Knowledge Enterprise Development	Page 1 of 2	
ARIZONA STATE UNIVERSITY	PREPARED BY: Richard Gilmour	APPROVED BY: Kristy Macdonald
DOCUMENT TITLE: ASU IRB Guidance for Human Subjects Research Involving Secondary Data	DEPARTMENT: Research Compliance	EFFECTIVE DATE: 08/27/2025

ASU IRB Guidance for Human Subjects Research Involving Secondary Data

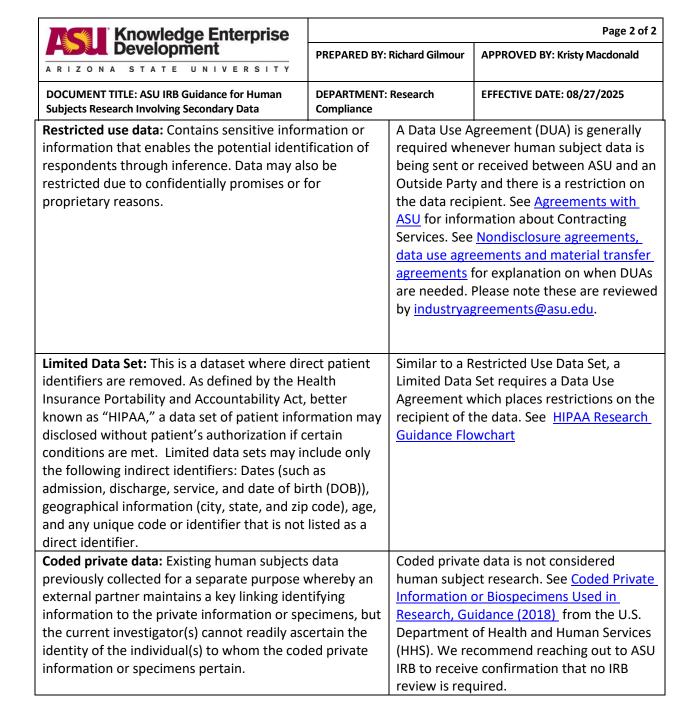
What is secondary research?

 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.
 - o Individual vs. aggregate (group) level data:
 - If your analysis involves <u>individual student educational records or individual patient</u> <u>records</u>, then you are conducting secondary data analysis of records on an individual level. IRB review is required.
 - If your analysis involves data only in <u>aggregate form</u>, such as unemployment rates or infant mortality rates, then IRB review is not required. This means not at the individual level.

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.	Research involving secondary human subjects data that are publicly available are eligible for the IRB exempt wizard. This type of data is generally available on a website with no restriction on who can access the data. (No data provider application process with restrictions on data use.)
De-identified data: All identifiable information has been removed prior to ASU receiving it. Data is de-identified when any direct or indirect identifiers linking the data to the subject's identity have been destroyed, or if received from another researcher, the link to re-identify is not disclosed to the receiving researcher.	How were the data originally obtained? Who owns the data and permission(s) needed to access de-identified data? When data is de-identified but not publicly available, the IRB application should explain the data provider's requirements to access the data.
Anonymous data: Anonymous data is data where at the time of the data collection neither the researcher nor a third party can connect the data to the research participant.	Is the data actually anonymous? Are there any direct identifiers such as IP address or a worker ID #? In online studies, often a third party such as Prolific or Qualtrics will have assigned a participant a worker ID # which is linked to the participant's identity. The participant's identity is not known by the researcher however it is known to the third party and should not be described as anonymous.



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