This research plan is for projects that will collect new data (those projects might also utilize existing data or specimens). It should provide the IRB with your research objectives, the scientific rationale behind those objectives, and the scientific methods for achieving those objectives in accordance with regulatory and institutional requirements. The parts of the research plan which ask for specific details about how human participants will be involved in the research activity should be clear and detailed, so that the IRB understands each interaction as a link in a chain from recruitment through follow up (if applicable) without any missing links. The research plan must explain how participants will be identified and informed about the study (recruitment); who will obtain informed consent, and how, when, and where that process will occur over time; what documentation, including consent forms, assent scripts, oral scripts, telephone scripts, letters, etc. will be used to communicate with participants; what specific procedures will be performed, including when, where, and by whom, and so on. It should address the protections that the PI will put into place to ensure the safety and welfare of the study participants, including those who are vulnerable and need added protections. The role of the JHSPH investigators and their collaborators must be clear, and each person who will obtain informed consent or collect data from participants must be trained in human subjects research ethics. The responsibility of the PI continues throughout the course of the study from development through implementation and manuscript writing; details about the oversight and management plans, and data security are critical.

II. Background and Rationale:

Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.

This section provides the scientific justification for the research activity. If this section is weak, the IRB may not be able to permit involvement of human participants, exposing them to risk or inconvenience, without the prospect of yielding useful scientific information. This is not a grant application – be concise. Briefly present the case for the research project, including its design, identified research population, and procedures as necessary. More invasive protocols require more extensive justification.

III. Study Design

A. Provide an overview of your study design and methods. The study design must relate to your stated aims/objectives. Details will be requested later. If your study also involves analysis of existing data, please complete Section XI, “Secondary Data Analysis of Existing Data” in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (JHSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens).
This section should explain the methodology selected to achieve the study objectives. If a certain design is selected, such as a placebo-controlled randomized clinical trial, and there are ethical issues associated with that design, the PI should explain why this design was selected. If useful, explain why one design was selected over another. If the study involves multiple phases, explain each one clearly and how they are related. If the new application seeks IRB approval for a first phase only, there is no need to provide all the details of subsequent phases, especially when those details may not yet be available. However, the IRB will need to understand how you plan to proceed in general, and that the PI will submit amendments to the research plan prior to initiating future phases.

B. Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample a table may be helpful.

The IRB must evaluate whether the research application provides adequate justification for the sample size requested. Otherwise, two negative outcomes are more likely from the start: if the number is too low, there is a reduced likelihood that the research activity will produce a meaningful result; if too high, more human subjects will be put at risk or inconvenienced than is necessary. The PI must explain the sample size chosen and the rationale for that choice. Since there is variation across scientific disciplines in how samples are determined, explanation of research standards or practices for specific methodologies may be helpful to provide.

IV. Participants

Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

Provide details about the population or community from which you plan to recruit your participants. If the research involves multiple populations (for example, key informants, index participants, associates of index participants identified through snowball recruiting; or community leaders, heads of household, individual members of a household), list and describe each of them. If an individual enrolled in a study provides identifiable private information about family members or social contacts, the IRB will consider the protections in place for those individuals as well. The IRB must also evaluate whether the study population includes individuals considered to be “vulnerable”, including children, pregnant women, prisoners, and adults who lack capacity to consent for themselves. These populations are subject to specific ethical and regulatory protections. Involvement of special populations, such as children who are in foster care, trigger concerns about who actually has legal authority to provide informed consent.

A. Inclusion criteria:

B. Exclusion criteria:

If you will enroll only a subset of the population identified above, explain how you will identify that subset. Any inclusion and exclusion criteria must be consistent with the aims and objectives of the study, and must also meet scientific and ethical principles. For example, inclusion based on ethnicity or gender (and the associated exclusion criteria based on failure to meet that ethnic or gender requirement) cannot be based on a convenience rationale; there must be a scientific justification underlying that selectivity. Otherwise, the inclusion/exclusion criteria may not meet the ethical requirement for equitable selection.
Note: IRB oversight begins as soon as a PI obtains private information about a person for research purposes. This means that if there is a "screening process" which winnows down the select population members to the desired subset, that process must be clearly explained to the IRB. If you will interact with a potential participant for screening purposes to determine eligibility, that activity is part of the study and requires consent or a waiver of informed consent, if appropriate.

NOTE: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. Check “yes” to the HIPAA question in the PHIRST application.

HIPAA covers personal information collected in any U.S. clinic, hospital, or other care-providing entity. It includes medical record information, claims and billing information. The IRB follows the definition of “identifiers” provided in the HIPAA legislation – these identifiers are listed in the HIPAA section of the PHIRST application. Please contact us if you are not certain whether or not you fall under HIPAA.

V. Study Procedures

In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear. If the JHSPH will serve as data coordinating center, indicate in the sections below which procedures JHSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section. If your study will develop in phases, address each item below by phase.

A. Recruitment Process:

“Recruitment” includes any communication of information about the study to the target population. This process is distinct from “obtaining informed consent.” “Referral” is not recruitment; clinicians may “refer” a patient to a study by providing the individual information about the study. The IRB needs to know all the details about the recruitment plan: who will communicate about the study, where will that communication take place, and through what mechanism(s). How will potential subjects be able to respond to those communications, and who will receive those inquiries? How will this process integrate with the informed consent process? Provide step by step details for each population or subgroup that will be included in the study.

