RUTGERS UNIVERSITY
Office for Research

RESEARCH PROTOCOL GUIDE FOR eIRB+

15.308 (HRP-503Plus)

INSTRUCTIONS

This documented is intended to help you prepare your eIRB+ application. This document does NOT need to be uploaded / submitted in eIRB+. You may use this as a worksheet as you prepare your application narrative. When ready, you may copy and paste your responses into the eIRB+ application.

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

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.

RUTGERS UNIVERSITY
Office for Research

STUDY INFORMATION

- **Title of Project** (eIRB+ application section 1.0, question 1.0)**:**
  [Add Protocol Title]
- **Principal Investigator Name** (eIRB+ application section 1.0, question 3.0)
  [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]
- **Document Date:**
  [e.g. v1 09.08.18]

Table of Contents

Skip To Section: Hold **CTRL** + **Click (Below)** To Follow Link in **Blue**

1.0 Research Design

1.1 Purpose/Specific Aims (eIRB+ application section 6.02, question 1.0)

Clearly state the overall purpose of the study.

A. Objectives (eIRB+ application section 6.02, question 2.0)

Describe the specific aims or objectives (i.e., what will be achieved by conducting the study).

B. Hypotheses / Research Question(s) (eIRB+ application section 6.02, question 3.0)

Describe underlying reasons/motivations for this project and/or the research question (s) that will guide the study, which are specific to the topic and/or populations targeted. **OR** Express any scientific hypotheses that correspond directly to the objective(s).

1.2 Research Significance (Briefly describe the following in 500 words or less)
(eIRB+ application section 6.02, question 4.0)

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

1.3 Research Design and Methods (eIRB+ application section 6.02, question 6.0)

This section should describe how you would accomplish the goals and objectives of the study, and the means by which the data will be collected. Identify and justify the type of research proposed: qualitative, quantitative or mixed method approach (e.g. experimental, correlational, survey, qualitative). Describe and explain the study design or choice or research methodology (e.g., cross sectional, descriptive, case/control, cohort, observations, program evaluations, surveys, focus groups, interviews, quality of life/quality improvement, retrospective chart/record/secondary data review/pre-test /post-test/ test control group design; prospective longitudinal cohort design).

A. Research Procedures (eIRB+ application section 6.02, question 6.0)

Describe in order of occurrence all research procedures being performed, when and where they are performed, and by whom. Include procedures being performed to monitor subjects for safety or minimize risks of harm to them, if applicable.

B. Duration for Study and Each Subject (eIRB+ application section 6.02, question 7.0)

Define the duration of the study and the length of time each subject will participate.

1.4 Preliminary Data (eIRB+ application section 6.02, question 5.0)

Describe any relevant preliminary data.

1.5 Sample Size Justification (eIRB+ application section 6.02, question 8.0)

Include the anticipated enrollment number in this study. Include a break-down in numbers if there is more than one subject population. Include the statistical analysis or other justification for the number of subjects to be observed, targeted and/or enrolled.

1.6 Study Variables

(If this section does not apply to your research, replace the instructions below with "N/A")

A. Independent Variables, Interventions, or Predictor Variables
(eIRB+ application section 6.02, question 10.0)
Describe any treatments or interventions to be compared for their effects on participants. Clearly differentiate interventions or procedures that are a part of standard of care from those that are experimental. In the case of chart reviews, indicate if you will be comparing specific treatments or other interventions performed in the past. For correlational studies, indicate what variables you will be using to predict outcomes or performance.

B. Dependent Variables or Outcome Measures
(eIRB+ application section 6.02, question 11.0)
List and describe outcome measures that "depend on" your intervention(s) or predictor variables.

1.7 Specimen Collection

(If this section does not apply to your research, replace the instructions below with "N/A")

A. Primary Specimen Collection (eIRB+ application sections 5.0 and 6.03)
If you plan to collect specimens directly from subjects for the research (i.e., buccal swab, tissue biopsy, blood draw, etc.) provide the following details:

- **Types of Specimens**: List the types and amount of specimens that will be collected from each subject, where and how they will be collected, and by whom;
- **Annotation**: List the data to be annotated or associated with each specimen, including identifiers;
- **Transport**: State how the specimens will be transported to the lab and by whom;
- **Processing**: Identify who will process the specimens;
- **Storage**: Describe where the specimens will be stored, how they will be accessed and by whom and how long the specimens will be stored;
- **Disposition**: How and by whom they will be destroyed upon study completion.

