

SECONDARY RESEARCH WITH DATA OR BIOSPECIMENS RESEARCH PROTOCOL TEMPLATE

15.303 (HRP-503c)

DO NOT INCLUDE INSTRUCTIONS PAGE WITH YOUR SUBMISSION

This template should be used by biomedical and social behavioral investigators proposing secondary research with data—which may include written text, images or audio-/visual-recordings—or biospecimens that were or will be collected for other purposes. Examples of types of research for which this protocol template is applicable include research plans proposing to obtain, use, study or analyze:

- (a) Data that is or will be archived in medical records, student records, data repositories, restricted or public data sets, or investigator-held data sets from previous primary research; and/or
- (b) Biospecimens that are or will be archived in hospitals or clinics, Biospecimen research repositories, other restricted-access archives or publicly available.



NOTE: If the researcher plans to contact, identify or re-identify individuals from whom data or biospecimens derive or conduct tests or merge data sets that may generate identifiable information, use instead the Non-Interventional Protocol Template.

Note: If the research is conducted, supported or otherwise subject to regulation by any Federal Department or agency, such as Depts. of Defense, Energy, Justice, Education or the Environmental Protection Agency, additional protocol plans may be required. Go to Toolkit 1.003 (HRP-103A) Appendices to learn more.

INSTRUCTIONS:

- ✓ **[BLUE]** highlighted text guides you to construct a protocol for your research so that the IRB can better understand what you are doing.
- ✓ **[RED]** highlighted text tells you when additional supporting documents must be uploaded to eIRB+.
- ✓ If a Section of the protocol does not apply to your proposed study, keep the Section heading but replace the text that appears beneath it with “Not Applicable”, or “N/A”.
- ✓ **Delete** all instructional text highlighted in **[BLUE]** and **[RED]** prior to uploading the protocol to eIRB+.
- ✓ **Do not include this instruction page with your submission.**

Need Help?

Visit the Human Research Protection Program (HRPP) website <https://go.rutgers.edu/HRPP-Toolkit> to obtain referenced Toolkit Forms & Templates and <https://go.rutgers.edu/HRPP-Guidance> to obtain referenced Guidance documents. Contact your IRB Office at <https://go.rutgers.edu/ContactUs> if you need further assistance.

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STUDY INFORMATION

- **Title of Project:**
[Add Protocol Title]
- **Principal Investigator Name:**
[Add PI Full Name and Credentials]
- **Principal Investigator Div. & Dept.:**
[Add Division & Department]
- **Principal Investigator Contact Info:**
[Add PI Work Email]
[Work Address]
[Work Phone Number]
- **Protocol Version:**
[Update the version date that appears in the footer]

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1.0 Research Design

1.1 Purpose/Specific Aims

Clearly state the overall purpose of this study.

A. Objectives: Outline specifically what will be achieved by the study.

B. Hypotheses / Research Question(s): Describe underlying reasons/motivations for this project specific to the topic and/or populations being studied. OR express any scientific hypotheses that are testable and that include measurable outcomes/endpoints that correspond directly to the objective(s).

1.2 Research Significance

Provide the scholarly or scientific background rationale and significance of the research based on the existing literature and how it will add to existing knowledge. [Be brief. Limit your narrative to 500 words or less.]

1.3 Research Design and Methods

Describe how you will accomplish the aims and objectives of the proposed secondary research, and the means by which the data and/or biospecimens will be obtained. [Secondary research means that the data and/or biospecimens to be obtained, used, studied or analyzed were or will be collected for purposes other than what is proposed in this protocol.]

A. Study Duration: Specify the overall duration of the study.

1.4 Secondary Data Collection

If you plan to obtain, use or analyze data—which may include written text, images or audio/visual-recordings—provide the following details: If this section does not apply, keep this heading but delete all of the sub-headings and text that appear beneath it and replace with N/A.