Recruitment itself may pose risks to individuals if the study involves populations vulnerable to social stigma. The PI must address this issue, and describe ways to minimize this risk. If the study involves populations (for example, sex workers or injection drug users) whose behaviors are illegal in a country where the study will take place, the PI must describe the plan to protect potential participants from adverse legal consequences stemming from recruitment or enrollment in the study.

1. Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and what their qualifications are.

“Recruitment materials” include advertisements, posters, letters, flyers, information cards, study contact materials, video or audio presentations, scripts used before groups or on the telephone, etc. The IRB must examine and approve each material, in English, and must also understand and approve the plan for its use. Once approved, the item will be stamped with the IRB approval seal. Translated versions of recruitment materials that will be distributed in a language other than English must also be submitted to the IRB for approval, with Certificates of Translation.
2. **Address any privacy issues associated with recruitment.** If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks.

Potential study participants have certain expectations of privacy that the PI must understand and respect. During recruitment, those expectations must be protected. For example, the IRB will not approve a process which involves approaching potential participants in a clinic waiting room, where conversations might be overheard and an individual's privacy compromised. Generally, for clinical recruitment, the IRB will not allow a PI to “cold call” potential participants by telephone; there must be some connection between the research team and the potential participant, such as referral from a clinician. In settings involving recruitment of a family member and a head of household’s consent must first be obtained, the privacy of the family member may not be compromised in the discussions with the head of household. Similarly, if enrolling adolescents in studies that collect personal information, the PI must be transparent with the adolescents and parents/guardians about what information collected will or will not be shared between them.

B. **Consent Process:**

The Office of Human Research Protections issued a guidance which makes clear than any individual who obtains informed consent from a participant is “engaged” in human subjects research. That person must be trained in human subjects research ethics and be qualified to provide information about the study and answer questions that potential participants may ask. The PI must explain who will obtain informed consent, and why they are qualified to do so.

Consent must be obtained from a participant in a setting which allows for the individual adequate time to properly consider the information about the study and to make a decision whether or not to provide consent. The PI must provide details about the timing and the setting, and must consider issues like the presence of other family members or peers that might influence the potential participant’s ability to make a free decision.

The IRB will anticipate that the informed consent will be documented, meaning that the participant will sign or make a mark like a thumbprint on the approved consent form. If the consent process will not involve obtaining a signature, the PI must provide justification.

If children will participate in the study, the PI must obtain permission from the parents or legal guardian of the children. This obligation will only be waived if the IRB determines that parental permission is not a “reasonable requirement”, for example, if the study involves children who have been abused or neglected by a parent. In such cases, the PI must identify another mechanism for protecting the children, such as another, appropriate, adult advocate.

In studies involving children, the IRB will expect the PI to obtain the “assent”, or agreement, of any child whose age, maturity, and psychological state qualifies them to consider participation. The IRB may waive assent in the event that the child is too young or lacks maturity or is psychologically unprepared to provide assent, or in cases where the intervention offers the prospect of direct benefit to the child, is important to the child’s health, and is only available through the research. If the IRB requires assent from the child, and a child does not want to participate, a parent’s consent will not override the child’s preferences; both parent and child must agree to study participation. Like consent, assent may be obtained without documentation (signature) where appropriate; that justification may be provided below.

Some study populations are “vulnerable”, in the sense that they have a condition that may compromise an individual’s ability to provide voluntary informed consent. That compromise may be to the individual’s freedom,
as with prisoners, or mental capacity, as with adults with dementia. Social and economic pressures may also
unduly influence an individual’s decision making capacity, such as when an offer for enrollment includes free
medical care in a resource-poor setting. The PI must address any known vulnerabilities in the target
population, and how the consent process will address them.

1. Describe the following details about obtaining informed consent from study participants. If a screening
   process precedes study enrollment, also describe the consent for screening.
   • Who will obtain informed consent, and their qualifications
   • How, where, and when the consent discussion(s) will occur
   • The process you will use to determine whether a potential participant meets eligibility criteria
   • Whether you will obtain a signature from the participant or will use an oral consent process
   • Whether you will obtain a legally authorized representative’s signature for adults lacking capacity
   • If children are included in the study, if and how you will obtain assent from them
   • If children are included in the study, how you will obtain permission for them to participate from their
     parent, legal guardian, or other legal authority (if child is in foster care or under government
     supervision.)
   • If you are seeking a waiver of informed consent or assent, the justification for this request
   • Whether you will include a witness to the consent process and why
   • If the language is unwritten, explain how you will communicate accurate information to potential
     participants and whether you will use props or audio materials.

Consent is required for all research when it is “practicable” to obtain it. Generally that means that there
will be a direct contact between the researcher and the participant. If a researcher is using secondary
data with identifiers, contact with all of the individuals who provided that data may be “impracticable”
because of the difficulty of contacting them all without updated personal contact information. People
move, change phone numbers, and pass away. In such situations, the IRB may waive the consent
requirement altogether.
When there will be a contact between the researcher and the participant, even if that contact is a one-time
electronic one – such as a SurveyMonkey web-based questionnaire – the investigator must ask for
consent. The form of that consent may vary, from a web page explanation about the research and
statement that completion of the survey signifies “implied consent”, to an in-person discussion which is
evidenced by a consent document with the participant’s signature and date, and the consent designee’s
signature and date.

