



# INTERVENTIONAL RESEARCH PROTOCOL TEMPLATE

15.301 (HRP-503a)

**DO NOT INCLUDE INSTRUCTIONS PAGE WITH YOUR SUBMISSION**

## INSTRUCTIONS

This template should be used by biomedical and social-behavioral investigators conducting research in which subjects are assigned to receive one or more interventions\* and manipulations of the subject or the subject's environment that are performed for research purposes so that the investigators can evaluate their effects (e.g., clinical trials, CBT, Behavioral Modification studies, or randomized outcome studies).

*NIH defines an intervention as "a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies."*

**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.]

- ✓ **[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+. Feel free to delete the Table of Contents Section if you no longer need to use it as a guide after you have finished constructing your protocol.

## 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.



# INTERVENTIONAL RESEARCH PROTOCOL TEMPLATE

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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 and Date:**  
[e.g. v1 09.08.23]  
[Be sure Protocol #, short title, and version date appear in the footer]



### Table of Contents

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

<b>1.0</b>	<a href="#">Research Design</a>
1.1	<a href="#">Purpose/Specific Aims</a>
1.2	<a href="#">Research Significance</a>
1.3	<a href="#">Research Design and Methods</a>
1.4	<a href="#">Preliminary Data</a>
1.5	<a href="#">Sample Size Justification</a>
1.6	<a href="#">Study Variables</a>
1.7	<a href="#">Drugs/Devices/Biologics</a>
1.8	<a href="#">Specimen Collection</a>
1.9	<a href="#">Data Collection</a>
1.10	<a href="#">Timetable/Schedule of Events</a>
<b>2.0</b>	<a href="#">Project Management</a>
2.1	<a href="#">Research Staff and Qualifications</a>
2.2	<a href="#">Research Staff Training</a>
2.3	<a href="#">Other Resources</a>
2.4	<a href="#">Research Sites</a>
<b>3.0</b>	<a href="#">Multi-Center Research</a>
<b>4.0</b>	<a href="#">Subject Considerations</a>
4.1	<a href="#">Subject Selection and Enrollment Considerations</a>
4.2	<a href="#">Obtaining Identifiable Information About Non-Subjects</a>
4.3	<a href="#">Number of Subjects</a>
4.4	<a href="#">Consent Procedures</a>
4.5	<a href="#">Special Consent Populations</a>
4.6	<a href="#">Economic Burden and/or Compensation For Subjects</a>
4.7	<a href="#">Risks of Harm/Potential for Benefits to Subjects</a>
<b>5.0</b>	<a href="#">Special Considerations</a>
5.1	<a href="#">Health Insurance Portability and Accountability Act (HIPAA)</a>
5.2	<a href="#">Family Educational Rights and Privacy Act (FERPA)</a>
5.3	<a href="#">Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)</a>
5.4	<a href="#">General Data Protection Regulation (GDPR)</a>
5.5	<a href="#">NJ Access to Medical Research Act (Surrogate Consent)</a>
<b>6.0</b>	<a href="#">Data Management Plan</a>
6.1	<a href="#">Data Analysis</a>
6.2	<a href="#">Data Security</a>
6.3	<a href="#">Data Safety And Monitoring</a>
6.4	<a href="#">Reporting Results</a>
6.5	<a href="#">Secondary Use of Data</a>
<b>7.0</b>	<a href="#">Research Repositories – Specimens and/or Data</a>
<b>8.0</b>	<a href="#">Approvals/Authorizations</a>
<b>9.0</b>	<a href="#">Bibliography</a>



## 1.0 Research Design

### 1.1 Purpose/Specific Aims

Clearly state the overall purpose of the study.

#### A. Objectives

Outlining 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

This section should describe how you will accomplish the aims and objectives of the study, and the means by which the data will be collected. Describe and explain the study design (cross sectional, descriptive, case/control, cohort, or retrospective chart/record review).

#### A. Research Procedures

Describe, in order of occurrence, all research procedures being performed, when and where they will be performed, and by whom (including procedures being performed to monitor subjects for safety or minimize risks of harm to them). Describe how subject interventions will be randomized, if applicable.

#### B. Data Points

Describe the data elements that will be collected including during long-term follow-up, if applicable.

#### C. Study Duration

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

#### D. Endpoints

Describe any primary and secondary study or safety endpoints.

### 1.4 Preliminary Data

Describe any relevant preliminary data.

### 1.5 Sample Size Justification

Describe and justify the sample size, expected accrual rates, and your sampling strategy. [Include power calculations and give references for pilot data and method of sample size calculation, where possible and applicable to the research.]

### 1.6 Study Variables

#### A. Independent Variables, Interventions, or Predictor Variables

Describe any interventions—treatments or procedures—to be compared for their effects on subjects. Clearly differentiate interventions that are a part of standard of care from those that are experimental. For correlational studies, indicate what variables—quantitative or categorical—you will be using to predict outcomes or performance.

#### B. Dependent Variables or Outcome Measures



List and describe all outcome measures that “depend on” your intervention(s) or predictor variables.

