**INSTRUCTIONAL TEMPLATE: JHSPH IRB Research Plan for New Data Collection**

*24Aug2021*

|  |
| --- |
| *For new data collection, new data collection plus secondary data analysis, biospecimen repositories, and data coordinating center protocols.* |

**This research plan is for projects that will collect new data, and may also utilize existing data or specimens. Please review the guidance we provide in the boxes to help you write your research plan. Provide the IRB with your research objectives, scientific rationale behind those objectives, and the scientific methods for achieving those objectives in accordance with regulatory and institutional requirements. In particular, provide specific details about how human participants will be involved in the research activity so that the IRB understands each interaction as a link in a chain from recruitment through follow up (if applicable) without any missing links. 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. Include references to documentation, including consent forms, assent scripts, oral scripts, telephone scripts, letters, etc. that will be used to communicate with participants. Explain the specific study procedures, including by whom, when, where, and so on. 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. Clarify the role of the JHSPH investigators and their collaborators, and confirm that each person who will obtain informed consent or collect data from participants will 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; provide the requested details about study oversight and management, including data sharing and security through the life of the data.**

**PI Name:**

**Study Title:**

**IRB No.:**      

**PI Version No. / Date:**

**I. Aims of the Study:** *Describe the aims/objectives of the research and/or the project’s research questions or hypotheses.*

Each aim/objective described in this section should be related to the background/rationale behind the study, and to the design, study population, and study procedures that will produce the data that will address each aim/objective.

**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 the state of the science, the study design, identified research population, and procedures as necessary. More invasive protocols require more extensive justification.

**III. Study Design:**

A. *Provide a BRIEF 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, distinguish the screening sample size from the enrolled sample size; a table may be helpful. For electronic survey studies involving online recruitment and survey completion: consider how you will set controls on how many people will join your study.*

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 for each study activity 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. If your project involves population surveillance or something similar such that it is not possible to determine how many individuals may be included, you may provide a rough estimate of individuals you estimate may be involved and/or households or communities that will be included.

C. *Does your study meet the NIH definition of “clinical trial”: “*“**A research study in which one or more human subjects are prospectively assigned to one or more interventions** (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes”? *If yes, the study must be listed on clinicaltrials.gov, study personnel must complete GCP training, and federally funded studies must post consent forms on approved sites, like clinicaltrials.gov.*

**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 or who are wards of the State. 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 these individuals to be secondary subjects and will evaluate 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. The IRB will consider other types of vulnerabilities that could affect an individual’s ability to provide a voluntary, informed consent free of coercion or undue influence.

1. **Inclusion Criteria:**

1. **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 convenience; 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 determines whether individuals meet eligibility requirements, and 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 (for example, to access existing medical records), 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 and upload the appropriate HIPAA application (JHM or non-JHM).*

**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 you will collaborate with other institutions or organizations, or plan to subcontract JHSPH responsibilities to others, make clear their responsibilities in the Study Oversight section of this document. Be aware that all recipients of federal funding for non-exempt human subjects research must have a Federal Wide Assurance (FWA) , which is a promise to comply with human subjects research regulations (see:* [*https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html*](https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html)*).*

*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.*

1. **Recruitment Process:**

The IRB review focuses heavily on all interactions with human participants and their personal information, starting with recruitment. This focus is more intense than what you might expect from the scientific reviewer of a grant application. We need all the incremental details. **If you have different subgroups that you will approach in different ways, separate out the groups into different descriptive sections.**

“Recruitment” includes any communication of information about the study to the target population with the intent to enroll individuals into a research study. 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, but not obtaining informed consent. 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 such that the recruitment interaction itself could expose individuals to risk. The PI must address this issue, and describe ways to minimize this risk. If the study involves populations (for example, men who have sex with men, 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 or social stigma 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 their qualifications*.

“Recruitment materials” include advertisements, posters, letters, flyers, information cards, study contact materials, video or audio presentations, scripts used before groups or on the telephone, social media applications, contests, lotteries, etc. The IRB must examine and approve each material, in English, and must also understand and approve the plan for its use. Once approved, documents for non-exempt studies 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. The translated items may or may not not be stamped, depending upon local IRB requirements.