There are two situations when “waiver of documentation” is appropriate:
1) when the study poses minimal risk to participants and involves a procedure for which a signed consent
   is not routinely required (such as an interview or focus group); or
2) when the only risk of the study is the harm associated with a breach of confidentiality, the study involves
   collection of sensitive information which could cause harm if disclosed, and the only record linking the
   participant with the research is the consent form. In these two instances, the PI may ask the IRB to
   approve an oral consent process, and should submit appropriate oral consent scripts for IRB review.

2. Identify the countries where the research will take place, and the languages that will be used for the consent
   process.
Many countries have populations who speak numerous languages, and the IRB needs to know how many consent documents, including oral scripts and documents for signature, will be used and translated in the study. For unwritten languages and illiterate populations, the PI must explain how the study will be explained in a way that the individual will be able to make an informed decision whether or not to join.

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<tr>
<th>Country</th>
<th>Consent Document(s) (adult consent, parental permission, youth assent, etc.)</th>
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C. Study Implementation:
Answer the following:

1. Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate.

This section should be presented as methodically as possible. The IRB will compare the procedures listed here with those explained in the consent form. The research plan should include information about who will be conducting and overseeing each procedure, as well as details about where and when they will occur. It is helpful to put oneself in the place of a potential participant in an effort to include all the details the participant would want to know. If the study involves multiple subgroups of participants, the PI must explain the procedures associated with each one.

2. Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place.

The IRB, and the study participants, need to know what the burden of time and inconvenience associated with the study might be. The location of the visits is relevant to that assessment. Describe the total period an individual subject will be activity involved (e.g., three 1-hour visits over 6 months; two weekly, 2-hour phone calls, etc).

3. Describe the expected duration of the study from the perspective of the individual participant and duration overall.

The IRB needs to know how long the PI believes it will take to complete the proposed data collection. This information sets an expectation as to the pace of data collection and analysis. As the study proceeds, the IRB will review progress reports and compare them to the initial time projection in the research plan. Slow progress could indicate a feasibility or recruitment problem that would, in turn, affect the exposure of participants to risk or inconvenience. If a study will create a repository of data or biospecimens which will be used for future research, the PI must distinguish between the duration of the data or sample collection phase and the duration of the ongoing repository afterwards.

4. Provide a brief data analysis plan and a description of variables to be derived.
This section should relate to the sample size information provided in Section 2c. The IRB must understand how the PI will analyze the data to address the aims/objectives set out in Section 1. However, the analysis plan should not be as detailed or lengthy as in a grant application.

5. Describe whether you are collecting or storing personal identifiers, and if yes, why you need them, and when and how you plan to dispose of them. Signatures on consent forms are considered to be identifiers.

The IRB must know whether it will be possible to reconnect the research data collected with the participants who provided them. There is a sliding scale of risk associated with data identification. The highest risk is associated with data that are directly identified with the participant; risk is reduced if the data are coded with a study identification number that has no association with the participant (e.g., is an arbitrary number). Risk is further reduced when the links or codes are destroyed, leaving no association at all between the data and the participants. The term “identifiers” refers to obvious collected information including name, address, SSN, hospital record number, etc. It can also include indirect identifiers (e.g., date of birth) that, when combined with other variables, may make a subject identifiable.

Note: the destruction of codes or links does not always reduce the risk of a research activity to a minimal level. If the collection of the data itself involves risk in that it could expose the participant to adverse physical, legal or social consequences, the IRB may still consider the activity to be “more than minimal risk.”

6. **Answer the following if they are relevant to your study design:**
   a. If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.
   b. If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about who will collect the specimen, the volume (ml) and frequency of collection, how the specimen will be used, stored, identified, and disposed of when the study is over. If specimens will be collected for use in future research (beyond this study), complete the Biospecimen Repository section below.

The IRB needs to know what specimens the PI intends to collect, by whom (with what qualifications and/or credentials), how, where, and what will be done with those specimens. This part of the research plan addresses only the biospecimens that will be used up during the course of the study and not the specimens retained for future research. That topic is discussed the last part of this research plan. If specimens are collected over time, a table showing the types of specimens, timing of collection, and other relevant factors such as where the collection will take place, and by whom, may be useful.

Biosafety training is required to ensure safe handling procedures for biohazard purposes. The Biosafety Office also handles registration of labs which handle biohazardous materials, and issues associated with transport of biospecimens.

   c. If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or other large dataset. Address returning unanticipated incidental genetic findings to study participants.

The IRB requires details about genetic and genomic research so that it may assess the risks associated with the analyses, and ensure that the participants are properly informed about those risks. These details must be very clear, too, so that material transfer agreements and other contractual arrangements may be consistent.
with participant expectation. If a PI intends to submit genomic data for Genome Wide Association Studies (GWAS), those details should be included here so the IRB may produce the appropriate certification.

d. If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.
e. If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.). Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants.

The IRB needs to know how accurate diagnostic tests conducted in a research study are; results of all kinds of which, if disclosed, may be used to make decisions about a participant’s welfare. With such test results, participants may choose to undergo additional expensive testing or make decisions relying on questionable information. Investigators should not return laboratory results from labs that do not meet clinical standards in the U.S. or in the country where the testing takes place. Results from investigational tests generally should not be returned unless validated against the gold standard. Explain the plan for reporting, or not reporting, diagnostic test results back to participants and justify the choice.

f. If your study involves medical, pharmaceutical or other therapeutic intervention, provide the following information:
   • Will the study staff be blind to participant intervention status?

