**Deciding whether this is the right form for you to use:**

If your **ONLY** research procedure is **analysis of data or specimens** and you are not planning to prospectively collect biospecimens solely for research purposes, this is the appropriate protocol template to use. (For example, medical record review, you plan to analyze data or biospecimens that were collected in prior research studies or data that are available from student education records, government datasets, etc.)

If your study involves procedures **other than data/specimen analysis (e.g., surveys, interviews, collection of biospecimens), do NOT use this protocol template** -- use the appropriate protocol template on the IRB website at <https://irb.northwestern.edu/templates-forms/templates-forms-sops>.

If your project is not research with human subjects (or you are not entirely sure whether your project is human subjects research), submit the Human Research Determination Form (HRP-503) instead of this form. This form should only be submitted for projects that are research with human subjects (see below on this page for discussion of when analysis of data/specimens requires IRB review).

**Are the data/specimens identifiable? If the data/specimens are de-identified, do not use this protocol template.**

If your project **solely** involves analyzing **de-identified** data and/or specimens, and is not part of a larger-scope project that is human subjects research, you do not need IRB review to analyze de-identified data/specimens. If you need the IRB to issue a formal determination that analysis of de-identified data/specimens does not constitute research with human subjects, upload the Human Research Determination Form (HRP-503) in the eIRB+ application.

In general, data/specimens are considered to be identifiable when the data/specimens 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 and specimens are considered to be de-identified, see [HHS Office of Human Research Protections Guidance on Research using Coded Data and Specimens](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html). If you are unsure whether the data/specimens you plan to analyze would be considered de-identified for IRB purposes, please contact the IRB.

**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 those situations, the IRB will review your study even if the data do seem to be de-identified.

**The protocol template begins below the red line – please provide all the information requested below and upload your completed protocol to the electronic application in eIRB+ in the “Basic Information” section of the electronic application form, Question 8 (where it says “Attach the protocol”). Please make sure all study team members have up-to-date human subjects training – further information on human subjects protection training is available at:** <https://www.irb.northwestern.edu/training-education/> **==============================================================================**

1. **PROTOCOL TITLE: (include full study title)**
2. **VERSION DATE: (MM/DD/YYYY)**
3. **NU RESEARCH TEAM**

**PRINCIPAL INVESTIGATOR:**

Name

Department

**STUDENT INVESTIGATOR** [if applicable]:  
 Name

Department

1. **STUDY PURPOSE:**

* Describe the problem/condition 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/specimens were collected?
* What is the ultimate intended purpose and audience(s) for the results of the study?

1. **INCLUSION/EXCLUSION CRITERIA**

Describe the population characteristics that will determine which data/specimens you analyze for this study (e.g., diagnosis with certain medical conditions/diseases, specific age range, gender, data collected from prisoners, and/or pregnant women etc.) Specify the age range of individuals from whom the data/specimens were collected and whether any of the data/specimens were collected from any individuals under 18 years old.

1. **PROCEDURES INVOLVED**

**Study type: Indicate if this study is 1) retrospective; 2) prospective; or 3) BOTH retrospective and prospective.**

**NOTE:** if you plan to collect biospecimens prospectively solely for research purposes as part of this study (e.g., through biopsies), then you cannot use this template.

**Retrospective Review** (the data and/or specimens already exist at the time this study is submitted for initial IRB review)

**Date Range of data/specimens to be reviewed:**

**Prospective Review** (the data and/or specimens do not exist when this study is submitted to the IRB for initial review – for specimens, you can use this template only if the specimens are being collected for non-research purposes such as medical treatment/diagnosis)

**BOTH Retrospective and Prospective Review**

**Date Range of data/specimens to be reviewed:**

1. **CHARACTERISTICS OF DATA/SPECIMENS TO BE ANALYZED**

* What datasets/specimens do you plan to analyze, who will provide you with the data/specimens, and who originally collected the data/specimens? List the specific data elements that will be collected or, if preferred, you may attach the list of specific data elements as an appendix to this protocol. Note: The HIPAA Privacy Rule allows a covered entity to de-identify data by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members – for further detail on what elements must be removed to de-identify information under HIPAA, see <https://privacyruleandresearch.nih.gov/pr_08.asp>
* Explain if the data/specimens 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/specimens were originally collected as part of a research study that was reviewed by the Northwestern University IRB, provide the NU IRB study number(s) [that is, the STU number(s)] assigned to the previous study. If you are accessing specimens from a biobank/biorepository, specify which biobank/biorepository will be providing the specimens.
* Provide internet links to descriptions of the datasets if available. If you plan to analyze multiple datasets, describe each dataset separately and explain who holds each dataset. If you already have access to the data/specimens for purposes other than this research study (e.g., to carry out your work responsibilities), explain why you already have access to the data.
* Describe whether use of the data/specimens requires any special permissions, restrictions, and/or agreements (e.g., a data use agreement (DUA), data transfer agreement (DTA), or material transfer agreement (MTA)). If there is a DUA, DTA, MTA or other type of agreement, upload the agreement in Supporting Documents in the eIRB+ 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 if they have the capability to meet the data security requirements** – if you need assistance with compliance with data security requirements, please contact NU Information Technology.

