ORARC Tip Sheet:
PRIMARY COLLECTION VS. SECONDARY USE

Purpose:

The purpose of this tip sheet is to differentiate between primary collection and secondary use of information and/or biospecimens. While not defined in the regulations, per se, this tip sheet provides guidance on the difference between primary vs. secondary.

Definitions:

Primary refers to information and/or biospecimens collected firsthand, directly from the original source/participant, by the research staff of the research study.

Secondary is described in the Final Rule preamble[1] as "re-using…information and…biospecimens that are collected for some other 'primary' or 'initial' activity." Typically, secondary refers to information and/or biospecimens that have been previously collected by others and will be re-used for an entirely new research purpose/question/hypothesis.

Case Examples:

- **Case 1:** A researcher wants to conduct a sleep study of college students. The researcher interviews students about their sleep habits, collects survey data from them about sleep quality, and collects sleep tracking information from their FitBit. This is primary data collection because all of the data about participants is collected directly by the researcher and is original to the proposed research study.
- **Case 2:** A researcher accesses patient medical records to collect data about their kidney function and dialysis drug usage. This is secondary data use because all of the information that will be used in the study has or will be collected as part of routine clinical care and the researcher will not collect additional, original information from the participant.
- **Case 3:** A researcher will obtain cancerous brain and lung tissue specimens from a commercial biorepository. The researcher plans to study the cell structure of such tissues and compare their findings to the current literature. This is secondary use because all of the specimens that will be used in the study are available in a biobank for secondary use.
- **Case 4:** A researcher collected program evaluation data as part of an institutional quality improvement project in 2015. At that time, the outcomes of the project were not generalizable beyond the researcher's institution and thus, the project did not meet the regulatory definition of research. The researcher has developed a new, generalizable hypothesis about the program and now wants to use that same data set for generalizable purposes. This is secondary data use because no new information will be collected from participants and the data will be used for a new study with a different aim/purpose.

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[1] https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects