Data-only Protocol Template[1]

Preliminary guidance for consideration:

1. Is this the right protocol template to use?

This protocol template should only be submitted for projects that are data-only and defined as human research. If your **ONLY** research procedure is **analysis of data** and you are not planning to prospectively collect additional information solely for research purposes, this is the appropriate protocol template to use.

If your study involves additional procedures other than data analysis such as surveys, interviews, **do NOT use this protocol template** -- use the appropriate IRB approved protocol template.

2. Are the data identifiable?

If your project **solely** involves analyzing **de-identified** data, and is not part of a larger-scope project that is human research, you do not need IRB review to analyze de-identified data. If you need the IRB to issue a formal determination that analysis of de-identified data does not constitute human research, contact your IRB for the process of submitting research that does not meet the definition of human research.

In general, research data are considered identifiable when the information can be linked to specific individuals by the researcher either **directly or indirectly through coding systems**, or when characteristics of the information obtained are such that a reasonably knowledgeable person could ascertain the identities of individuals. Keep in mind that, even though a dataset has been stripped of direct identifiers (e.g., names, addresses, student ID numbers, etc.), it may still be possible to identify an individual through a combination of other characteristics (e.g., age, gender, ethnicity, place of employment). For further detail on when data are considered to be de-identified, see HHS Office of Human Research Protections Guidance on Research using Coded Data and Specimens. If you are unsure whether the data you plan to analyze would be considered de-identified for IRB purposes, please contact the IRB.

3. What if the data provider insists on an IRB exemption or approval?

Some data providers will not release a dataset for analysis unless you provide an IRB letter showing that you have an exemption or IRB approval; for example, if you wish to access a restricted use dataset from ICPSR, ICPSR will require an IRB exemption or approval. In that situation, the IRB will review your study even if the data do seem to be de-identified.

[Remove this page before submitting the research protocol to the IRB.]

[1] This template is a version of the Data and Specimen Protocol found on the Northwestern University IRB website (https://www.irb.northwestern.edu/templates-forms-sops/) It has been edited to be specific to data-only projects and to remove the references to biologic specimens.

[On the template, read the guidance for each section first. Retain the outline (each section in bold) but remove everything in red before providing your project specific narrative.]

1. **Protocol Title: (include full study title)**

2. **Version Date: (today's date)**

3. **Study Team:**

   Principal Investigator:
   Name
   Department

   Student Investigator [if applicable]:
   Name
   Department

4. **Study Purpose** (brief, no more than 500 words)**:**
   - Describe the problem to be explored. What are the research questions or hypotheses?
   - How is the study intended to be generalizable beyond the specific context in which the data were collected?
   - What is the ultimate intended purpose and audience(s) for the results of the study?

5. **Inclusion/Exclusion Criteria:**

   Describe the population characteristics that will determine which data will be analyzed for this study (e.g., geography, specific age range, race or ethnicity (if applicable), gender, data collected from vulnerable populations, etc.). Specify the age range of individuals from whom the data were collected and whether any of the data were collected from any individuals under 18 years old.

6. **Type of Data Involved:**

   Study type: Indicate if this study involves **1) retrospective, 2) prospective, or 3) BOTH retrospective and prospective data. NOTE:** if you plan to collect or access additional data prospectively solely for research purposes as part of this study do not use this template.

   ☐ Retrospective Review (The data already exist at the time this study is submitted for initial IRB review.) Data range: _____

   ☐ Prospective Review (The data do not exist when this study is submitted to the IRB for initial review.) Data range: _____

   ☐ BOTH Retrospective and Prospective Review. Data range: _____

7. Characteristics of Data to be Analyzed:

- What data sets do you plan to analyze, who will provide you with the data, and who originally collected the data?
- If using data that were collected internationally, specify where and indicate any relevant local or country regulations that may apply. If the General Data Protection Regulation of the European Economic Area apply, ensure the data producer has met the GDPR requirements. An IRB in the US may not waive GDPR requirements.
- Explain whether the data were collected in a previous research study, collected as part of a government program or as part of an organization's standard operations, or for other purposes. If the data were originally collected as part of a research study that was reviewed by this IRB, provide the IRB study number(s) assigned to the previous study.
- If you are accessing data from a data repository, specify the repository that will be providing the data and any repository specific requirements.
- Provide URLs to descriptions of the data sets if available. If you plan to analyze multiple data sets, describe each data set separately and explain who holds each data set. If you already have access to the data for purposes other than this research study (e.g., to conduct your work responsibilities), explain how you already have access to the data.
- Describe whether use of the data requires any special permissions, restrictions, and/or agreements (e.g., a data use agreement (DUA) or data transfer agreement (DTA)). If there is a DUA, DTA, or other type of agreement, upload the agreement as a supporting document with the IRB application.