A. Source and Context of Original Primary Collection: Specify the entity from where you will obtain the data—such as Hospital A medical records, Clinic B Radiology images, Dept. X student records, Investigator at Institution Z, Public or Privately-held Database or Repository*, etc. Specify also what permissions you must obtain in order to access or obtain the existing data (e.g. Data Use Agreement), as well as, the context of its original collection from each—such as clinical care, education, research, other (specify), context unknown, etc. (*If available, consider adding online links to published information about the Database/Repository.)

a. Database Location: Specify the current location of the existing database(s) (such as in Medical Records—Logician, Epic, or Sunrise, etc., Rutgers Dept. X student records, CMS Database, Private Company B, Research Repository ABC, etc.) and what permissions you must obtain in order to access it.

b. Prior Consent Considerations: If a subject's consent governs the secondary use of the data, please state that here and explain the plan on how you will ensure that subjects' expressed wishes prevail.

B. Format and Number of Records: Describe the format of records that will be accessed (paper, digital, image (specify), audio- and/or visual recording) and the number of records you will obtain.

C. Date Range: Provide a date range of when the data were or will be collected for the original (primary) purpose of its collection.

- D. Inclusion/Exclusion Criteria:** Explain the parameters you will use to select records and where you will review these records to abstract data.
- E. Data Abstraction Form(s):** Upload a data abstraction form reflecting all of the data elements you plan to abstract from each database, including identifiers, if applicable. See Toolkit 6.205 (HRP-330) HIPAA Authorization for additional information. The data you propose to collect must be relevant to the aims & objectives of the research and the minimum necessary to accomplish it. If applicable, explain when and how identifiers will be removed from the data collected.
- F. Sample Size Justification:** Scientifically justify the types and amount of data you propose to obtain for the secondary research.
- G. Data Analysis:** Describe the data analysis plan. Include any statistical procedures and power analysis, if applicable to the research.
- H. Data Management:** Describe how data will be handled study-wide:
- a. **Access**
 - i. Who will have access to the data?
 - ii. Who is responsible for receipt or transmission of the data?
 - b. **Storage**
 - i. Where, how and for how long data will be stored?
 - ii. How will you transport, manage and store the data? Identify any data storage provider you will use (e.g. RedCap, Rutgers Box.com, DropBox, Office365 OneDrive, etc. (**Note:** check with your School/Department’s data storage policies as some types of data may require additional protections, e.g. HIPAA protected data, etc.).
 - iii. Describe the steps you will take to secure the data (e.g., authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers from the data, etc., during storage, use and transmission.
 - i. **Disposition:** Detail how and by whom data will be destroyed upon study completion. [**NOTE:** If a waiver of consent is granted, identifiers should be destroyed with no possibility of re-identifying subjects, as soon as practicable after data is obtained and verified for accuracy.] If data will be stored for secondary research not yet defined, complete “**Section 7.0 Research Repository**” in this Protocol.
 - J. **Intent to Contact, Identify, Re-Identify or Generate Identifiable Information:** (If this section does not apply to your research keep the section heading but replace the text below with “Not Applicable”). If the research plans to contact, identify or re-identify individuals from whom data derive or conduct tests or merge data sets in ways that may generate identifiable information, **STOP**. Use instead Toolkit 15.302 (HRP-503b) Non-Interventional Research Protocol Template to describe your research plan.

UPLOAD to eIRB+ - the protocol, study instruments and data abstraction forms to be used in the course of the research;

UPLOAD to eIRB+ - any Data Use Agreements necessary to govern transfers of data, if applicable; AND Consent to Research Forms that govern the secondary use of data, if applicable.

1.5 Secondary Use of Biospecimens: (If this section does not apply to your research keep the section heading but replace the text below with “Not Applicable”). If you plan to obtain, use or analyze biospecimens, provide the following details:

- A. **Source and Context of Original Primary Collection:** Specify the entity or entities from where you will obtain specimens—such as Hospital X, Repository Y, Investigator at Institution Z, etc.—and the context of its original collection from each—such as clinical care, research, other (specify). Also, specify what permissions you must obtain in order to access or obtain the existing specimens (e.g. Material Transfer Agreement).
 - a. **Prior Consent Considerations:** If a subject's consent governs the secondary use of the specimens, please state that here and explain the plan on how you will ensure that the subject's wishes prevail.
- B. **Types of Number and Specimens:** List the types and estimate the number of specimens you will receive.
- C. **Date Range:** Provide a date range of when the specimens were or will be collected for the original (primary) purpose of its collection, if applicable.
- D. **Inclusion/Exclusion Criteria:** Describe the inclusion/exclusion criteria for specimen use in the secondary research.
- E. **Annotation:** List the data elements that will be annotated or associated with the specimens to be obtained, including any identifiers, if applicable. See Toolkit 6.205 (HRP-330) HIPAA Authorization for additional information.]
- F. **Sample Size Justification:** Scientifically justify the types and number of specimens you propose to obtain for the secondary research.
- G. **Data Analysis:** Describe the data analysis plan. Include any statistical procedures and power analysis, if applicable to the research.
- H. **Transport:** State how the specimens will be provided to your lab (in-person pick-up, courier, etc.). If in person, state who will transport them to the lab.
- I. **Storage:** Describe where the specimens will be stored, how they will be accessed and by whom, and how long the specimens will be stored;
- J. **Disposition:** Detail how and by whom specimens will be destroyed upon study completion. If specimens will be stored for other secondary research not yet defined, complete [Section 7.0 Research Repositories – Data or Biospecimens](#) in this protocol.
- K. **Intent to Contact, Identify, Re-Identify or Generate Identifiable Information:** (If this section does not apply to your research keep the section heading but replace the text below with “Not Applicable”). If the research plans to contact, identify or re-identify individuals from whom specimens derive or conduct tests that may generate identifiable information, **STOP**. Use instead Toolkit 15.302 (HRP-503b) Non-Interventional Protocol Template to describe your research plan.

UPLOAD to eIRB+ - the protocol;

UPLOAD to eIRB+ – Biosafety Approval and evidence of Biosafety Training AND agreement(s) (MTAs) which govern the transfer of specimens, if applicable.

2.0 Project Management

Describe the resources available to conduct research in a way that will ensure the integrity of the research and the rights and welfare of subjects:

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Protocol Title: ****Add Short Title**

Protocol Version Date: ****Add Protocol Version Date**

2.1 Research Staff Qualifications & Training

Describe the qualifications (e.g., training, experience, oversight) of study personnel. Also, describe your training plan to ensure that all study personnel are informed about the protocol, the procedures, and their duties and functions.

2.2 Resources Available

Describe other resources available to ensure proper conduct of the research (such as storage/archiving facilities, etc.)

2.3 Research Sites

List domestic and international sites.

For international sites, please complete and upload Toolkit Form 11.301 (HRP-285) Full/Expedited Studies Involving International Research or Toolkit Form 11.302 (HRP-286) Exempt Studies Involving International Research, as applicable, or call your IRB Office for guidance.

UPLOAD to eIRB+ - Site agreements such as Letters of Cooperation—when no personnel at the site are engaged in the research—or, the Sites' IRB-approval or an Institutional Authorization Agreement—when personnel at the site are engaged in the research, for International Research, upload completed Toolkit Items 11.301 (HRP-285) or 11.302 (HRP-286), as applicable.

3.0 Multi-Center Research

For cooperative research carried out at more than one institution, please contact the IRB Reliance Administrator for guidance on requirements and procedures use of a Single IRB. (Email: IRBRelianceAdmin@research.rutgers.edu).

4.0 Subject Considerations

4.1 Consent Process (Is Not Applicable to Secondary Research)

(If this section does not apply to your research keep the section heading but replace the text below with “Not Applicable”). If you plan to consent or re-consent individuals from whom data or biospecimens derive, **STOP**: Use instead Toolkit 15.302 (HRP-503b) Non-Interventional Research Protocol Template.

4.2 Waiver or Alteration of Consent Process

If you are requesting a waiver of consent, state that here. Justify your reasons why a waiver is necessary to accomplish the research. Review Toolkit 6.208 (HRP-410) Waiver or Alteration of Consent Process to learn more about what criteria must be satisfied for an IRB to permit a waiver, alteration or omission of a consent process.