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. Privacy includes physical privacy and the right of the individual to choose when and how to disclose personal information that otherwise would not be accessible. During recruitment, those expectations must be protected. Physical privacy requires study staff to be discreet when conducting research-related exams. Protecting informational privacy may also require discretion. 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 among them.

1. **Consent Process**:

The U.S. 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 individual should be sensitized to being able to assess when a potential participant understands what the study is about and whether or not the potential participant is literate and has mental capacity to provide informed consent. 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 and request a waiver of documentation.

If children will participate in the study, the PI must obtain permission from the parents or legal guardian of the children. The law of the research site jurisdiction governs the definition of “adult” and when a person reaches the “age of majority”. The PI should know what this age is and incorporate it into the research plan. Some jurisdictions permit minors to provide consent for certain health related services as adults (without parental involvement). In such cases, the minors are equivalent to adults – and it is not appropriate to ask for parental permission. There also may be studies for which parental permission is not a “reasonable requirement” because of family circumstances; for example, if the study involves children who have been abused or neglected by a parent. In such cases, parental permission may be waived and the PI must identify another mechanism for protecting the children, such as another, appropriate, adult advocate whose sole role is to advise the child about whether or not to participate in the study.

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; the PI must provide a justification and a request for waiver of documentation.

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*.

1. *Who will obtain informed consent, and their qualifications*:

1. *How, where, and when the consent discussion(s) will occur*:

1. *The process for determining whether a potential participant meets eligibility criteria. If you will collect personally identifiable information for screening purposes, collect only data needed for this purpose and explain what will happen to the data for individuals who are not eligible*:

1. *Whether you will obtain a signature from the participant or will use an oral consent process*:

1. *Whether you will obtain a legally authorized representative’s signature for adults lacking capacity*:

1. *If children are included in the study, if and how you will obtain assent from them*:

1. *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 any of the children are “wards of the state”, additional regulatory requirements will apply:*

1. *If you are seeking a waiver of informed consent or assent, the justification for this request*:

1. *Whether you will include a witness to the consent process and why*:

1. *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.

|  |  |  |
| --- | --- | --- |
| **Country** | **Consent Document(s)**  **(Adult Consent, Parental Permission, Youth Assent, etc.)** | **Languages** |
|  |  |  |
|  |  |  |
|  |  |  |

1. **Study Implementation**:

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, when, how, and by whom they will occur. Clinical procedures must be performed by trained clinicians. If laboratory tests are conducted, clarify whether test results will be returned to participants and/or their personal physicians.

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, or multiple phases, the PI must explain the procedures associated with each one and clearly separate them. It may be helpful to provide a table to explain the study procedures.

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. *Answer the following* ***if they are relevant to your study design***:

1. *If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.*

|  |
| --- |
| The IRB needs to know how the study team will make assignments, particularly in studies that use any type of randomization. Will you use a numerical sequence? Computer generated algorithm? This question relates to issues of masking, or blinding, study team members (see below). |

1. *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 in the Biospecimen Repository section. 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.

1. *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 and consistent with material transfer agreements and other contractual arrangements. 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. Be aware of the requirements of NIH’s Genomic Data Sharing Policy (see: <https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/>) if NIH is your sponsor.

1. *If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.*

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

1. *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.).* ***For clinical tests of human biospecimens, no results may be returned unless completed in a certified lab.*** *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*.

*In vitro* diagnostic tests are “medical devices” regulated in the U.S. by the FDA. FDA approved tests have a known sensitivity and specificity that give clinicians information about their reliability. Investigational tests are not validated, making the information they produce uncertain in their accuracy and value to the participant. The IRB needs to know how accurate diagnostic tests conducted in a research study are.

In general, the IRB will anticipate that clinicians are familiar with the sensitivity and specificity of approved tests. If those tests are used for standard of care purposes, and results provided to participants, the IRB will expect the study to provide the usual referrals that a participant may receive outside the study.

The IRB will consider results of all kinds of which, if disclosed to participants, may be used to make decisions about a participant’s welfare. The IRB will think about whether participants will consider having 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. (CLIA certified or CLIA waived) 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.