For comparative studies which involve two or more groups who will receive different interventions/placebo, the PI should explain whether participants, study team members, and/or investigators will be blinded. If there is one or more persons who will not be blinded, or if there are procedures for unblinding, those details should be explained here.

• Will participants receive standard care or have current therapy stopped?

For treatment studies which may involve placebo, or which may involve cessation (temporarily or otherwise) of treatment for wash-out or other purposes, provide details and justification about withholding routine care or change of therapy.

• Will you use a placebo or non-treatment group, and is that justifiable?

This issue is particularly important in resource-poor research sites. If the study design involves use of placebo, and use of a product approved in a developed country in the intervention group, the ethical justification of withholding the proven product from the placebo group must be addressed. Provision of the product at a later time may be an acceptable compromise.

• Explain when you may remove a participant from the study.

For therapeutic studies, if there are criteria for removing participants for medical reasons, please explain. For all studies, identify any reasons for which a participant might be removed from a study (noncompliance, failure to come to study visits, etc.)
- What happens to participants on study intervention when the study ends?

The IRB’s concern for participant welfare extends to the end of that participation. If a participant’s care or access to resources will change once the individual is no longer a participant in a study, that information must be explained here and in the consent document.

- Describe the process for referring participants to care outside the study, if needed.

If investigators anticipate learning information about participants which may require professional attention outside the study, the research plan should explain how those referrals will be made. For example, if the investigators administer a depression scale and learn that a participant’s response indicates severe depression, the research plan should explain how the participant will be referred for mental health assessment and care.

VI. Data Custody, Security, and Confidentiality Protections

Data security plans must be part of a study’s Operating Procedures. The IRB will not evaluate the details of your data security plan, but requires the PI to establish a plan which adheres to institutional, regulatory, and sponsor norms. The JHSPH Data Security Guidance will provide some guidance on this topic. See http://www.jhsph.edu/irb/Guidance_and_Policies.html.

The sections below describe types of data sources and how they will be protected. For the type(s) of data you will have, put an “X” in the appropriate box to the left of the section that best describes how you will minimize the risk of a breach of confidentiality for your study. Note, as appropriate, how you will record/store data. These descriptions represent MINIMAL measures; you may add more stringent protections and other relevant information in B.

Confidentiality: The LOSS OR THEFT of 1) original/duplicate version of physical data collection instruments (forms, tapes, etc) or 2) physical devices containing electronic data (i.e. laptop/mobile device, external flash drive(s)), is a threat to subject confidentiality. Risk of such a loss/theft is increased during movement/transport of data (in any format), such as in a vehicle or other move. Be sure to train anyone (co-investigators, staff, students, etc.) who might be engaged in the oversight of data handling/storage about this problem. Some typical risk-mitigation strategies would include:

- minimizing the physical movement of data and/or devices containing data
- encrypting electronic data (especially when stored on any mobile device, including flash memory tools, phones, tablets, etc, or when transferring across networks)
- making use of reliable courier services (FedEx, DHL, etc) when physical transport of bulk data forms is necessary
- minimizing the transfer of identifiable data in physical or electronic form (i.e. removing/separating/destroying identifiable data) when physical transfer of data is necessary

The title of this section has been changed to include “custody” of data. Most of the adverse events reported to the IRB concerning breach of confidentiality are related to stolen or lost data, both hard copy and electronic. Each investigator must train individuals who are responsible for transport of data how to protect it. Investigators must also track who has copies of the data and whether or not those copies are identifiable. Think about this as a “chain of custody” issue; the PI must know who has what data and how data are protected for the life of the study.

A. Data Storage
1. **Hard Copies of Data Collection Forms.**

   This activity will not involve receiving and/or accessing hard copies of data.

   Data collection forms **RECORD NO PERSONAL IDENTIFIERS** connecting study participants, and there are no codes providing a link. Data are anonymous.

   Data collection forms **INCLUDE IDENTIFIERS**. The forms are locked in a secure cabinet or room with limited access by authorized individuals. Forms will be kept in study team’s possession during transport and will not be left unattended in a vehicle. When possible, de-identified copies will be used for coding and analysis.

   Data collection forms **ARE CODED** with study participants’ random study ID numbers. Codes/links between study IDs and identifiers are stored securely in a separate place (locked storage cabinet or secure electronic database.)

   **Other:**

2. **Electronic Data**

   The data do not contain personally identifiable information.

   These data are stored on a secure server protected by limited access and strong password systems. Data are coded when possible. Portable electronic devices will not contain identifiable information unless encrypted.

   **Other:**

3. **Other Identifiable Data Storage, Retention, and Destruction (Audiotapes, videotapes, photographs, etc.)**

   will be retained and stored securely (locked in cabinet or room) until:

   - Transcription is complete, then will be destroyed.
   - Analysis is complete, then will be destroyed.
   - Study is complete and file is closed.
   - Indefinitely. Provide justification for indefinite retention:

4. **Existing Biospecimens to be used in this study:**

   **HAVE NO PERSONAL IDENTIFIERS.**

   INCLUDE IDENTIFIERS AND ARE CODED; the PI **will not have access** to the link or code connecting the identifiers to the specimens.

