OFFICE *of* RESEARCH & GRADUATE STUDIES

IRB Guidance for Secondary Data Analysis

Secondary data analysis involves the use of existing data that was originally collected for different purposes in order to answer a research question. Some projects involving existing data sets do not meet the definition of human subjects research requiring IRB review. Other types of secondary data analyses do meet the definition of human subjects research and must be submitted to the IRB for either an Exempt determination, or IRB review (either Expedited or Full Board). Secondary data analysis requires IRB review when the data is identifiable. When IRB review is required, the level of review depends on how identifiable data is managed and how much risk is involved.

Secondary Data Analysis that is Not Regulated Research (NRR)

Secondary data analysis involving the use of existing data about living individuals does not meet the federal definition of human subjects research when the information in the data set is **not individually identifiable** (i.e., the identity of the subject is not and may not be readily be ascertained by the investigator or associated with the information). In other words, secondary data analysis does not require IRB review if the dataset is **completely de-identified** when the investigator accesses it for research purposes, and there is **no way of linking the data back to the subjects** (either through a key to a coding system or other means).

Secondary Data Analysis that is Eligible for Exempt Status

The federal regulations identify specific types of research that are considered Exempt from IRB review. It is important to understand that the Exempt research must still be submitted to the UIW IRB to confirm its Exempt status – per UIW policy, investigators may not make this determination themselves.

Secondary research use of **identifiable private information** or **identifiable biospecimens** for which consent is not required is eligible for exempt determination if at least **ONE** of the following conditions is met:

- The identifiable private information or identifiable biospecimens are **publicly available**, or
- Information is **recorded by the investigator** in an **unidentifiable manner**, and the investigator does not contact and will not re-identify the subjects, or
- The investigator's use is regulated under HIPAA as "health care operations," "research," or "public health", or
- Research is conducted by, or on behalf of, a Federal agency using information collected or generated by the government for non research purposes, and the information is protected by federal privacy standards.

Investigators conducting research that meets one of the conditions listed above must submit an application to the UIW IRB and identify the research as "Exempt" on the application form. The Research Protocol must specifically describe how the research meets the criteria for Exempt status described in this manual.

Secondary Data Analysis that is Eligible for Expedited Review

If secondary data analysis of data about human subjects does not qualify for Exempt status, the project may be eligible for Expedited IRB review. More specifically, nonexempt research involving materials (data,

documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis), is eligible for Expedited review **IF** it presents **no more than minimal risk** to the subjects. The regulatory definition of minimal risk is: the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. If the research presents more than minimal risk to subjects, Full Board review is required.