERAL DEFINITIONS

Research is defined 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, whether or not these activities are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

A **human subject** as a living individual about whom an investigator conducting research obtains:

- (1) Data through intervention or interaction with the individual; or
- (2) Identifiable private information.

III. DESCRIPTIONS AND EXAMPLES

The descriptions and examples below correspond to types of data collected activities listed on the **Request for Human Subjects Research Determination** form.

A. Public Health Programs

Public health programs include service delivery, health education, social marketing, risk reduction interventions, and program monitoring and evaluation. For the purpose of determining whether an activity constitutes human subjects research, a public health program does *not* constitute human subjects research IF its primary objective is to benefit the distinct population in which it is conducted. A public health research program may constitute human subjects research *if* its primary objective is to formulate knowledge intended to benefit a population beyond that served by the program.

B. Quality Improvement (QI) Activities

Quality improvement (QI) activities are typically not considered research. QI includes those activities whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes.

C. Collection or analysis of data about health facilities or other organizations/units which are NOT individual persons

Activities within this category are those in which individual-level data is NOT collected.

D. Collection or analysis of data or specimens from known deceased persons

Activities within this category include collection or analysis of data or specimens from persons who are known to have already deceased. Data which is collected from persons who are *assumed* but not *confirmed* to have deceased (for example, due to a fatal illness) are not included in this category. Requirements for confirmation of death vary by country. They may include, but are not limited to date of death provided by a national Ministry of Health, registration in a national database of births and deaths, and/or copies of death certificates.

E. Collection or analysis of unlinked/anonymous data or specimens

Data or specimens are not considered individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. For example, the data or specimens were not collected specifically for the proposed research project through an interaction or intervention with living individuals and the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded data or specimens pertain.

IV. Dissemination

Planning to publish an account or report of what is learned through the implementation of non-research activities is an important aspect of FHI 360's work. However, it is important that we are consistent in how data collection activities are described so that non-research is not re-framed as "research" or "a study" to suit the audience.