   INCLUDE IDENTIFIERS, and the PI **has access** to those identifiers or to the link/code connecting specimens to individuals. The identifiers and/or code will be stored securely until the study is complete.

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**Federal regulations require that study data (physical or electronic records) must be retained for at least 3 years after study completion; but institutional requirements may be longer. (See: JHU policy as described here: http://jhuresearch.jhu.edu/Data_Management_Policy.pdf) There are no institutional prohibitions to electronic storage of study data, if allowed by the sponsor and appropriate for the study. FDA regulated studies may need to keep hard copies for audit purposes. The IRB may approve the destruction of study identifiers for participant protection purposes. The PI must explain the plan for the identifiers; whether they will be retained for the period of the study or longer, or whether and how they will be destroyed. Consent forms must also be retained for the same period as other study records, unless the IRB approves otherwise. If consent forms have signatures, and the PI wishes to destroy them for participant protection purposes, the rationale should be provided.**

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**B. Certificate of Confidentiality**

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*Instructional Research Plan for New Data Collection_ 19May2014*
Will the study data stored in the United States be protected by a Certificate of Confidentiality? If yes, explain who will apply for and maintain the Certificate. (http://grants.nih.gov/grants/policy/coc/appl_extramural.htm)

Certificates of Confidentiality are tools for protecting research information from legal process issued by the Federal, State, or local government for research conducted in the United States. They are not applicable to information held in other countries. The IRB will require a PI to acquire a Certificate of Confidentiality to protect sensitive personal information collected in a study which, if disclosed in court, could expose the participant to adverse legal, social, or economic consequences. Certificates of Confidentiality are awarded by application to NIH or one of the other federal agencies (such as the Dept. of Justice) which grants them.

If your study is part of a multi-site project, and is covered by a Certificate of Confidentiality obtained by the sponsor or lead site, please provide that information.

C. Data Security and Sharing

The PI has the responsibility to manage collection, storage, access, sharing, and destruction of study data. A tracking plan is advisable, as well as periodic verification that security measures are followed.

PIs have the responsibility for responsible stewardship of data and protecting data confidentiality. This responsibility includes protecting physical custody of the data, storage and sharing with appropriate data use agreements that contain the appropriate security provisions. Describe any additional plans beyond those identified in the table that you have for storing and sharing the study data and/or materials, and how responsibility for the data will be managed. Include the following details:

1. Where will the study data be stored?
2. Who controls access to the data?
3. Will data be shared only if de-identified?
4. What additional (if any) security controls will be in place?

VII. Risks of the Study

All studies pose some sort of risk or discomfort, even a survey study may introduce boredom or inconvenience to its participants. The PI must consider all reasonably foreseeable consequences of participation – the good and the bad – and describe them in the research plan. The consequences of a breach of confidentiality require particular thought. Consent documentation must be consistent with the risks listed here. Reportable “unanticipated problems,” which may later occur while the study proceeds, are those which are NOT identified here.

A. Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. These risks should be described in the consent documents.

The IRB weighs the risks you identify in this section, against the potential direct benefit to participants offered by study procedures, and against the new knowledge which could result from the study. It does make a difference whether the possibility of the harm from an identified risk happening is “likely” versus “rare”, or the frequency of occurrence is among “100%” of the study population versus “1%.” In addition, the severity of the known harm is important; for example, if diarrhea may occur, is it likely to last 1 day or 1 week? Will a psychological harm be temporary, or longer lasting? The PI should make an effort to provide the details of frequency and severity of possible harms so the IRB may better evaluate these factors, and ensure provision to potential participants more accurate information in the consent process.
B. Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing “x” test/assessment, or dispensing “y” drug, how often do you expect an “anticipated” adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?

C. Describe steps to be taken to minimize risks. Include a description of your efforts to arrange for care or referral for participants who may need it.

For clinical procedures, minimizing risk might include avoiding duplicating procedures the results of which may be available from the clinical record, or ensuring proper qualifications and training for the study team members who will perform the procedures. For psychological testing, minimizing risk might include providing adequate access to care for participants should a test reveal psychological distress. For a survey study involving collection of data about illegal behaviors, the precautions surrounding the timing and site of the data collection add protections which minimize risk. Data security minimizes risk of informational harm for all participants.

D. Describe the research burden for participants, including time, inconvenience, out-of-pocket costs, etc.

This section invites a description of the practical consequences associated with participant enrollment. How many visits or sessions does the study require, and how long will each of them take? Is transportation, distance or cost, an issue? These details should be included in the consent document.

E. Describe how participant privacy will be protected during data collection if sensitive questions are included in interviews.

Privacy involves the physical and personal zones where participants expect no “invasion” without explicit permission. For example, participants do not expect to have personal questions about their health conditions or their sexual behaviors asked in a place where other people can hear. They do not expect to have a physical exam in a place where others can watch. And they expect the sanctity of their homes to be respected; so if an investigator is permitted to enter the home, the investigator must clearly explain the parameters of that visit in the consent process and adhere to them during the visit. The research plan should address the privacy issues associated with the study.

VIII. Direct Personal and Social Benefits

A. Describe any potential direct benefits the study offers to participants (“payment” for participation is not a direct personal benefit).