B. Secondary Specimen Collection (eIRB+ application sections 5.0 and 6.03)
If you plan to collect/use specimens already existing "on the shelf" (such as, from Pathology, a Research Repository, other research, etc.), provide the following details:

- **Types of Specimens**: List the types of specimens you will receive and from where, and context of its original collection, if it from other research—yours or another investigators' research;
- **Annotation**: List the data that will be annotated or associated with the specimens, including identifiers;
- **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;
- **Storage**: Describe where the specimens will be stored, how they will be accessed and by whom, and low long the specimens will be stored; and
- **Disposition**: How and by whom they will be destroyed upon study completion.

UPLOAD to eIRB+ Section 10.0 - Biosafety Approval and evidence of Biosafety Training AND agreement(s) (MTAs) covering the transfer of specimens, if applicable.

1.8 Data Collection

A. Primary Data Collection
If you plan to collect data directly from subjects for the research (i.e., surveys, questionnaires, focus groups, evaluations, observation, etc.) provide the following details:

- **Process of Data Collection** (eIRB+ application section 6.06, question 4.0): Explain how and by who data collection will occur or be administered and who will oversee the process.

- **Timing and Frequency** (eIRB+ application section 6.06, question 5.0): Describe the approximate time and frequency where data collection will occur.

- **Procedures for Audio/Visual Recording** (eIRB+ application section 6.06, question 6.0): Describe any plans to record subjects as a part of the research. Be specific. [If consent to recording is required, provide details about it in the main body of the consent document; if optional, provide recording details in an addendum to the consent. See Consent Addenda Templates for suggested language.

- **Study Instruments** (eIRB+ application section 6.06, question 7.0): Discuss the details of each of the research instruments: surveys, questionnaires, focus groups, and other evaluation instruments you plan to use. Provide validity and reliability data for selected measures. For well-known or standardized instruments, these can be provided as a list with references; for a novel or newly developed instrument, then include the specific instrument with your application.

- **Ethnographic Studies, Interviews, Or Observation** (eIRB+ application section 6.02, question 4): Provide the general framework for observations and/or process of semi-structured or open-ended interviewing procedures for data collection. Include a detailed description of the procedures and/or design to be followed (what will subjects be asked to do), and describe each interaction with the subjects and/or their data.

- **Subject Identifiers** (eIRB+ application section 6.02, question 4): For each data collection method or instrument you plan to use, specify what identifiers, if any, will be collected and linked to the data.

B. Secondary Data Collection (eIRB+ application section 6.04)

If you plan to collect/use data already existing 'on the shelf' (such as in a medical record, employee record, student record, public or private database, a Data Repository, etc.) provide the following details:

- **Type of Records** (eIRB+ application section 6.04, question 1.0): Describe the types of records that will be accessed (i.e., medical charts/EMRs/employee or student records etc.) and what data elements will be collected.

- **Location** (eIRB+ application section 6.04, question 2.0): Specify the current location of the existing data (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. Specify where you will review these records to abstract data.

- **Inclusion/Exclusion** (eIRB+ application section 6.02, question 9.0): Explain the parameters you will use to select records and where will you review these records to abstract data. Date Range of Data: Enter in a mm/dd/yyyy to mm/dd/yyyy format.

- **Data Abstraction Form(s)** (eIRB+ application section 6.04, question 4.0)**:** Describe how the data will be identified and who will identify data to be abstracted/reviewed. Upload a data abstraction form reflecting *all* of the data elements you plan to abstract from each data base, including identifiers, if applicable. 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. Upload a 2nd data abstraction form reflecting what the dataset will look like after identifiers are removed. Indicate on the uploaded files which form reflects the identifiable dataset and which form reflects the dataset after the identifiers have been removed.

- **Date Range** (eIRB+ application section 6.04, question 3.0)**:** Provide a date range of when the data were or will be collected for the original (primary) purpose of its collection.

UPLOAD to eIRB+ Section 10.0 – all study instruments and data abstraction forms to be used in the course of the research.

