RESEARCH INVOLVING THE SECONDARY USE OF EXISTING DATA

A. Scope

This guidance applies only to activities that involve the secondary analysis of existing data, such as medical records, student records, data collected from previous studies, audio/video recordings, etc. that were initially collected for another purpose. In order to be existing, the information must be “on the shelf” (i.e., it has already been collected) at the time that the current research is proposed.

Though such projects do not involve interactions or interventions with humans, they may still require CPHS/OPHS review, since the definition of “human subject” at 45 CFR 46.102(f) includes living individuals about whom an investigator obtains identifiable private information for research purposes.

Data analysis activities that meet the definition of research with human subjects may qualify for an exemption or require expedited or even full committee review. Any such project must receive CPHS approval or a determination of exemption before the investigator accesses the data.

B. When does the secondary use of existing data not require review?

In general, the secondary analysis of existing data does not require CPHS/OPHS review when it does not fall within the regulatory definition of research involving human subjects, as referenced above.

Note: Although the definition of a human subject includes only living individuals, thereby excluding decedents, there are cases in which the health information of the deceased and death data files may require CPHS review. See What Needs CPHS/OPHS Review for more details.

Public data: Public use data sets (such as portions of U.S. Census data, data from the National Center for Educational Statistics, National Center for Health Statistics, etc.) are data sets prepared with the intent of making them available for the public. The data available to the public are not individually identifiable and therefore their analysis would not involve human subjects.

In addition to being identifiable, the existing data must include “private information” in order to constitute research involving human subjects. Private information is defined as 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., a medical or school record). Information that contains identifiers and can be accessed freely by the public (without special permission or application) is not “private” and the research therefore does not therefore involve human subjects. For example, a study involving only analysis of the published salaries and benefits of public university presidents would not need CPHS/OPHS review since this information is not private.

De-identified data: If the dataset has been stripped of all identifying information and there is no way that it could be linked back to the subjects from whom it was originally collected (through a key to a coding system or by any other means), its subsequent use by the PI or another investigator would not constitute human subjects research, since it is no longer identifiable. Identifiable means the identity of the subject is known or may be readily ascertained by the investigator or associated with the information. In general, information is considered to be identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person could ascertain the identities of individuals. Therefore, even though a dataset may have been stripped of direct identifiers (names, addresses, student ID numbers, etc.), it may still be possible to
identify an individual through a combination of other characteristics (e.g., age, gender, ethnicity, and place of employment).

**Example:** Many student research projects involve secondary analysis of data that belongs to, or was initially collected by, their faculty advisor or another investigator. If the student is provided with a *de-identified, non-coded data set*, the use of the data does not constitute research with human subjects because there is no interaction with any individual and no identifiable private information will be used. The project does not therefore require CPHS/OPHS review.

**Coded data:** Secondary analysis of coded private information is not considered to be research involving human subjects and would not require CPHS/OPHS review if the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information pertains as a result of one of the following circumstances:

1. The investigators and the holder of the key have entered into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (DHHS regulations for human subjects research do not require the IRB to review and approve this agreement);
2. There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigator under any circumstances, until the individuals are deceased; or
3. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

**Note:** If a student is analyzing *coded data* from a faculty advisor/sponsor who retains a key, this would be human subjects research, because the faculty advisor is considered an investigator on the student’s protocol, and can readily ascertain the identity of the subjects since he/she holds the key to the coded data. If the student’s work fits within the scope of the initial protocol from which the dataset originates, the faculty advisor (or investigator who holds the dataset) may wish to consider adding the student and his/her work to the original protocol by means of an amendment application rather than having the student submit a new application for review.

**Example:** Researcher A plans to examine the relationships between attention deficit hyperactivity disorder (ADHD), oppositional defiance disorder, and teen drug abuse using data collected by Agencies I, II, and III that work with “at risk” youth. The data will be coded and the agencies have entered into an agreement prohibiting release of the key to the researcher that could connect the data with identifiers. The use of the data would not constitute research with human subjects and does not require CPHS/OPHS review.