The prospect of a direct benefit means that the objective of the study, if accomplished, may have a direct, positive impact on the participant. In general, that benefit must be something unavailable outside the research study. The IRB will take into consideration the site-specific availability of the potential benefit. Payment or tokens of appreciation are NOT benefits. Studies do not need to have specific direct benefits for participants; if there are no direct benefits to the participant, please state that fact explicitly.

B. Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

Benefit to society, or to the community, is a broader benefit usually connected to the scientific or clinical knowledge gained by the research. All studies should have some benefit to society.

IX. Payment:

A. Describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not “payment,” and if the study will reimburse, explain.

Payment for participation in the study may not unduly influence the potential participant’s decision to join. The type of payment (tokens, gifts, food, gift cards, cash) must be appropriate and clear, as must be the amount of
the payment and when it will be provided to participants. The information in this section must be consistent with the information provided in the consent form. The IRB will expect that if payment is offered, and the level of research burden on different groups of participants differs, payment will reflect those differences. Lotteries are discouraged because only the expectation of payment is equal across participants, not the payment itself.

B. Include the possible total remuneration and any consequences for not completing all phases of the research.

If payment to participants may come in increments, depending upon completion of various phases or procedures, those details must be provided here. The total amount of payment also must be provided. The plan for payment must be clear if a participant leaves such a study early, whether due to a change in eligibility, or a decision to terminate participation for any reason.

X. Study Management

A. Oversight Plan:

The adequacy of the oversight plan depends on the various factors which increase or decrease the possibility of noncompliance, harm to participants, and threats to data integrity and security. In general, there is no substitute for physical oversight by the PI to ensure appropriate study implementation and adherence to protocols. However, there are situations when oversight can be adequately provided remotely using well-developed channels of communication, monitoring and evaluation, particularly when there is clear delegation of duties to experienced co-investigators. Monitoring study operation may include the use of periodic audits of executed consent forms and research instruments submitted via email, videotaping of study procedures, and other methods of remote supervision.

1. Describe how the study will be managed.
2. What are the qualifications of study personnel managing the project?
3. How will personnel involved with the data collection and analysis be trained in human subjects research protections? (Use the JHSPH Ethics Field Training Guide on our website.)
4. If the PI will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.

B. Recordkeeping:

Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. For assistance, contact housecall@jhsph.edu.

C. Safety Monitoring

Describe the safety monitoring for the study, both at a site level (medical monitoring of participants enrolled at the specific study site), and for the study overall. Who will be responsible for reviewing safety reports and adverse event reports, and how will that information be communicated to individual sites? If an individual monitor is used, clarify what specific steps that person will follow to ensure participants safety.

1. Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role?
2. If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following:
   a. The DSMB membership, affiliation and expertise.
   b. The charge or charter to the DSMB.
   c. Plans for providing DSMB reports to the IRB.
3. Describe plans for interim analysis and stopping rules, if any.

D. Reporting unanticipated problems/adverse events (AE’s) to the IRB (all studies must complete this section):
Describe your plan for reporting to the IRB and (if applicable) to the sponsor. Include your plan for government-mandated reporting of abuse or illegal activity.

Describe the report plan for unanticipated problems/adverse events, including reports to sponsor, data coordinating center (if applicable), DSMB, and IRBs. JHSPH IRB policy requires prompt report of events that are: 1) unanticipated, 2) related to the study activity, and 3) harm, or pose harm to participants – using the Problem Event Report Form available on the IRB website. (See policy 103.06, available under “Policies” at this IRB website page: http://www.jhsph.edu/irb/Guidance_and_Policies.html). Other unanticipated events, and anticipated events which are consistent with those projected by the research plan and consent form, may be reported in the Progress Report.

NOTE: The IRB does not require submission for all AEs, only those that are unanticipated, pose risk of harm to participants or others, and are related to the study.

E. Other IRBs/Ethics Review Boards:
If other IRBs will review the research, provide the name and contact information for each IRB/ethics review board and its Federal Wide Assurance, if it has one (available on OHRP’s website at http://www.hhs.gov/ohrp/assurances). It is useful for the IRB to know how many IRBs are involved in the project, and what redundancies may exist in the review process. We need to know which IRBs have Federal Wide Assurances with the U.S. Government (see the OHRP website for IRBs that have FWAs). Additionally, for international studies, there must be local IRB/ethics board review to assure that the proposed research is culturally and legally appropriate. If there is no local board available, an alternative must be worked out with the reviewing IRB to assure that the research is culturally appropriate for the proposed local context, and that all local laws and regulations are followed.

F. Collaborations with non-JHSPH Institutions:
For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

The IRB will try to limit its review to the responsibilities of the JHSPH investigator and JHSPH agents. This section is critical – the more detail you provide about how responsibilities are delegated, and which collaborator has which responsibility, the better the JHSPH IRB may tailor its review. Our assumption is that collaborators who are direct grant recipients of federal funding, who have with significant responsibilities over data collection and/or informed consent (including hiring and/or supervising the data collectors), or who have access to identifiable private information, will have an IRB overseeing their human subjects research activities. It will not be the JHSPH IRB unless there is an agreement in place through which the JHSPH IRB agrees to assume that responsibility.

Insert Name of Institutions in Partner column(s); add additional columns if necessary.