2.0 Project Management

2.1 Research Staff and Qualifications (eIRB+ application section 6.02, question 14.0)

Describe the qualifications (e.g., training, experience, oversight) the study personnel listed on the e-IRB+ Application possess to accomplish their role/responsibilities in the research and noting any period of or limits on availability. When applicable, highlight their knowledge of the local study site(s), culture and society.

2.2 Research Staff Training (eIRB+ application section 6.02, question 14.0)

Describe your process to ensure that all persons assisting with the research are informed about the protocol, the procedures, and their duties and functions.

2.3 Resources Available (eIRB+ application section 6.02, question 4)

Describe the resources available to protect subjects. Such resources include (a) psychological, social and medical services, including counseling or social support services that may be required because of research participation; (b) psychological, social or medical monitoring or ancillary care; (c) equipment needed to protect subjects; and (d) resources needed for communicating with subjects, such as language translation services, as applicable.

2.4 Research Sites (eIRB+ application sections 4.0 and 4.1)

Indicate the research sites.

UPLOAD to eIRB+ Section 10.0 - 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.

3.0 Drugs/Devices/Biologics

A. Schedule and Administration (eIRB+ application section 7.0)

Describe the regimen—drugs, doses and schedule by which the treatment(s) will be given—and drug administration guidelines (i.e., route of administration, infusion solution, concentration, rate of infusion and packaging).

B. Drug/Device Accountability and Storage Methods (eIRB+ application section 7.0)

Specify the location where study drugs, devices, and/or biologicals will be stored and secured. Indicate who will be responsible for preparation, dispensing and disposal including any special precautions.

UPLOAD to eIRB+ Section 10.0 - FDA Approval Status/Correspondence, Investigator Brochure, etc., for drugs, devices and biologics.

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects (eIRB+ application section 6.06, question 8.0)
Describe the methods that will be used to identify/select potential subjects.

B. Recruitment Details (eIRB+ application section 6.06, question 9.0)
Describe when, where, how and by whom potential subjects will be recruited. Describe materials that will be used to accomplish your recruitment efforts.

C. Subject Screening (eIRB+ application section 6.06, question 10.0)
Describe whether and how individuals will be screened for eligibility and by whom.

- **Inclusion Criteria** (eIRB+ application section 6.02, question 9.0)
  Describe the target subject population. Provide all relevant demographic (e.g., age, ethnicity), biomedical (e.g., disease status, laboratory values, pregnancy) and behavioral characteristics (e.g., cognitive abilities, mood) relevant for inclusion and exclusion.

- **Exclusion Criteria** (eIRB+ application section 6.02, question 9.0)
  Describe what relevant demographic, biomedical or behavioral characteristics exclude persons from participating in your research. Provide clear justification(s) for exclusions. Note any efforts you will take to overcome any anticipated barriers to participation.

D. Privacy Protections (eIRB+ application section 6.07, question 1.0)
Describe provisions made to protect privacy by the method in which prospective subjects are identified and recruited for participation in the research.

UPLOAD to eIRB+ Section 10.0 – *all* recruitment materials, such as: in-person or telephone scripts, emails, flyers, posters, social media posts, and radio or television advertisement scripts, etc. that will be used to recruit individuals to the study.

4.2 Obtaining Identifiable Information About Non-Subjects
(eIRB+ application section 6.02, question 4.0)

When research obtains identifiable private information from subjects o
or their records about other individuals who did not enroll in the research—such as family members, friends, or colleagues—these individuals become subjects of the research and human research protections accrue to them. Describe whether and how you will obtain consent to use identifiable data from individuals who become subjects during the course of your research.

4.3 Number of Subjects

A. Total Number of Subjects (eIRB+ application section 6.0, question 4.0)
Indicate the total number of subjects to be enrolled.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process** (eIRB+ application section 8.1, question 2.0)
  Indicate where the consent process will take place.

- **Ongoing Consent** (eIRB+ application section 8.1, question 3.0)
  If the duration of subjects' participation in the research is lengthy, outline any plans to contact them, to determine whether they have any questions or concerns about continued participation in the research.

- **Individual Roles for Researchers Involved in Consent** (eIRB+ application section 8.1, question 4.0)
  Indicate the roles individual study members listed in the application will have in the consent process.

- **Consent Discussion Duration** (eIRB+ application section 8.1, question 5.0)
  State the length of time that will be devoted to the consent discussion and any waiting period between the consent discussion and obtaining consent.