For other diagnostic tests not regulated by the FDA, such as psychological tests, the same principles apply. You may return the results of validated tests used routinely as standard care; unvalidated test results should not be returned to study participants as their accuracy is not well understood and could lead to misinformation. The IRB will consider how accurate proposed tests are and what the consequences may be for participants who receive the test results. If you are using diagnostic devices, please complete the “Medical Devices” section of this Research Plan.

1. *If your study involves medical, pharmaceutical or other therapeutic intervention, provide the following information:*
2. *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, pharmacists, statisticians, 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.

1. *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. Make sure to consider any risk to participants from the cessation of treatment, and include that risk in the research plan section on Risk and in the consent form.

1. *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. The IRB will want to review the ingredients of any placebo product that participants may ingest or absorb into their bodies.

1. *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.). Explain also the consequences of removal, including follow-up (for medical intervention studies), reduction in payment, use of data collected to date, etc.

1. *What happens to participants on a study involving a study product when the study ends*? *Will participants continue to have access to the study intervention? What happens if they leave the study early?*

The IRB’s concern for participant welfare extends to the end of that participation. If a participant’s care or access to care or other 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.

1. *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. This is true even for questionnaire and survey studies. 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. If a medical assessment or lab test uncovers a health concern, referral should be provided.

**VI. Data Custody, Management, Security, and Confidentiality Protections:** *Data security and management plans must meet institutional standards. If you need assistance, contact* [*jhsph\_cybersecurity@jhu.edu*](mailto:jhsph_cybersecurity@jhu.edu)*.*

Investigators are responsible for ensuring the safety and security of the data collected/used in a study from the time it is obtained until it is archived – through the entire life cycle of the data. Please answer all the questions below thinking about the protections that you will put into place to ensure confidentiality and integrity of the study data.

*Investigators are responsible for ensuring the security of data from the time of collection, through any transfers from one system to another, analysis, sharing, storage, and ultimate archiving and disposal. The questions below seek to elicit your plans for these protections. Feel free to add information.*

|  |
| --- |
| 1. **Data Sources**: Identify the source(s) of data. |
| Participant/Parent-Guardian/Legally Authorized Representative  JHM medical records (from Epic)  *Note: Please complete the* ***Data Trust Risk Tiers Calculator*** *available on the Applications and Forms page on the JHSPH IRB website:* [*https://www.jhsph.edu/offices-and-services/institutional-review-board/applications-and-forms/*](https://www.jhsph.edu/offices-and-services/institutional-review-board/applications-and-forms/)*, and upload a copy of the those documents to the “Miscellaneous” section of your PHIRST application. In addition, review the Data Protection Attestation for Research and/or Healthcare Operations at the link below and certify your attestation of compliance to those requirements: (*<https://intranet.insidehopkinsmedicine.org/privacy_office/_docs/additional_information/Data%20Protection%20Attestation.pdf>.  **I certify my attestation of compliance to JHM Data Protection Requirements**  non-JHM medical records  Outside data provider (CMS, National Death Index, Insurance Co., etc.)  Other existing records |
| 1. **Data Content**: Will you collect, use, and/or record personal identifiers about study participants for any purpose? Please look at the list of identifiers in Question 3 to help answer this question. **Note: Limited Data Sets (including dates, ages, and zip codes) are considered to be “identifiable”.** |
| Yes Continue with Question 3  No Skip to Question 9 |
| **3. Data Identification:** Identify the Personally Identifiable Information (PII)/Protected Health Information (PHI) you will access/collect by checking the boxes below for “Recruitment” and “Study Data” needs: |

|  |  |  |
| --- | --- | --- |
| Recruitment | Study Data | PII/PHI to be accessed/collected |
|  |  | Name, signature, initials or other identifiable code |
|  |  | Geographic identifier (address, GPS location, etc.) |
|  |  | Dates (birth, death, clinical service, discharge, etc.) |
|  |  | Contact information (phone number, email address, etc.) |
|  |  | Identification Numbers (SSN, driver’s license, passport, etc.) |
|  |  | Health Records Identifiers (medical record #, insurance plan, etc.) |
|  |  | Text of clinical record notes |
|  |  | Device identifiers (implants, etc.) |
|  |  | Internet identifiers (IP address, social media accounts, etc.) |
|  |  | Biometric identifiers (fingerprints, retinal scan, voice print, etc.) |
|  |  | Audio Recordings |
|  |  | Video or full-face photographic images |
|  |  | Genomic / Genetic data |
|  |  | Other identifiers: (list here) |

