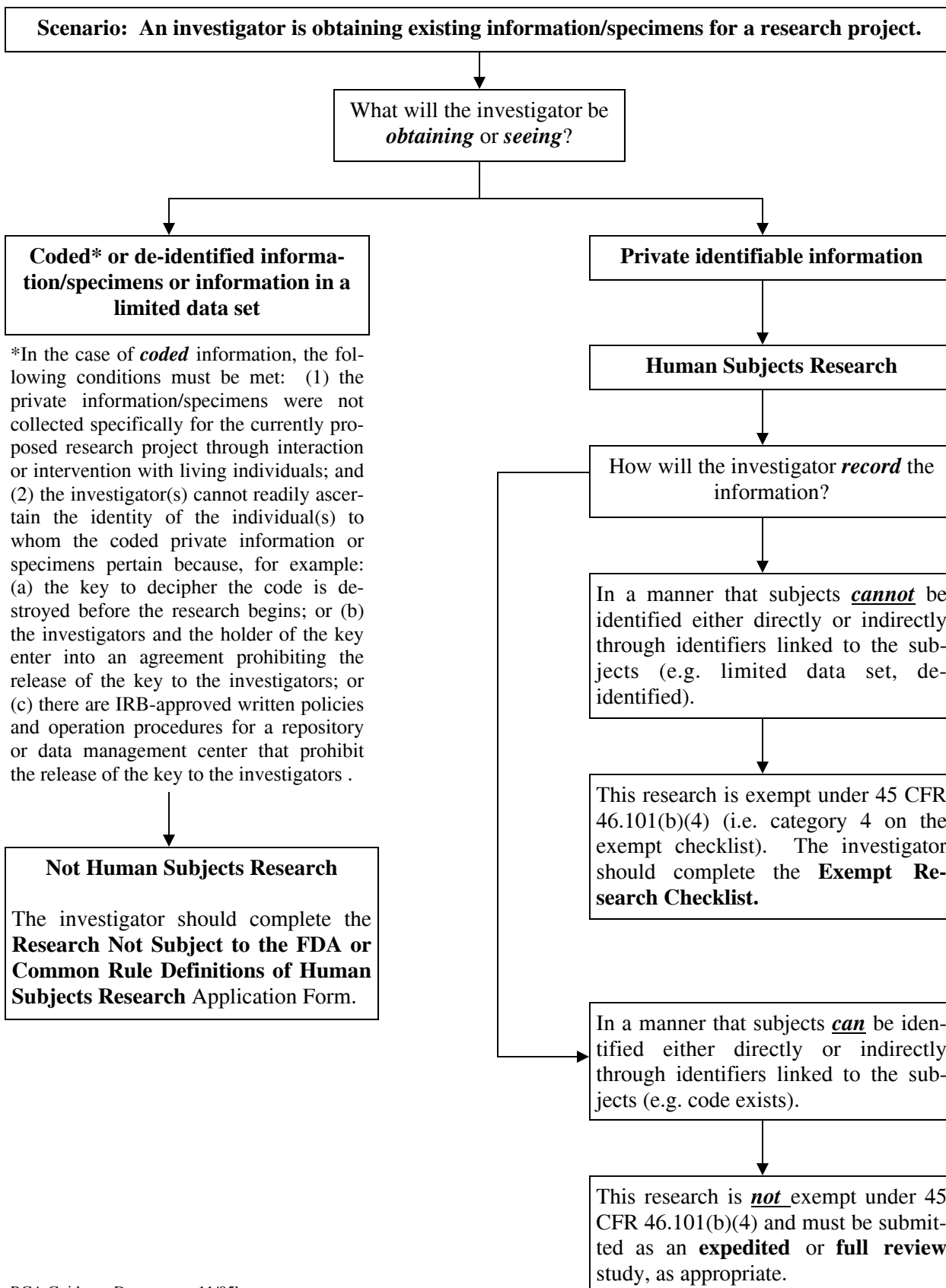


Guidance on determining the appropriate IRB submission for an activity involving research with existing information or specimens (non-genetic)



Guidance on determining the appropriate IRB submission of an activity involving research with existing information or specimens

References:

Guidance on Research Involving Coded Private Information or Biological Specimens

<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>

Definitions:

Private information includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place or information that has been provided for specific purposes that the individual can reasonably expect will not be made public (e.g., medical record, employee or student records).

Private information is considered **Identifiable** if (1) the identity of the individual from whom the information was obtained is ascertained or may be readily ascertained by the investigator; or (2) the identity of the individual from whom the information was obtained is associated or may be readily associated with the information. OHRP considers private information to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Limited Data Set – This set of data excludes facially identifiable information, but still includes some identifiable information. As a result, the data is still “identifiable” and may be used for limited purposes, including research, public health or healthcare operations as long as there is a data use agreement with the recipient of the limited data set.

A limited data set must exclude 16 specified identifiers that are listed in the Rule including: name, street address, telephone and fax numbers, email address, social security number, certificate/license number, vehicle identifiers and serial numbers, URL’s and IP addresses, and full face photo’s and any other comparable images.

The limited data set could include the following identifiable information: admission, discharge, and service dates, date of death, date of birth, age (including age 90 and older), and the five digit zip code.

De-Identified – Health information is de-identified if there is no reasonable basis to believe that the data can be used to identify an individual, or if the provider has no reasonable basis to believe it can be used to identify the individual. All of the following 18 identifiers must be removed for the data to be considered de-identified: name, all geographic subdivisions smaller than a State including street address, city, county, precinct, zip codes and equivalent geocodes, (except for the initial 3 digits of a zip code if more than 20,000 people reside in the area), all dates including birthdays (other than the year) and ages over 89, phone numbers, fax numbers, email addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers (including license plate #), device identifiers and serial #’s, URLs, IP addresses, biometric identifiers, full face photographic images and any comparable images, any other unique identifier, characteristic or code. Note: Other demographic information, such as gender, race, ethnicity, and marital status are not included in the list of identifiers that must be removed.

Coded (per OHRP) means that (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Obtaining (per OHRP) means receiving or accessing identifiable private information or identifiable specimens for research purposes. This includes an investigator’s use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.