- **Coercion or Undue Influence** (eIRB+ application section 8.1, question 6.0)
  Outline steps that will be taken to minimize the possibility or perception of coercion or undue influence. Identify whether additional possibility or perception of coercion or undue influence concerns exist if the research proposes to enroll subjects likely to be vulnerable to coercion or undue influence—such as children, prisoners, adults represented by a surrogate, students, economically or educationally disadvantaged individuals— and outline additional safeguards you have included in the study to protect their rights and welfare.

- **Subject Understanding** (eIRB+ application section 8.1, question 7.0)
  Outline steps that will be taken to ensure subjects comprehend the key study elements.

B. Waiver or <u>Alteration</u> of Consent <u>Process</u>

- **Waiver** (eIRB+ application section 8.8)
  If you are requesting a waiver of consent or omission/alteration of the consent document from subjects state that here. Specify what you wish to waive, alter or omit and justify your reasons why you believe this is necessary in order to accomplish the research. [Review Toolkit 6.208 (HRP-410) Checklist: 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.]

- **Alteration** (eIRB+ application section 8.6)
  If you are requesting a waiver of consent or omission/alteration of the consent document from subjects, state that here. Specify what you wish to waive, alter or omit and justify your reasons why you believe this is necessary in order to accomplish the research. [Review Toolkit 6.208 (HRP-410) Checklist: 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.]

    i. **Destruction of Identifiers** (eIRB+ application section 8.6, question 2.0)
    If a waiver of consent is granted, identifiers should be destroyed with no possibility of linking the data with these identifiers as soon as possible. Explain when and how destruction of identifiers will occur.

ii. **Use of Deception/Concealment** (eIRB+ application section 8.6, question 2.0)
If the research involves deception (refers to when an investigator intentionally misleads or withholds information to the subject about the true nature of the experiment/research study) or concealment (refers to any procedures involved where the researcher intentionally does not reveal initially to the participant all details of the protocol because the subjects' behavior would be altered if they knew the real objectives) then you must request a waiver, omission or alteration of informed consent to withhold key informational elements from the consent process. A plan to deceive or conceal potential subjects, then key information is typically only acceptable in research that poses no more than minimal risk of harm to subjects. Describe the information that will be withheld from research participants (or misinformation that will be provided to participants).

a. Minimal Risk Justification (eIRB+ application section 8.6, question 2.0)
Detail why this study poses only minimal risk of harm to subjects and the justification for using deception/concealment (incomplete disclosure).

b. Alternatives (eIRB+ application section 8.6, question 2.0)
Explain whether and why there are no alternatives available to address the scientific question in a valid manner but to use deception/incomplete disclosure.

c. Subject Debriefing (eIRB+ application section 8.6, question 2.0)
Provide details about when and how you will debrief subjects about the deception and, if you have no plans to debrief subjects, justify your reasons why you do not plan to debrief them.

C. Documentation of Consent

- **Documenting Consent** (eIRB+ application section 8.1)
  Explain here how you plan to document in writing that you have informed and obtained individuals consent to take part in the research, such as by asking individuals to sign the consent document.

- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**
  (eIRB+ application section 8.1, question 8.0; and section 8.5)
  If you will obtain, but not document consent in writing, describe your process for ensuring potential subjects are informed and actually consent to take part in the research, even though they will not sign the consent document. Be sure your plan includes providing each subject with a copy of the consent document to keep.
  Go to HRPP website to find consent language when not requiring a signature to indicate consent. [Review Toolkit 6.207 (HRP-411) 'Waiver of Written Documentation of Consent'] to ensure that you have provided sufficient information to the IRB about your request to waive documentation of consent.

UPLOAD to eIRB+ Section 10.0 - The consent form(s) and consent script(s) you plan to use to inform and consent individuals to take part in the research.

4.5 Special Consent/Populations

A. Enrolling Minors-Subjects Who Are Not Yet Adults

- **Parental Permission** (eIRB+ application section 8.1)
  Note here whether you plan to obtain parental permission. If not, provide your justification for not doing so.

- **Non-Parental Permission** (eIRB+ application section 8.1)
  Note here whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine the authority of such individuals to give permission on behalf of a child to take part in the research.

