ASU IRB Guidance for Human Subjects Research Involving Secondary Data

What is secondary research?

- Secondary research refers to research using archival data or data that has already been collected by someone else. This type of research could also involve records, information or biospecimens that were collected for non-research purposes, such as materials that are left over from routine clinical diagnosis or treatments. [Refer to 45 CFR 46.116(d) of the revised Common Rule.]

When is secondary research considered human subjects research?

- The answer to this depends on the types of data that are being requested, how those data were obtained, how it is being accessed, and how it is being used. Secondary data must already be in existence at the time of submission. **To protect researchers, the ASU IRB reviews all protocols involving the use of secondary data at individual level that include the intent to generalize knowledge from living individuals.**
    - Individual vs. aggregate (group) level data:
        - If your analysis involves **individual student educational records or individual patient records**, then you are conducting secondary data analysis of records on an individual level. IRB review is required.
        - If your analysis involves data only in **aggregate form**, such as unemployment rates or infant mortality rates, then IRB review is not required.

Types of data	**Considerations**
Publicly available data: Information that can be freely used, reused and redistributed by anyone with no restrictions on access or usage.	In the IRB protocol, include the website or otherwise detail how the data are publicly available.
De-identified data: All identifiable information has been removed prior to ASU receiving it.	How were the data originally obtained? Who owns the data and permission(s) needed to access de-identified data
Restricted use data: Contains sensitive information or information that enables the potential identification of respondents through inference. Data may also be restricted due to confidentially promises or for proprietary reasons.	A Data Use Agreement (DUA) may be required whenever human subject data are being sent or received between ASU and an Outside Party. For questions on DUAs, contact ORSPA: https://researchadmin.asu.edu/agreements.
Coded private data: Existing human subjects data previously collected for a separate purpose whereby an external partner maintains a key linking identifying information to the private information or specimens but the current investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain.	May not require IRB review. For more information visit: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html.

Researchers who are unsure whether their project requires IRB review should contact ORIA at research.integrity@asu.edu for consultation. **v1_08072020**