  NOTE: Data providers often require that the researcher enter into a data sharing agreement or other type of agreement setting forth data security requirements and associated non-disclosure agreements. In all of these cases, **principal investigators must determine whether they have the capability to meet the data security requirements.** If you need assistance with compliance with any data security measures, please contact your institutional IT office for support.

  Researchers may not sign a DUA, DTA, or other agreement on behalf of the University. The agreement must be submitted to the appropriate university office for review of the document and signature.

- Are any identifiers associated with the data? If so, please list the specific identifiers that are included (e.g., names, phone numbers, residential addresses, social security numbers, etc.). You can upload a separate list of the identifiers as a supporting document with the IRB application if preferred.
- If the data have identifiers associated with them now, but the identifiers will be removed prior to starting your analysis, answer the following questions: who will de-identify the data? Is that person a study team member or going to be collaborating on this study in any way?
- Are the data linked to an individual participant by a code? If yes, will anyone on the research team have access to the key linking the codes to individuals? If the research team will have access to the key, where will the key linking the codes to identifiers be stored?

8. Access, Security, And Management:

- Where and how will you access, transmit, and store the data? Describe whether the data provider places any restrictions on how the data can be accessed and where the data can be stored. Identify whether the data will be accessed at a repository, data enclave, or whether the data will be transferred to your custody.

- What will you do with the data when your analysis is complete? If the data will be destroyed at the completion of this study, explain the planned method for destruction.

- Describe whether there are plans to store any of the data long-term or to deposit the data in a databank/repository/registry. If yes, for what purposes and where will the data be stored?

- Describe any other information relevant to how you will protect the confidentiality of the data.

9. Potential Risks:

Discuss possible risks (both the probability of the harm and the magnitude of the harm) that could occur in the case of a breach of confidentiality (social, economic, legal, reputational, or other possible harms to individuals or a community/group).

10. Potential Benefits of this Project:

Briefly discuss potential benefits of this project to society. This is typically directly related to the purpose of the study.

11. Informed Consent / Waiver of Informed Consent:

When applicable, explain whether consent was obtained from the participants in the original study or program in which the data were collected. (Not all types of data require consent in order to be collected (e.g., some types of government data and private sector data).

If you wish to request a waiver of informed consent for this research, please explain below why your request meets all of the following regulatory criteria:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the individuals whose data you are analyzing;
3. The research could not practicably be carried out without a waiver of consent;
4. If the research involves analyzing identifiable private information, the research could not practicably be carried out without using information in an identifiable format; **and**

5. Whenever appropriate, the participants will be provided with additional information about their participation in the research (most often not necessary for secondary data analysis projects).
6. For informed consent language specific to data sharing, the Inter-university Consortium for Political and Social Research (ICPSR) has [examples](https://www.icpsr.umich.edu/web/pages/datamanagement/confidentiality/conf-language.html) of model language, language to avoid, and known concerns and recommended alternatives.

NOTE: Educational records are protected by the **FERPA** law. Under the FERPA law and regulations, the general rule is that consent must be obtained from the parent or student (from the student at the University level) for access to personally identifiable information contained in student education records. The IRB cannot waive consent for research access to personally identifiable information contained in student educational records, unless the information to be analyzed consists of "directory information" or the project falls under an exception to [FERPA's consent requirement] (https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html). For research projects that seek to access student education records held by other institutions (including other universities and K–12 schools), you will need to verify with the institution holding the data that appropriate steps are in place to ensure FERPA compliance.

12. HIPAA Authorization and Waiver of HIPAA Authorization (if applicable):

Review the following for research studies that involve analysis of medical record data. If the data are protected health information (PHI) under HIPAA and were collected before this current research study, the IRB (if serving as the HIPAA Privacy Board) or the HIPAA Privacy Board will consider whether to waive the requirement for HIPAA Authorization.

If you wish to request a waiver of HIPAA Authorization for this research, please explain below why your request meets all the following criteria:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

   (1) an adequate plan to protect the identifiers from improper use and disclosure;
   (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
   (3) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the HIPAA Privacy Rule;
2. The research could not practicably be conducted without the waiver or alteration; **and**
3. The research could not practicably be conducted without access to and use of the protected health information.

NOTE: analysis of mental health information is generally covered by state law. Verify whether your state law will permit a waiver of HIPAA for mental health records, as some will not.