- **Assent Process** (eIRB+ application section 8.1)
  Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. Depending on the study's design or chronological age, it may not be appropriate to assent some children. [See Toolkit 6.002 (HRP-090) & 6.003 (HRP-091) to learn about flexibility around when and how to document a child's assent to take part in research.]

- **Documentation of Assent** (eIRB+ application section 8.1)
  When assent of children is obtained describe whether and how it will be documented.

- **Reaching Age of Majority During Study** (eIRB+ application section 6.06, question 1.0)
  Indicate your plan for tracking and consenting subjects who are minors who reach the age of majority during their participation in your study.

B. Enrolling Wards of the State (eIRB+ application section 8.1, question 1.0)
For information about research with children, who are wards of the state, see Toolkit 7.205 (HRP-416). For guidance about research conducted in the state of NJ involving minors, see Toolkit 7.001 (HRP-013).

- **Research Outside of NJ Involving Minors**
  For research conducted outside of New Jersey, identify the laws applicable in the jurisdiction where the research will be conducted and describe what qualifications a person must possess to be able to legally provide permission on behalf of a child. See also Toolkit 7.001 (HRP-013).

C. Enrolling Non-English-Speaking Subjects (eIRB+ application section 8.1, question 1.0)
Indicate what language(s) other than English are understood by prospective subjects or representatives. See Toolkit 6.002 (HRP-090).

- **Process for Non-English-Speaking Subjects**
  If subjects who do not speak English will be enrolled, describe the process to ensure that the information about the research—oral or in writing—that is provided to subjects will be in that language. Indicate the language that will be used by those obtaining consent.

- **Short Form Consent for Non-English Speakers**
  Indicate whether you will be using a consent short form for non-English speakers. See Toolkit 6.202 (HRP-317) and 16.360-16.377 (HRP-507).

D. Enrolling Adults Unable to Consent / Decisionally Impaired Adults
(eIRB+ application section 8.10)

Outline your plans to enroll adults lacking decision-making capacity in the research. **NOTE:** See Guidance: Surrogate Consent Process to learn about Surrogate Consent and NJ Law governing the consent process.

- **Assessing Adult Capacity to Consent** (eIRB+ application section 8.10, question 2.0)
  Describe your process to assess potential subjects' capacity to consent. See Toolkit 6.203 (HRP-390) Worksheet Surrogate Consent—Determining Decisional Capacity for more information about the steps to follow when assessing capacity to consent, as required by NJ Law.

- **Selecting a Surrogate & Consent Process** (eIRB+ application section 8.10)
  Describe the process to be used to select a surrogate to provide consent for the adult lacking the capacity to consent. Describe also your plan to review the study's details and obtaining consent from the surrogate. See Toolkit 6.204 (HRP-391) Worksheet Surrogate Consent – Selecting a Surrogate for more information how to select an individual to serve as a surrogate, as required by NJ law.

- **Subject Assent** (eIRB+ application section 8.10, question 3.0)
  Indicate whether assent will be obtained from all, some, or none of the adult subjects lacking the capacity to consent. If assent will be obtained from some adults, indicate which adults will be approached to assent. Depending on the study's design or extent of incapacity, it may not be appropriate to assent some adult subjects. Describe your process for obtaining assent, such as before, after or at the same time as obtaining surrogate consent. See Guidance: Surrogate Consent Process.

- **Selecting a Witness to the Surrogate Consent Process**
  (eIRB+ application section 8.10, question 5.0)
  Describe the process for selecting a witness to the consent process, as required by NJ Law. For studies at RWJUH, the Chaplain is the designated witness for studies utilizing surrogate consent.

- **Removing a Subject** (eIRB+ application section 8.10, question 4.0)
  Describe your plans to safely remove a subject from the research if the subject expresses dissent to continued participation or if a surrogate withdraws consent.

E. Special Consent Considerations (eIRB+ application section 8.1, question 1.0)
Outline your plans to enroll individuals who cannot read or write (illiterate or low literacy), who cannot see (blindness or visually-impaired), or who cannot hear (deafness or visually-impaired). In such research scenarios, special protections apply, such as the need for a witness to observe the consent conversation, interpretation of the consent conversation (American Sign Language) or translation of the consent and other study documents the subject will view (Braille). For more information, go to HRPP Toolkit Forms & Templates Special Consent Considerations.