|  |
| --- |
| **4. Identifiers:** If you have checked any of the boxes above, how will you protect personal identifiers? |
| Will delete all identifiers (explain **when** you will delete identifiers):    Will separate identifiers from analytic data and will store the link/code. *Please explain where you will store link/code:*  Will use a method to make it harder to connect the data with the study participant (jiggering date, use other methods to obfuscate, etc.). *Please explain:* |
| 5. Will you obtain consent (or Authorization if governed by HIPAA) from participants for this study? |
| Yes  No |
| **6. Data Transit Plans and Protections:** Identifiable data may transfer, sometimes with multiple steps, from mechanisms for collection to storage. For example, participants may complete a web-based survey, which is then downloaded to a storage platform. Briefly identify these steps and the protections for each step (including encryption used at each step). |
| Will delete all identifiers prior to transfer  Will separate identifiers from analytic data and will store the link/code prior to transfer. *Please explain where you will store link/code:*  Other: |
| **7.** **Device(s) used for data collection:** Identify the computing device(s) being used for identifiable data receipt/collection. Check all that apply. |
| Provided or managed by JHSPH IT  Study-provided, and not managed by JHSPH IT. These must include the following protective controls:   * Data encrypted while “at rest” (on a storage device) * Security patches and updates are routinely or automatically applied * Devices have access controls so that:   o Each person accessing the device is uniquely identified (username)  o Passwords are sufficiently strong to prevent compromise  o All access is logged and recorded  o Unauthorized access is prevented   * Approved access list is reviewed periodically for correctness * Other. Specify: |
| **8. Data Collection:** Describe the format of data received/collected. Check all that apply. |
| Paper/Hard Copy (must be secured in transit and placed in a secure cabinet/room)  Audio recording  Video recording  Received directly by research team member and entered into file/database  Mobile or Web App (custom developed). *Review* [*guidance*](https://www.jhsph.edu/offices-and-services/institutional-review-board/_pdfs-and-docs/JHU_Guidance_Regarding_Security_of_Custom_Developed_Mobile_and_Web_Applications.docx2.pdf) *and provide attestation of compliance*  Mobile or Web App (purchased). *Specify product and version*:  Online survey. *Specify mechanism/platform*:  3rd party collector. *Specify*:  Existing data shared with JHSPH by data provider via electronic access/transfer  Duplicate and backup copies will be secured with same rigor as original data  Other. *Specify*: |
| **9. Devices/Platforms used for Analysis, Storage, Processing:** Identify where the identifiable or de-identified data will be analyzed/stored. Check all that apply. |
| Pre-approved storage and analysis platforms managed by JH/JHSPH for which security and risk mitigation measures are known.  *Identify preapproved storage platform(s) being used:*  **JHM Preferred:** **Other Approved**:  JH SAFE Desktop  JH OneDrive/JHSPH OneDrive  JHSPH HPCC  JH PMAP  JHSPH Shares  JHM/JHSPH Qualtrics  JHSPH Sharepoint  MARCC Secure Environment  JHU RedCap  JH IT-managed Network Storage    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Platform(s) not managed by JH/JHSPH, not pre-approved, and require a risk assessment review from JHSPH Data Security. Describe:  *Describe risk mitigation measures in place:*  Note: The following are examples of platforms/storage solutions that are **not pre-approved to store identifiable information** and require a risk assessment from JHSPH Data Security.   * Other solutions not managed by IT@JH, e.g., commercial cloud storage (Box, Dropbox, iCloud, personal OneDrive, Google Drive, Amazon storage, etc.) * JHU Independent Departmental Servers * Local Computer owned by JH * Other computers or devices owned/managed by study team members and used for other than secure web access * USB/Portable data storage device |
| **10. Access to Data and Access Controls:** How will you ensure that only authorized individuals can access the data? What access controls will you put into place to ensure that only authorized individuals may access and use the data. (For example, OneDrive [*guidance*](https://my.jhsph.edu/Offices/InformationTechnology/ComputerSupport/SharedFolders/OneDrive-JHSPH/Documents/JHSPHGuidanceRegardingOneDriveSharing.pdf) illustrates how to share files with “people you specify”. [*JHSPH-Shares*](https://my.jhsph.edu/Offices/InformationTechnology/ComputerSupport/SharedFolders/jhsph-shares/Pages/default.aspx) addresses providing permissions to individual people.) Check all that apply. Note: If you need assistance implementing secure access controls, contact [*jhsph\_cybersecurity@jhu.edu*](mailto:jhsph_cybersecurity@jhu.edu)*.* |
| Will provide access to data in accordance with OneDrive/JHSPH-Shares guidance posted on JHU IT websites  Will use secure access controls to limit access to individual-level data  Will use secure access controls to provide other researchers controlled access only to aggregated study data |
| **11. Data Sharing:** Clarify if data are to be shared externally with third parties, including sponsors and other investigators, and whether only aggregated data will be shared, or if you will share individual-level data. Describe sharing and protection plans for that sharing, including the proposed use of data agreements.  *Consider the following:*   * *Information about your data sharing in the consent forms* * *Information about data sharing laws in the country where data will be collected, and if they limit sharing, how you will comply with those limitations?* * *Whether data will be shared in aggregate only, or individual level data* * *Whether you plan to make the data publicly available, and in what form.* |
| Will not share data with outside investigators  Will share aggregated data only  Will share individual-level data without identifiers  Will deposit data into an existing data repository for future research (e*xplain*):  Other sharing information: |
| **12. Duration and Destruction**: Explain how long data will be retained and the plan for eventual return, deidentification or destruction of data, including moving data to an archive. |
|  |