## 1.7 Drugs/Devices/Biologics

### A. Schedule and Administration

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

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

**UPLOAD to eIRB+ when prompted in the appropriate section - FDA Approval Status/Correspondence, Investigator Brochure, etc., for drugs, devices and biologics.**

## 1.8 Specimen Collection

### A. Primary Specimen Collection

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 type 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. If specimens will be banked for future research, complete **Protocol Section 7.0 Research Repository**.

### B. Secondary Specimen Collection

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 how long the specimens will be stored; and
- **Disposition:** How and by whom they will be destroyed upon study completion. If specimens will be banked for future research, complete **Protocol Section 7.0 Research Repository**.

**UPLOAD to eIRB+ when prompted in the appropriate section - Biosafety Approval and evidence of Biosafety Training AND agreement(s) (MTAs) covering the transfer of specimens, if applicable.**

## 1.9 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:



- **Location:** Identify the location where data collection will occur and explain what permissions you must obtain in order to conduct research there;
- **Process of Data Collection:** Explain how and by who data collection will occur or be administered and who will oversee the process.
- **Timing and Frequency:** Describe the approximate time and frequency where data collection will occur.
- **Procedures for Audio/Visual Recording:** 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. Relevant Consent Template language is found at the HRPP website.
- **Study Instruments:** 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 and generally accepted test instruments, these can be provided as a list with references; for a novel or newly developed instrument, include the specific instrument with your application.
- **Ethnographic Studies, Interviews, Or Observation:** Provide the general framework for observation, or line of questioning and means for data collection. Include a description of what subjects will be asked to do.
- **Subject Identifiers:** 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**

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:** 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:** 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:** Explain the parameters you will use to select records and where will you review these records to abstract data.
- **Data Abstraction Form(s):** 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 2<sup>nd</sup> 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.

**UPLOAD to eIRB+ when prompted in the appropriate section – the protocol and all study instruments and data abstraction forms to be used in the course of the research.**

### 1.10 Timetable/Schedule of Events

(Optional but recommended for long-term clinical or interventional studies that requires multiple visits or data collection points). Provide a detailed timetable scheduling all aspects of the research. You may reference an attached flow diagram.

## 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:

### 2.1 Research Staff and Qualifications



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

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 Other Resources

Detail other resources available to ensure the integrity of the research, such as Facilities that will be used to support the research. Detail also the resources available to protect the rights and welfare of 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

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+** when prompted in the appropriate section - 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 or 11.302 (HRP-285 or 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 for use of a Single IRB. [Email: [IRBRelianceTeam@research.rutgers.edu](mailto:IRBRelianceTeam@research.rutgers.edu)]

## 4.0 Subject Considerations

### 4.1 Subject Selection and Enrollment Considerations

#### A. Method to Identify Potential Subjects

Describe the methods that will be used to identify potential subjects.

#### B. Recruitment Details

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

Describe whether and how individuals will be screened for eligibility and by whom.

##### ▪ Inclusion Criteria

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

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



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+ when prompted in the appropriate section – *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

When research obtains identifiable private information from subjects 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. If you do not plan to obtain consent from these individuals, be sure to indicate that in **Protocol Section 4.4B** Waiver of Consent. If the research does not propose to collect identifiable information about individuals who did not enroll in the research, delete the instructional text and replace with 'N/A'.

#### 4.3 Number of Subjects

##### A. Total Number of Subjects

Indicate the total number of subjects to be accrued. (Distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

##### B. Total Number of Subjects If Multicenter Study

If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

##### C. Feasibility

Substantiate the feasibility of recruiting the required number of suitable subjects within the stated recruitment time period.

#### 4.4 Consent Procedures

##### A. Consent Process

- **Location of Consent Process**  
Indicate where the consent process will take place.
- **Ongoing Consent**  
If the duration of subjects' participation in the research is lengthy, outline any plans to re-contact them to determine whether they have any questions or concerns about continued participation in the research.
- **Individual Roles for Researchers Involved in Consent**  
Indicate the roles individual study members listed in the application will have in the consent process.
- **Consent Discussion Duration**  
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**  
Outline steps that will be taken to minimize the possibility or perception of coercion or undue influence. When some or all of the subjects are likely to be vulnerable to coercion or undue influence—such as children, prisoners, adults represented by a surrogate, students, economically or educationally disadvantaged individuals—outline additional safeguards you have included in the study to protect their rights and welfare.
- **Subject Understanding**  
Outline steps that will be taken to ensure subjects comprehend the key study elements.
- **Protecting Privacy**  
Outline provisions made to protect subjects' privacy during consent discussions.





## B. Waiver or Alteration of Consent Process

### ▪ Waiver or Alteration Details

If you are requesting a waiver of consent or omission/alteration of the consent document from subjects [and/or from individuals identified at **Protocol Section 4.2**], 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) – WORKSHEET - 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.]

### ▪ Destruction of Identifiers

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.

### ▪ Use of Deception/Concealment

If the research plan involves deception—purposely misleading subjects by omission, overt misdirection or false information about some aspect of the research—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 from potential subjects, key information is typically only acceptable in research that poses no more than minimal risk of harm to subjects.

#### a. Minimal Risk Justification

Detail why this study poses minimal risk of harm to subjects and the justification for using deception/concealment.