UPLOAD to e-IRB+ Section 10.0 0 – child assent, parental permission, and/or surrogate consent forms to be used in the study, as applicable.

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses (eIRB+ application section 6.07, question 3.0)
List all expenses the subject will likely incur by taking part in the research. If expenses will be reimbursed by the research, state that here and explain your plan for making such disbursements.

B. Compensation/Incentives (eIRB+ application section 6.07, question 4.0)
Indicate what compensation and/or incentives, if any, will be provided and whether it will be pro-rated depending on what parts of the study the subject completes. Explain the types of payments to subjects including justification for the amounts. State the form the compensation or incentive will take (such as cash, course credit, gift certificate, tickets, coupons, etc.) and schedule of payment. For more information, see 9.203 (HRP-316) Worksheet Payments.

C. Compensation Documentation (eIRB+ application section 6.07, question 5.0)
Indicate how you will document that compensation was provided to subjects. Note: you are required to maintain a full accounting of all funds disbursed to subjects.

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Subject Risks of Harm (eIRB+ application section 6.07, question 6.0)
List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Investigators must consider any physical, psychological, genetic, social, legal, economic risks, privacy and/or confidentiality risks for subjects and/or their families.

- **Risks** (eIRB+ application section 6.07, question 6.0)
  Comment specifically on risks of including someone who may have an existing psychological/physical condition or disorder. For observational studies, consider whether the observation could include sensitive information. Consider the impact of the presence of a researcher.

- **Minimizing Risks** (eIRB+ application section 6.07, question 8.0)
  Describe any procedures to be instituted to minimize any reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. Procedures may be needed to prevent additional risks (e.g., encryption methods to prevent a breach of confidentiality for certain types of sensitive data collections).

- **Certificate of Confidentiality** (eIRB+ application section 6.07, question 9.0)
  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.), indicate that here. See HRPP Guidance: Certificates of Confidentiality for more information.

- **Risks of Harm to Non-Subjects** (eIRB+ application section 6.07, question 7.0)
  If applicable, describe risks to others who are not subjects (e.g., photographs being collected that might include others in the background, Facebook posts where non-consented individuals post on the subject's feed etc.).

B. Potential Direct Benefits to Subjects (eIRB+ application section 6.07, question 10.0)
If there are any potential direct benefits that individual subjects may experience from taking part in the research, describe them here, such as therapeutic benefit, education, information, resources or empowerment. Include the probability, magnitude, and duration of these potential

direct benefits, if applicable. If there is no direct benefit to subjects, indicate as such. Do not include benefits to society or others.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

(eIRB+ application section 8.9 and / or section 8.91)

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) (eIRB+ application section 6.02, question 6.0)

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

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

(eIRB+ application section 6.06)

Indicate here if vulnerable populations will be enrolled in the research. Review the following guidance to ensure you have sufficient information when specific populations are included in your research study.

A. Special Populations

- Pregnant Persons or Fetuses [See Toolkit 7.201 (HRP-412)]
- Prisoners: [See Toolkit 7.204 (HRP-415)]
- Neonates: [See Toolkit 7.202 (HRP-413)]
- Neonates of Uncertain Viability: [See Toolkit 7.203 (HRP-414)]
- Children: [See Toolkit 7.205 (HRP-416)]
- Students/Employees: [Refer to HRPP Guidance]
- Adults with Impaired Decision-Making Capacity: [See Toolkit 7.101 (HRP-417) and HRPP Guidance Surrogate Consent Process]

5.4 General Data Protection Regulation (GDPR) (eIRB+ application section 4.1)

If GDPR applies, indicate that here. GDPR regulates the use and processing of data 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 U.S. See Toolkit 11.201 (HRP-335) GDPR Compliance to determine whether the research requires compliance with GDPR.

5.5 NJ Access to Medical Research Act (Surrogate Consent) (eIRB+ application section 8.10)

If the research plans to enroll adults represented by a surrogate, indicate that here. NJ's "Access to Medical Research Act;" authorizes certain persons to give informed consent for medical research if subject of research is unable to give consent" (i.e., "Surrogate Consent"). If this act applies to your research, then additional procedures and/or documentation may be required. For more information,

[see HRPP Guidance: Surrogate Consent Process]. When conducted outside of NJ, the research must comply with the applicable surrogacy laws in the jurisdictions where the research is taking place. List the applicable surrogacy laws here.