4.3 Risks of Harm/Potential for Benefits to Subjects

- A. **Risks of Harm to Subjects:** List the reasonably foreseeable risks of harm to subjects should a breach of confidentiality occur as a result of loss, theft or mismanagement of data or specimens. Consider psychological, genetic, social, legal, economic, and privacy/confidentiality risks of harm.
- B. **Risks of Harm to Non-Subjects:** If applicable, describe risks of harm to others who are not subjects, such as individuals whose images appear in the background of photographs obtained for the research, etc.
- C. **Minimizing Risks of Harm:** Describe the procedures you plan to use to minimize risks of harm.

- D. Potential Benefits to Subjects:** If there are any potential direct benefits to individuals from whom data or specimens derive, describe them here. If there is no direct benefit to subjects, say that. Do not include benefits to society or others.
- E. Certificate of Confidentiality (CoC):** Certificates of Confidentiality protect research subjects' privacy interests by prohibiting disclosure of identifiable, sensitive research information to others not connected to the research except under certain conditions. If this study is NIH-funded for which a Certificate of Confidentiality is automatically issued to protect the data obtained, or if there are plans to apply for a Certificate of Confidentiality through a different grantor or at the NIH KIOSK for data collection which includes sensitive data (e.g., alcohol, drug use, sexual attitudes and behaviors, etc.), or the data to be obtained was originally collected under a CoC, indicate that here*. See HRPP Guidance: Certificates of Confidentiality for more information. [NOTE: *Per NIH: Investigators or institutions not funded by NIH who receive a copy of identifiable, sensitive information protected by a Certificate issued by the Policy, understand they are also subject to the requirements of subsection 301(d) of the Public Health Service Act and for ensuring that collaborators that are carrying out part of the research involving a copy of identifiable, sensitive information protected by a Certificate issued by NIH understand they are also subject to subsection 301(d) of the Public Health Service Act.]

5.0 Special Considerations

Complete each sub-section that applies to the research; if not applicable, replace instructional text with N/A.

5.1 Health Insurance Portability and Accountability Act (HIPAA)

Indicate here if you will be obtaining, creating, and using, and/or disclosing individually identifiable health information associated with a HIPAA-covered component or entity in the research. See Toolkit 6.205 (HRP-330) HIPAA Authorization for additional guidance. If yes, indicate whether you are requesting a waiver of HIPAA authorization. Justify your reasons why you believe this is necessary in order to accomplish the research. Review Toolkit 6.201 (HRP-441) HIPAA Waiver of Authorization to learn more about what criteria must be satisfied for an IRB to permit a waiver of authorization.]

5.2 Family Educational Rights and Privacy Act (FERPA)

Indicate here if student records protected under FERPA—other than publicly available directory information—will be accessed for the research. See HRPP Guidance FERPA. Ensure that your protocol includes what records will be accessed and include required information in the consent form or justification for a waiver of consent.

5.3 General Data Protection Regulation (GDPR)

If GDPR applies, indicate that here. GDPR regulates the use and processing of identifiable information collected from or about individuals residing in the EU or European Economic Area (EEA) member states. Under GDPR, investigators must disclose to subjects, information about the collection, processing, disclosure and any transfer of their personal information (including those via internet and/or cloud-based activities) to other countries, including the United States. See Toolkit 11.201 (HRP-335) GDPR Compliance to determine whether the research requires compliance with GDPR.

6.0 Reporting Results

6.1 Reporting Results Details

- A. Individual Subjects' Results:** If this section does not apply to your research keep the section heading but replace the text below with N/A. If you plan to contact individuals from whom data or biospecimens derive to provide clinically actionable information learned in the course of the

research, **STOP**. Use instead Toolkit 15.302 (HRP-503b) Non-Interventional Research Protocol Template.

B. Professional Reporting: Describe your plan to share the results of your research with the scientific community.

6.2 Further Secondary Uses of the Data or Biospecimens

Describe the details of any plans to share the data or biospecimens obtained for this research with other researchers (with or without identifiers) for other secondary research uses.

7.0 Research Repositories – Data or Biospecimens

NOTE: Identified or identifiable data or biospecimens obtained for this secondary research may not be stored for future research without consent from the individual from which the data or biospecimens derive.

8.0 Approvals/Authorizations

UPLOAD a copy of all approvals and agreements to [eIRB+](#).

9.0 Bibliography

Include all references cited in the protocol.