**C. When is the secondary use of existing data exempt?**

There are six categories of research activities involving human subjects that may be exempt from the requirements of the Federal Policy for the Protection of Human Subjects (45 CFR 46). However, only one category (Category 4) applies specifically to existing data. If research is found to be exempt, it need not receive full or subcommittee (expedited) review. In order to qualify for an exempt determination, an eProtocol application must be submitted to OPHS for review.

Research involving collection or study of *existing* data, documents, and records can be exempted under Category 4 of the federal regulations if: (i) the sources of such data are publicly available; or (ii) the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

The latter condition of this category applies in cases where the investigators initially have access to
identifiable private information but abstract the data needed for the research in such a way that the information can no longer be connected to the identity of the subjects. This means that the abstracted data set does not include direct identifiers (names, social security numbers, addresses, phone numbers, etc.) or indirect identifiers (codes or pseudonyms that are linked to the subject’s identity). Furthermore, it must not be possible to identify subjects by combining a number of characteristics (e.g., date of birth, gender, position, and place of employment). This is especially relevant in smaller datasets, where the population is confined to a limited subject pool.

**The following do not qualify for exemption:** Research involving prisoners, research involving protected health information from UCB HIPAA-covered entities (Tang Health Center, Human Resources Health Plan, Intercollegiate Athletics, the Optometry Clinic, or the Psychology Clinic), and FDA-regulated research.

**Examples:**

1) A researcher conducts a study of treatment outcomes for a certain drug that involves the review of patient charts at a non-UCB medical facility. The researcher records patient age, sex, diagnosis, and treatment outcome in such a way that the information cannot be linked back to the patient. This project could qualify for an exemption.

2) Student B will be given access to data from her faculty advisor’s health survey research project. The data consists of coded survey responses, and the advisor will retain a key that would link the data to identifiers. The student will extract the information she needs for her project without including any identifying information and without retaining the code. The use of the data does constitute research with human subjects because the initial data set is identifiable (albeit through a coding system); however, it would qualify for exempt status.

**D. When is the secondary use of existing data non-exempt?**

If secondary analysis of existing data *does* involve research with human subjects and does not qualify for exempt status as explained above, the project must be reviewed either through expedited procedures or by a full (convened) Board, and a non-exempt eProtocol application must be submitted for CPHS review.

**Consent:** Researchers using data previously collected under another study should consider whether the currently proposed research is a “compatible use” with what subjects agreed to in the original consent form. For non-exempt projects, a consent process description or justification for a waiver must be included in the research protocol. CPHS may require that informed consent for secondary analysis be obtained from subjects whose data will be accessed. Alternatively, CPHS can consider a request for a waiver of one or more elements of informed consent under 45 CFR 46.116(d). In order to approve such waiver, the CPHS must first be satisfied that the research:

1. presents minimal risk (no risks of harm, considering probability and magnitude, greater than those ordinarily encountered in daily life or during the performance of routine examinations or tests); and
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
3. the research could not practicably be carried out without the waiver or alteration; and
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

See [CPHS Informed Consent Guidelines](#) for more details regarding informed consent and waivers.

**“Restricted Use Data”:** Certain agencies and research organizations release files to researchers with
specific restrictions regarding their use and storage. The records frequently contain identifiers or extensive variables that combined might enable identification, even though this is not the intent of the researcher. Research using these data sets most often requires non-exempt level review.

**Examples:**

1) Student C will be given access to coded mental health assessments from his faculty advisor’s research project. The student plans to analyze the data with a code attached to each record, and the advisor will retain a key to the code that would link the data to identifiers. The use of the data does constitute research with human subjects and does not qualify for exempt status since subjects can be identified. This student project would require an application to be submitted for non-exempt review by the CPHS. **Note:** As previously noted, if the student’s work fits within the scope of the initial protocol from which the dataset originates, the faculty advisor (or investigator who holds the dataset) may wish to consider adding the student and his/her work to the original protocol by means of an amendment application rather than having the student submit a new application for non-exempt review.

2) Student D is applying to the National Center for Health Statistics for use of data from the National Health and Nutrition Examination Survey that includes geographic identifiers and date of examination. The analysis of this restricted use data would require non-exempt review by CPHS.