ASU IRB Guidance for Human Subjects Research (HSR) Involving Secondary Data II

Preparing the IRB Submission

Purpose

This guidance document provides some general recommendations to consider when preparing the IRB submission for review.

IRB Exempt Wizard Submissions

Some Human Subjects Research (HSR) studies involving secondary data are IRB Wizard eligible.

- The eligibility criteria can be found at: IRB exempt wizard.
- Research involves use of secondary human subjects data that are publicly available may be eligible.

Standard IRB Submissions

HSR projects involving Secondary Data IRB submission generally consists of a filled-out IRB protocol form and supporting documentation as required.

- Recruitment and consent materials are not required.
    - These are required for primary data collection.

The IRB Protocol

- There is no dedicated secondary data IRB protocol form.
- As a result, not every section of the protocol form is relevant for secondary data analysis.
    - For example, the IRB protocol includes a section on ‘Recruitment Methods.’
        - In secondary data research there will not be recruitment of participants. As mentioned above, this is applicable for primary research.
        - Therefore, stating ‘Not Applicable’ is an appropriate response or researchers can clarify the context under which participants were recruited.

- As is the case when there is primary data collection, the ‘Study Procedures’ section is a key section to outline the planned study.

- As stated in the form, "For secondary data analyses, identify if it is a public dataset (please include a weblink where the data will be accessed from, if applicable). If not, describe the contents of the dataset, how it will be accessed.
  - **Content of the dataset:** This part of the protocol should provide a clear description of the variables of the dataset.
    - If there is a date range, include that information. For example, in education studies, standardized testing data from a school year or multiple school years may be accessed from the Arizona Department of Education. The specific years accessed would be explained.
  - **Characteristics of the dataset**: Explain whether the dataset is de-identified. If identifiers are included explain what identifiers are included in the data. Explain if data is aggregated or on the individual level.
    - Limited Data Set: This is a dataset where facial identifiers are removed. A limited dataset may include such information as date of birth, zip code. See Definition of Limited Data Set.
    - Restricted Data Set: This is a dataset which contains data that cannot be released directly to the public research community due to possible risk(s) to study participants as well as the confidentiality promised to them. See Access to Restricted Data.
  - How will data be accessed: Explain how data will be transferred to ASU. If there is an associate agreement, this description should be consistent with the terms of the agreement.
  - Data Analysis: Explain what the data analysis consists of. If there will be linking of data from different sources explain.

- In the 'Privacy and Confidentiality' Section it is explained how data provided to the study team will be protected at ASU.
  - Explain who will have access to the data.
    - Who has access to the data should be consistent in the protocol with who is identified any agreement with the data provider.
  - Explain where, how, and how long data will be stored.
    - If a specific storage solution is not required by the data provider, use the Research Data Storage Selector to select an appropriate storage solution.
    - If specific storage requirements are required by the data provider, explain those requirements.
    - It should be clear how long data will be stored. Most agreements have a specific term, and this should be described in the IRB protocol.
    - A data use agreement may have specific requirements with respect to the destruction of data after completion of a project. For example, for sensitive data, a Certificate of Destruction may be required. This should always be consistent with the agreement with the data provider.
  - Data Use Agreement Additional Terms

- A common requirement is notification to the data provider if there is a data breach at ASU. If there are additional duties placed on the study team, that should be explained.
- Another common requirement is providing a copy of the research publication prior to publication.

Supporting Documents

- The supporting documents included in the submission will depend on the study and the data being accessed. Some human subject research studies with secondary data require no supporting materials. Other studies will include a data use agreement (DUA), an application to the data provider, and a confidentiality agreement signed by team members prior to accessing the data. The data provider will determine requirements to access the data.
  - For information regarding different types of agreements and when they are required. See Nondisclosure agreements, data use agreements and material transfer agreements.
  - See decision trees to determine whether a DUA is required at Sharing or Acquiring Research Data.
- If a DUA is required to access the data, the agreement will need to be reviewed by IAG (industryagreements@asu.edu).
  - IAG review contract terms on behalf of ASU to confirm contract terms are acceptable to ASU.
  - After the contract review, IAG reach out to ASU IRB to confirm terms are consistent with the IRB protocol. See Agreements with ASU.
  - While this review is part of the IRB submission, there may be separate questions. IAG may also advise if an agreement is needed and who the appropriate signatory is.
- On the timing of the IRB submission, this is generally dependent on the data provider.
  - Some data providers require IRB documentation prior to agreeing to provide the data (for example as part of an application) and in this case language is included in the IRB protocol explaining that the executed DUA will be added via modification.
  - Other data providers do not require IRB approval, and the DUA is included as part of the initial submission.
- Make sure to include the DUA # assigned by IAG as part of the submission. This assists the IRB reviewer in identifying the agreement and enables the reviewer to check on the progress of the contract review.

Additional Considerations

- **Arizona Department of Health Services Data Requests via the ASU Honest Broker.**
  - Knowledge Enterprise hosts health data on behalf of the Arizona Department of Health Services (ADHS) as the Honest Broker for Arizona State University (ASU)

and Northern Arizona University (NAU) faculty researchers. See Health data for additional information.
    - Prior to submitting data request.
        - ASU IRB approval is required.
        - As part of the data request, IRB information is provided (IRB #, approval date) and the IRB protocol is uploaded.
    - For questions related to the Honest Broker: contact Kathryn Claypool at kathryn.claypool@asu.edu.

- **Patient Records are subject to the Health Insurance Portability and Accountability Act (HIPAA)**
    - HIPAA provides detailed instructions for handling and protecting a patient's personal health information (PHI).
    - The presence of at least one of 18 HIPAA designated direct and indirect identifiers in a data set makes the whole data set PHI. See Health Insurance Portability and Accountability Act (HIPAA) for list of 18 identifiers.
    - When receiving PHI from a covered entity there are several options:
        - Obtain Subject Authorization. (HIPAA authorization form from individual participants.)
        - Use a Limited Data Set. (This is a data set where direct identifiers are excluded. A DUA is generally required.)
        - Obtain an IRB Waiver of Subject Authorization. (Approvals for waivers or alterations will be rare and in most cases researchers are advised to use an Authorization Form with their subjects to use/disclose PHI.)
        - Use a De-identified Data Set. (This a dataset where 18 identifiers have been removed and there is no reasonable basis to believe that information can be used to identify the individual.)
    - Resources
        - HIPAA for ASU Researchers 2025
        - HIPAA FAQ
        - What is a HIPAA Covered Entity?
        - What is PHI under HIPAA Rules? When is PHI not PHI?

- **Additional Resources.**
    - Federal Demonstration Partnership (FDP) Templates and Tools