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<th>JHSPH</th>
<th>Partner 1</th>
<th>Partner 2</th>
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<tr>
<td>Primary Grant Recipient</td>
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<tr>
<td>Collaborator</td>
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For the following, indicate “P” for “Primary”, “S” for “Secondary” as appropriate to role and level of responsibility.) Add additional items if useful.

1. Human subjects research ethics training for data collectors
2. Day to day management and supervision of data collection
3. Reporting unanticipated problems to the JHSPH IRB/Sponsor

4. Hiring/supervising people obtaining informed consent and/or collecting data

5. Execution of plan for data security/protection of participant data confidentiality, as described in Sect. 5.

6. Biospecimen processing, storage, management, access, and/or making decisions about future use

**COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY:**

### XI. Secondary Data Analysis of Existing Data

**A. Study Design**
1. Describe your study design and methods. The study design must relate to your stated aims/objectives.
2. Provide an estimated sample size and an explanation for that number.
3. Provide a brief data analysis plan and a description of variables to be derived.

**B. Participants**
1. Describe the subjects who provided the original data and the population from which they were drawn.
2. Describe whether the data contain personal identifiers of the individuals from whom the data originated. If yes, explain why you need them, and when and how you plan to dispose of them.
3. If you are receiving, accessing, or using data from a U.S. health care provider, the need for HIPAA review is likely. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. If either of these conditions is met, check “yes” to the HIPAA question in the PHIRST application.
4. If you plan to analyze human specimens or genetic/genomic data, provide details about the source of those specimens and whether they were collected using an informed consent document. If yes, explain whether your proposed use is “consistent with” the scope of the original consent, if it potentially introduces new analyses beyond the scope of the original consent, and/or if it introduces new sensitive topics (HIV/STDs, mental health, addiction) or cultural/community issues that may be controversial.
5. Explain whether (and how) you plan to return results to the participants either individually or as a group.

**C. Data Management**
Describe any additional plans beyond those described in Section VI that you have for storing and sharing the study data and/or materials, and how responsibility for the data will be managed.

The use of clinical data from Johns Hopkins Hospital and its affiliates requires a security review by Johns Hopkins Medicine. If you seek to access a dataset of 500 clinical records or larger, complete the **JHM Data Security Checklist** on the IRB Website.

### XII. Oversight plan for student-initiated studies:

JHSPH students are not faculty, thus the IRB needs to know how the faculty PI will ensure that the research will proceed in accordance with IRB approval. Please read the guidance posted on the IRB website, “What am I agreeing to do when I become a Principal Investigator on a JHSPH IRB protocol?” (see: [http://www.jhsph.edu/irb/Guidance_and_Policies.html](http://www.jhsph.edu/irb/Guidance_and_Policies.html).) The oversight requirements will vary depending upon collaborations in place, type of study procedures, complexity of the study, and academic degree sought.
A. For student-initiated studies, explain how the PI will monitor the student’s adherence to the IRB-approved research plan, such as communication frequency and form, training, reporting requirements, and anticipated time frame for the research. Describe who will have direct oversight of the student for international studies if the PI will not personally be located at the study site, with that person’s qualifications.

B. What is the data custody plan for student-initiated research? *(Note: Students may not take identifiable information with them when they leave the institution.)*

XIII. Creation of a biospecimen repository:

Biospecimen repositories may be created *de novo* through prospective collection of clinical specimens, or may remain after the primary study intervention is completed. In either case, the policies and procedures associated with the management, distribution, and use of those biospecimens must be clear to the IRB. The IRB is responsible for ensuring that participants understand how their specimens may be used and by whom, what risks are associated with those uses, and how those decisions will be made. They also need to know how they may withdraw consent later if they so decide.

Explain the source of the biospecimens, if not described above, what kinds of specimens will be retained over time. Clarify whether the specimens will be obtained specifically for repository purposes, or will be obtained as part of the core study and then retained in a repository.

A. Describe where the biospecimens will be stored and who will be responsible for them.

B. Describe how long the biospecimens will be stored, and what will happen at the end of that period.

C. Explain whether the biospecimens will be shared with other investigators, inside and outside of JHU, how the decision to share will be made, and by whom. Include the policy on commercial use and secondary distribution. Also explain how downstream use of the specimen will be managed, and what will happen to left-over specimens.

D. Describe whether future research using the biospecimens will include specimen derivation and processing (cell lines, DNA/RNA, etc.), genomic analyses, or any other work which could increase risk to participants. Explain what additional protections will be provided to participants.

E. If future research could yield unanticipated incidental findings (e.g., an unexpected finding with potential health importance that is not one of the aims of the study) for a participant, do you intend to disclose those findings to the study participant? Please explain your position.

**Investigators should consider whether or not to disclose incidental findings that may have some health significance to study participants and/or their families. The issue is complex and ethically challenging.**

F. Explain whether the specimens will be identifiable, and if so, how they will be coded, who will have access to the code, and whether the biospecimens will be shared in linked (identifiable) form.

G. Explain whether the repository will have Certificate of Confidentiality protections.

H. Explain whether a participant will be able to withdraw consent to use a biospecimen, and how the repository will handle a consent withdrawal request.

I. Describe data and/or specimen use agreements that will be required of users. Provide a copy of any usage agreement that you plan to execute with investigators who obtain biospecimens from you.