1. **Certificate of Confidentiality:**

*All NIH studies include Certificate of Confidentiality (C of C) protections with the grant; the consent form must include the C of C language provided in our template. Other funders may obtain C of C protections through NIH. (*[*https://humansubjects.nih.gov/coc/index*](https://humansubjects.nih.gov/coc/index)*)*

Does the study have Certificate of Confidentiality protections? Yes  No

**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 to participants, possible secondary subjects, and to the community – 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.

1. *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. Include risks beyond individuals to include the study population as a group and community risks. Ensure that the risks described in the consent documents are consistent with the risks outlined in the research plan*.

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. If the study may pose risks to a community, such as potential stigma, those risks should be addressed.

1. *Describe steps you will take to mitigate or minimize each of the risks described above. 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.

1. *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?*

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 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.

1. *Describe the research burden for participants, including time, inconvenience, invasion of privacy in the home, 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.

1. *Describe how participant privacy, and if relevant – family privacy - will be protected during data collection if sensitive questions are included in interviews, or if study visits occur in the home setting.*

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:**

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.

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

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

**IX. Payment or Token of Appreciation:**

For studies that offer no direct personal benefit, the IRB will expect the study to provide some token of appreciation if allowed by the local IRB. 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.

1. *Do you plan to provide a non-monetary token of appreciation (food, soap, tea, chlorine tablets, etc.) to study participants? If no payment is provided, the JHSPH IRB strongly encourages providing such tokens. If yes, please describe below.*

1. *If you plan to provide a monetary payment, 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*.

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

**X. Study Management:**

A. **Oversight Plan:**

The adequacy of the oversight plan depends on the various factors which increase or decrease the possibility of protocol 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 who are faculty-equivalents. 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 implemented*.  *List all parties, including collaborators and subcontractors, who will be “engaged” in the human subjects research project and their roles .*

According to the U.S. Office of Human Research Protections (OHRP), an investigator is “engaged” in human subjects research if they are a direct prime grant recipient (even if not collecting data), are obtaining informed consent from study participants, or are interacting directly or indirectly with study participants and/or their identifiable data or biospecimens. Referring people to a study does not make someone “engaged”, nor does merely providing identifiable information. The IRB can assist with making the “engaged” determination. The JHSPH IRB only oversees JHU faculty and staff, unless it has entered into a reliance agreement of some sort with another institution under which it agrees to take on the responsibility for overseeing the human subjects research activities of another institution or an external investigator who is reporting directly to the JHSPH PI. Other investigators must have IRB oversight by an IRB of an institution with which the individual has a formal association, e.g. is employed by, or is the agent of for purposes of performing human subjects research activities.