6.0 Data Management Plan

6.1 Data Analysis (eIRB+ application section 6.08, question 5.0)
Describe the data analysis plan. Where possible, include any discipline-specific analytical or statistical procedures and/or power analysis, as applicable to the research.

6.2 Data Security (eIRB+ application section 6.08, question 6.0)
Describe the steps that will be taken to secure the data through all phases of the research—from the time of its collection, to its storage, use and study closure— such as staff training, transporting or transmitting data from the study site or 'field' to Rutgers, methods to restrict access, password protection, encryption, use of key codes to separate identifiers from the data, and state how and when identifiers will be deleted from the data. Identify who will be responsible for each of these tasks.

6.3 Data and Safety Monitoring
[This information **is required** when research poses greater than minimal risk of harm to subjects.]

A. **Data/Safety Monitoring Plan** (eIRB+ application section 6.08, question 1.0)
Detail your plans to periodically evaluate the data collected regarding harms and benefits to determine whether subjects remain safe. Specify what data will be reviewed—such as safety data, untoward events and efficacy data—how often it will be reviewed, and by whom and when it will start. Also explain how the safety information will be collected—such as case report forms, by study visits or remote contact with subjects.

B. **Data/Safety Monitoring Board Details** (eIRB+ application section 6.08, question 2.0)
Detail also any plans to establish a data monitoring committee and regularly report committee findings to the IRB and sponsor, if applicable. Be sure to specify any conditions that trigger immediate suspension of the research. If not using a data monitoring committee, and if applicable, state the statistical tests that will be used for analyzing the safety data to determine whether harm is occurring.]

6.4 Reporting Results

A. **Subject Results Reporting** (eIRB+ application section 6.08, question 3.0)
Describe your plan, if any, to share research results with subjects. When applicable, if results to be shared are clinically actionable, provide evidence of appropriate lab certifications (e.g. CLIA) providing the results and qualifications of the study staff who will return such results.

B. **Aggregate Results** (eIRB+ application section 6.08, question 4.0)
Describe your plan, if any, to share aggregate research results with study subjects.

C. **Professional Reporting** (eIRB+ application section 6.08, question 8.0)
Describe your plan to share the results of your research with the scientific community.

D. **Clinical Trials Registration, Results Reporting and Consent Posting**
(eIRB+ application section 6.1)
Indicate whether the research qualifies as a clinical trial or Basic Experimental Study Involving Humans (BESH) that must comply with a requirement for public registration, results reporting, and

consent posting at its conclusion. For more information, see HRPP Clinical Trial Registration and Results Reporting.

6.5 Secondary Use of the Data (eIRB+ application section 6.08, question 9.0)

Describe the details of any plans to share the data with other researchers (with or without identifiers) for secondary research. Be sure disclosure of such a plan is included in the consent document.

UPLOAD to eIRB+ Section 10 – lab certifications, if applicable.

7.0 Research Repositories – Specimens and/or Data

(eIRB+ application section 6.08, question 9.0)

If data or specimens collected in the course of this research will be stored for future research, specify:

(1) What data elements and/or type(s) of specimens will be stored; and
(2) Whether data and/or biospecimens will be distributed to other investigators for future research:
   a. If yes, specify the Rutgers IRB-approved Research Repository and IRB Protocol Number where the data and/or specimens will be stored OR, if it is not a Rutgers IRB-approved Repository, state the name/address of the Repository and upload the other institution's IRB approval. Be sure the consent document discloses your plan to store data and/or specimens for future research; or
   b. If no—the data and/or specimens will only be used by the principal investigator for future research and not others—specify the location where data and/or specimens will be stored for such use.

8.0 Approvals/Authorizations

A any approvals that will be obtained prior to commencing the research. (e.g., Toolkit 13.305 (HRP-504) Letters of Permission/Cooperation from the study site, including schools, non-Rutgers IRB approval, Institutional Authorization Agreements, Data Use Agreements, Material Transfer Agreements, funding agency agreements, Bio-Safety Approvals, Radiation Safety Approval, etc.).

UPLOAD a copy of all approvals and agreements to eIRB+ Section 10.0

9.0 Bibliography

Include all references cited in the application.
UPLOAD a copy to eIRB+ Section 10.0