**Researchers cannot sign a DUA, DTA, or MTA on behalf of the University** – the agreement must be submitted to the NU Office of Sponsored Research for review and signature (see <https://osr.northwestern.edu/agreements/dua> and <https://osr.northwestern.edu/agreements/mta>).

* Are any identifiers associated with the data/specimens? 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 separate appendix to this protocol, if easier.
* If the data/specimens have identifiers associated with them now, but identifiers will be removed prior to starting your analysis: who did or will de-identify the data/specimens? Is that person going to be collaborating on this study in any way?
* Are the data/specimens linked to an individual 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?

1. **ACCESS, SECURITY, AND MANAGEMENT**

* Where and how will you access, transmit, and store the data/specimens? Describe if the data provider places any restrictions on how the data can be accessed and where the data can be stored.
* What will you do with the data/specimens when your analysis is complete? If the data/specimens will be destroyed at the completion of this study, explain the planned method for destruction.
* Describe if there are plans to store any of the data/specimens long-term or deposit the data/specimens in a databank/biobank/registry. If yes, for what purposes, and where will the data/specimens be stored if being kept long-term?
* Describe any other information relevant to how you will protect the confidentiality of the data/specimens.

1. **POTENTIAL RISKS**

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

1. **POTENTIAL BENEFITS OF THIS PROJECT**

Discuss potential benefits of this project to society.

1. **INFORMED CONSENT AND WAIVER OF CONSENT**

* When applicable, explain if consent was obtained from the participants in the original study/program in which the data/specimens 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 the following criteria:

* The research involves no more than minimal risk to the subjects;
* The waiver or alteration will not adversely affect the rights and welfare of the individuals whose data you are analyzing;
* The research could not practicably be carried out without a waiver of consent;
* If the research involves analyzing identifiable private information, the research could not practicably be carried out without using information in an identifiable format; **and**
* Whenever appropriate, the subjects will be provided with additional information about their participation in the research (most often not necessary for secondary data analysis projects).
* NOTE regarding **student educational records** 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 (at the University level, from the student) 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. For Northwestern University student records, directory information is defined at: <https://www.registrar.northwestern.edu/records/student-information-privacy/privacy-policy-ferpa.html>. If you wish to access Northwestern University student education records for analysis and are unsure whether you must obtain student consent to access those records for research purposes, please contact the NU Registrar’s Office. For research projects that wish 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.

1. **HIPAA AUTHORIZATION AND WAIVER OF AUTHORIZATION**

For research studies that involve analysis of **medical record data held by Northwestern Memorial Health Care or other Northwestern affiliates**: if the data are protected health information (PHI) under HIPAA and were collected before this current research study, the IRB (serving as 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 the following criteria:

* 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;
* The research could not practicably be conducted without the waiver or alteration; **and**
* The research could not practicably be conducted without access to and use of the protected health information.

NOTE regarding analysis of **mental health and developmental disabilities information**:

Under the Illinois Mental Health and Developmental Disabilities Confidentiality Act (IMHDDCA), if you plan to access mental health information or “all medical records” for analysis, you **must** have both the research participant and a witness sign the consent form. **A waiver of HIPAA authorization cannot be granted if your research project will access records to obtain information involving mental health or developmental disabilities services.**   The IMHDDCA applies to records of mental health and developmental disability services that are kept by a therapist or by an agency providing such services.  The term therapist is very broad and includes: psychiatrist, doctor, psychologist, social worker, nurse, mental health therapist, mental health counselor, or other person who provides services of this type. Records involving mental health or developmental disabilities services include documents relating to physical or mental examinations; diagnosis, treatment or training; evaluations; medications; aftercare, habilitation and rehabilitation, and notes about services provided (but not a reference to receipt of mental health or developmental disabilities services noted during a patient history, physical, or other summary of care).