1. *What are the qualifications of study personnel implementing the project*?

The IRB is responsible for ensuring that study personnel and investigators are qualified to perform the study procedures for which they are responsible. These qualifications go beyond ethics training as preparation and could involve specific expertise in the clinical, quantitative, qualitative, coordinating, repository, and analytic activities outlined in this research plan.

1. *How will non-professional personnel (data collectors) involved with the data collection and analysis be trained in human subjects research ethical protections? (Use the JHSPH Ethics Field Training Guide and Social/Behavioral GCP training Guide available on the JHSPH IRB website*: (<https://publichealth.jhu.edu/offices-and-services/institutional-review-board-irb/training>, and if the study is a clinical trial, consider using the JHSPH Good Clinical Practice (GCP) For Social and Behavioral Research Field Guide).
2. *If the JHSPH PI is responsible for data collection and 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. **Protocol Compliance and** **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@jhu.edu](mailto:housecall@jhu.edu)) *Please provide information about study oversight to ensure compliance with IRB approval and regulatory and institutional requirements.*  *If the study team does not follow study procedure, what is your plan for reporting protocol non-compliance?*

1. **Safety Monitoring:**

The IRB is responsible for ensuring that participant safety is ensured for the study. 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. For medical intervention studies involving more than minimal risk, safety oversight may require the creation of a Data Safety Monitoring Board or Committee with a charter that outlines their objective, or charter, the data they will review and the frequency of that review. It may be that the DSMB will set stopping rules for clinical trials or review data after a certain number of participants are enrolled. For less risky studies, or studies that will enroll fewer people, a medical monitor may be appropriate for safety oversight. Resource: <https://www.nimh.nih.gov/funding/clinical-research/nimh-policy-governing-the-monitoring-of-clinical-trials>. Please provide the details of your safety plan in this section.

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 and what is that person’s specific charge?*

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*.

1. *Describe plans for interim analysis and stopping rules, if any*.

1. **Reporting Unanticipated Problems/Adverse Events (AEs) to the IRB (*all studies must complete this section*)**:

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

***Anticipated*** *AEs may be reported with the Continuing Review/Progress Report.*

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) cause harm, or pose harm to participants – using the Problem Event Report available through PHIRST. (See policy 103.06, available under “Policies” at this IRB website page: <https://my.jhsph.edu/sites/ors/_layouts/15/WopiFrame.aspx?sourcedoc=%7BF83C983B-AA09-4600-AF16-4B56CCFDE149%7D&file=JHSPH%20IRB%20Policies_updated_22Nov2019_Clean.docx&action=default> ). Other unanticipated events that don’t pose risk of harm but could affect the conduct of the study, and anticipated events which are consistent with those projected by the research plan and consent form, may be reported in the Continuing Review/Progress Report.

*Describe your plan for reporting to the JHSPH IRB, local IRBs, and (if applicable) to the sponsor. Include your plan for government-mandated reporting of child abuse or illegal activity*.

E. **Other IRBs/Ethics Review Boards:**

*If other IRBs will review the research, provide the name of each IRB/ethics review board and its Federal Wide Assurance number, if it has one (available on OHRP’s website at* [*http://www.hhs.gov/ohrp/assurances*](http://www.hhs.gov/ohrp/assurances)*).* ***For federally funded studies, subrecipients MUST have a Federal Wide Assurance (FWA) number from the OHRP. The IRB overseeing the subrecipient should be registered with the OHRP. The JHSPH IRB will not have oversight responsibility for international subrecipients, and generally will not oversee data collection at external U.S. institutions Please contact jhsph.irboffice@jhu.edu with questions.***

|  |  |
| --- | --- |
| **Non-JHSPH IRB/REC** | **FWA Number** |
|  |  |
|  |  |
|  |  |

F. **“Engaged” in Human Subjects Research:**

*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.*

**Insert collaborator names and FWA numbers, if available. Note who will be “engaged” in human subjects research by filling in the following table:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | JHSPH |  |  |
| For federally funded studies, collaborators’ FWA | 00000287 |  |  |
| Primary Grant/Contract Recipient |  |  |  |
| Grant/Contract Subrecipient |  |  |  |
| Hiring Data Collectors |  |  |  |
| Training Data Collectors |  |  |  |
| Obtaining Informed Consent and/or Identifiable Data |  |  |  |
| Accessing/Analyzing Identifiable Data |  |  |  |
| Overseeing storage, access and use of biospecimens |  |  |  |

**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*.

1. *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.*

*Note: 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.*

1. *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.*

1. *Explain whether (and how) you plan to return results to the participants either individually or as a group*.