#### b. Alternatives

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

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.

**UPLOAD** to eIRB+ when prompted in the appropriate section - The consent form(s) and consent script(s) you plan to use to inform and consent individuals to take part in the research.

## C. Documentation of Consent

### ▪ Documenting Consent

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)

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 appropriate consent template when not requiring a signature to indicate. [Review Toolkit 6.207 (HRP-411) – WORKSHEET - 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.

## 4.5 Special Consent Populations

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

### A. Enrolling Minors-Subjects Who Are Not Yet Adults

#### ▪ Parental Permission

Note here whether you plan to obtain parental permission. If not, provide your justification for not doing so.

#### ▪ Non-Parental Permission



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**

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 and 6.003 (HRP-090 & HRP-091) to learn about flexibility around when and how to document a child's assent to take part in research.

- **Documentation of Assent**

When assent of children is obtained describe whether and how it will be documented.

- **Reaching Age of Majority During Study**

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

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

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 items 6.202 (HRP-317) and 16.360-16.377 (HRP-507).

## D. Enrolling Adults Lacking Decision-Making Capacity (Surrogate Consent)

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**

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**

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**

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**  
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**  
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

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 eIRB+ when prompted in the appropriate section – 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

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

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

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 Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**  
List the reasonably foreseeable risks of harm, discomforts, hazards, or inconveniences to subjects related solely to their participation in the research. Consider physical, psychological, genetic, social, legal, economic, and privacy/confidentiality risks of harm. Provide a description of the probability, magnitude, duration, and reversal of any known risks.
- **Risk of Harm from an Intervention on a Subject with an Existing Condition**  
If applicable, comment specifically on risks of imposing an intervention on someone who may have an existing psychological/physical condition or disorder.
- **Other Foreseeable Risks of Harm**  
Other foreseeable risks may include risks associated with a possible loss of confidentiality.



- **Observation and Sensitive Information**

For observational studies, consider whether the observation could include sensitive information. Consider the impact of the presence of a researcher. Detail whether individuals will be identifiable based on the data collected.

**B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects**

Indicate which procedures may have risks of harm to an embryo or fetus should the subject (all persons of any sex and gender) be or become pregnant, if applicable.

**C. 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 taken for the research, remarks posted on Facebook feed of a subject by non-subjects, etc.

**D. Assessment of Social Behavior Considerations**

The Investigator must consider any physical, psychological, genetic, social, legal, economic, privacy and/or confidentiality risks of harm for subjects and/or their families. If applicable, include referral information in the event that a participant scores high on a depression or suicidal scale.

**E. Minimizing Risks of Harm**

Describe any procedures you plan to use to minimize any reasonably foreseeable risks of harm, discomforts, hazards, or inconveniences to the subjects related their participation in the research. For example, use of results from blood drawn for therapeutic purposes reduces the need for additional needle-sticks for research minimizing risks of physical harm; encrypting data files better protects sensitive data from data breaches, etc.

- **Certificate of Confidentiality**

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 4.206 (HRP-333) - Certificates of Confidentiality for more information.

- **Provisions to Protect the Privacy Interests of Subjects**

Describe the steps that will be taken to protect subjects' privacy interests while taking part in the research. "Privacy interests" refers to a person's desire to place limits on who they interact with or provide personal information to about the research.

**F. Potential Direct Benefits to Subjects**

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

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 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)

Indicate here if vulnerable populations will be enrolled in the research. Review the following guidance to ensure you have sufficient information about subject protections detailed in the protocol 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)]
- Non-Viable 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 [See HRPP Guidance]
- Adults with Impaired Decision-Making Capacity [See Toolkit 7.101 (HRP-417) and HRPP 6.203 (HRP-390) Surrogate Consent Process]

### 5.4 General Data Protection Regulation (GDPR)

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. For more information, see HRPP Guidance: GDPR.

### 5.5 NJ Access to Medical Research Act (Surrogate Consent)

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

Describe the data analysis plan. Include any statistical procedures and power analysis, if applicable to the research.

### 6.2 Data Security

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 section **is required** when research poses greater than minimal risk of harm to subjects.]

#### A. Data/Safety Monitoring Plan



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

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. Individual Subjects' Results

Describe whether study results—such as results of investigational diagnostic tests, genetic tests, or incidental findings—will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared with them. If results are clinically actionable, provide evidence of the appropriate lab certifications (e.g., CLIA) providing the results and the qualification(s) of the study staff who will return such results.

#### B. Aggregate Results

Describe your plan to share aggregate research results with study subjects.

#### C. Professional Reporting

Describe your plan to share the results of your research with the scientific community.

#### D. Clinical Trials Registration, Results Reporting and Consent Posting

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

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+ when prompted in the appropriate section – lab certifications, if applicable.**

## 7.0 Research Repositories – Specimens and/or Data

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



Describe any approvals that will be obtained prior to commencing the research. (e.g., 13.305 (HRP-504) – Site Agreement (Letters of Cooperation) or School Permission 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 when prompted in the appropriate section.**

## 9.0 Bibliography

Include all references cited in the protocol.