XIV. Data Coordinating Center:

Data coordinating centers generally do not include a clinical site – at least that’s true here at JHSPH. Only multi-center studies will require a DCC, and the PI must explain structure and organization of the consortium so that the IRB understands how decisions are made and information communicated to all sites. We are most concerned about adverse event evaluation and communication amongst all sites. The responsibilities of the DCC are significant, and the PI must explain the distribution of duties associated with this aspect of a study. Once a data coordinating center application is reviewed and approved, an IRB may consider the risks to participants associated with the study at the DCC site to be minimal, since no participants will be exposed to...
the study intervention at the DCC site. The IRB expects that in most cases, no identifiable personal information will transfer to the DCC; please be explicit if that expectation is not correct for your study.

Complete if JHSPH serves as the Data Coordinating Center.
A. How will the study procedures be developed?
B. How will the study documents that require IRB approval at each local site be developed? Will there be some sort of steering or equivalent committee that will provide central review and approval of study documents, or will template consent forms, recruitment materials, data collection forms, etc. be developed by and provided to the local sites by the coordinating center without external review?
C. Will each local clinical site have its own IRB with an FWA? State whether the coordinating center will collect IRB approvals and renewals from the clinical centers or not; if not, explain why not.
D. How will the coordinating center provide each local site with the most recent version of the protocol and other study documents? What will be the process for requesting that these updates be approved by local clinical center IRBs?
E. What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?
F. What is the process for reporting and evaluating protocol events and deviations from the local sites? Who has overall responsibility for overseeing subject safety: the investigators at the recruitment site, Coordinating Center, the Steering Committee, or a data and safety monitoring board (DSMB)? Is there a DSMB that will evaluate these reports and provide summaries of safety information to all the reviewing IRBs, including the coordinating center IRB? Please note that if there is a DSMB for the overall study, then the coordinating center PI does not have to report to the coordinating center IRB each individual adverse event/problem event that is submitted by the local site PIs.
G. Who is responsible for compliance with the study protocol and procedures and how will the compliance of the local sites be monitored and reviewed? How will issues with compliance be remedied?

XV. Drug Products, Vitamins, Food and Dietary Supplements

The IRB must have all available information about any products that human subjects will ingest or have inserted into their bodies. Some of these products will fall within the regulatory jurisdiction of the FDA or international regulatory authorities. Provide any information available about guidelines you are following, such as WHO guidelines, or about the regulatory approval, including importation if relevant, status of the product. Provide also clear information about what is standard care in the study site, and whether the drug regimen selected for the study is consistent with, or departs from, standard care. In cases where the regimen departs from the local standard of care, it may be helpful to note U.S. and/or WHO recommendations, if applicable.

Complete this section if your study involves a drug, botanical, food, dietary supplement or other product that will be applied, inhaled, ingested or otherwise absorbed by the study participants. If you will be administering drugs, please upload the product information.

A. List the name(s) of the study product(s), and the manufacturer/source of each product.

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<th>Name of study product</th>
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B. List each study product by name and indicate its approved/not approved status.

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<thead>
<tr>
<th>Approved by the FDA and Commercially Available</th>
<th>Approved by Another Gov’t Entity (provide name)</th>
<th>Cleared for Use at Local Study Site</th>
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Instructional_Research Plan for New Data Collection_19May2014
C. If your study product has an Investigational New Drug (IND) application through the U.S. Food and Drug Administration, provide the IND number and attach the Investigators Brochure and the Drug Data Sheet available on the IRB website.

D. If your study product is a marketed drug, provide the package inserts or other product information. If the study product WILL NOT be used for its approved indication, dose, population, and route of administration, provide a detailed rationale justifying the off label use of the study product.

E. If the study product is not an FDA approved drug, and is being used without an IND (e.g., dietary supplements, botanicals, etc.), provide safety information (as applicable) and a certificate of analysis.

F. Explain who will be responsible for drug management and supply, labeling, dispensing, documentation and recordkeeping,

G. What drug monitoring and/or regulatory oversight will be provided as part of the study?

XVI. Investigational Medical Devices

“Medical devices” include everything from bandaids to in vitro diagnostic devices; from medical software which calibrates drug dosing, to implants. For federally funded studies, and studies conducted in the United States, investigational devices fall under the FDA device regulations. Devices used in other countries must follow local laws and regulations.

Complete this section if your study will involve an investigational medical device (diagnostic, non-significant risk, significant risk).

A. List the name(s) of the study product(s), the manufacturer/source of each product, and whether or not it is powered (electric, battery). Provide product information. If it is electric, upload documentation of clinical engineering approval.

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B. List each study product by name and indicate it’s approved/not approved status.

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<th>Approved by the FDA and Commerically Available</th>
<th>Approved by Another Gov’t Entity (provide name and approval information)</th>
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C. If the investigational device is a Significant Risk Device, provide the IDE number given by the FDA, or if not under FDA jurisdiction, explain why it is appropriate to use this device in this study.

D. If you believe the investigational device is not IDE exempt under 21CFR 812.2(c), but is a “Non-Significant Risk” device considered to have an approved IDE application, provide information from the manufacturer supporting that position.

E. If your investigational device is Exempt from the FDA IDE regulations, explain which section of the code applies to your device and why it meets the criteria provided. If it is a diagnostic device, provide pre-clinical information about the sensitivity and specificity of the test and the anticipated failure rate. If you plan to provide the results to participants or their physicians, justify doing so.