**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: <https://www.jhsph.edu/offices-and-services/institutional-review-board/_pdfs-and-docs/pi-responsibilities-final-2010-01-21.pdf> .) The oversight requirements will vary depending upon collaborations in place, type of study procedures, complexity of the study, and academic degree sought.

1. *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, and their qualifications.*

1. 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, and 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.*

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

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

* 1. *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 your plans, if any, for commercial use. Also explain how downstream use of the specimen will be managed, and what will happen to left-over specimens*.

* 1. *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.*

* 1. *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.*

* 1. *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*.

* 1. *Explain whether the repository will have Certificate of Confidentiality protections.*

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

* 1. *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:**

*Complete if JHSPH serves as the Data Coordinating Center for a multi-site study.*

Data coordinating centers often 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.

1. *How will the study procedures be developed?*

1. *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?*

1. *Will each local clinical site be overseen by its own IRB with an FWA, or will a Single IRB review the study? State whether the coordinating center will collect IRB approvals and renewals from the clinical centers; if not, explain why.*

1. *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?*

1. *What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?*

1. *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, the 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.*

1. *Some FDA regulated studies have different AE reporting criteria than that required by the IRB (IRB Policy No. 103.06). How will you reconcile the different requirements, and who is responsible for this reconciliation?*

1. *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:**

*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.*

The IRB must have all available information about any products that human subjects will ingest or have absorbed 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.

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

|  |  |
| --- | --- |
| **Name of Study Product** | **Manufacturer/Source** |
|  |  |
|  |  |
|  |  |

1. *List each study product by name and indicate its approved/not approved status.*

|  |  |  |
| --- | --- | --- |
| **Approved by the FDA and Commercially Available** | **Approved by Another Gov’t Entity (provide name)** | **Cleared for Use at Local Study Site** |
|  |  |  |
|  |  |  |
|  |  |  |

1. *If your study product has an Investigational New Drug (IND) application through the U.S. Food and Drug Administration, provide the IND number, and the Investigators Brochure.*
   1. *Who will hold the IND?*

1. *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.*

1. *If the study product does not require FDA approval (e.g., dietary supplements, botanicals, products not subject to the U.S. FDA, etc.), provide safety information (as applicable) and a certificate of analysis.*

1. *Explain who will be responsible for drug management and supply, labeling, dispensing, documentation and recordkeeping.* *Complete and upload into PHIRST the Drug Data Sheet available on the JHSPH IRB website at* [*https://publichealth.jhu.edu/offices-and-services/institutional-review-board-irb/forms*](https://publichealth.jhu.edu/offices-and-services/institutional-review-board-irb/forms)*.*

1. *What drug monitoring and/or regulatory oversight will be provided as part of the study? Please describe.*

**XVI. Medical Devices:**

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

“Medical devices” may include everything from bandaids and mobile apps 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.

1. *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 or its equivalent from a local authority, to ensure that the device is in good working order.*

|  |  |  |
| --- | --- | --- |
| **Name of Study Product** | **Manufacturer/Source** | **Powered?** |
|  |  |  |
|  |  |  |
|  |  |  |

1. *List each study product by name and indicate its status as approved by a government authority or not approved.*

|  |  |  |
| --- | --- | --- |
| **Approved by the FDA and Commercially Available** | **Approved by Another Gov’t Entity (provide name and approval information)** | **Not Approved** |
|  |  |  |
|  |  |  |
|  |  |  |

1. *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, and explain how those results will validated (or not) against the current “gold standard”.*

1. *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.*

1. *If you are using an investigational device that 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. Provide a description of the device, and upload a picture or manufacturing schematics into PHIRST. Provide any other information relevant to a determination of its safety to be used for the purposes outlined in this research plan.*