

**Institutional Review Board Member Review of Proposal**

**(Expedited or Full Committee Review)**

**Proposal Title:**

**PI:**

**Type of Review (Initial or Resubmission):**

|  |  |  |  |
| --- | --- | --- | --- |
| **General Overview** | **Yes** | **No** | **N/A** |
| Do the research questions/ hypotheses/ outcomes align with the stated purpose or aims of the study? |  |  |  |
| Are descriptions of how each question/ hypothesis/ outcome will be measured clearly stated? |  |  |  |
| Do measurement tools (e.g., surveys, interview guides, observations, etc.) seem appropriate to gather the data needed to address study questions/ hypotheses/ outcomes? |  |  |  |
| **Comments**: | | | |
| **Recruitment of Subjects** | **Yes** | **No** | **N/A** |
| Do the planned sampling procedures appear appropriate to obtain a sample well-poised to address the study’s purpose, aims, and questions? |  |  |  |
| Is the recruitment source(s) sufficient to provide an appropriate sample? |  |  |  |
| Do criteria for inclusion/ exclusion appear reasonable? |  |  |  |
| Will the burdens and benefits of study participation (equity) be shared reasonably among categories of potential subjects?  *Source: 45 CFR Part 46.111(a)(3)* |  |  |  |
| Does the collection of personally identifiable and/ or sensitive information about subjects appear reasonable considering the study’s purpose/ aims/ questions? |  |  |  |
| **Comments**: | | | |
| **Criteria for Informed Consent** | **Yes** | **No** | **N/A** |
| Will informed consent (either written or oral) be provided to each prospective subject or the subject’s legal representative?  *Source: 45 CFR Part 46.111(a)(4)* |  |  |  |
| Unless a waiver is approved (see below), will documentation of informed consent (signed informed consent form) be appropriately collected?  *Source: 45 CFR Part 46.111(a)(5)* |  |  |  |
| Does the informed consent process allow the potential subject or his or her legal representative sufficient opportunity to discuss and consider whether to participate and minimize the possibility of coercion or under influence?  *Source*: *45 CFR Part 46.116(a)(2)*  Points to Consider:   * Has the investigator indicated whether consent will be obtained from the participant, from a legally authorized representative, or both? * Are steps taken to help the participants or representatives understand the facts? * Are adequate steps taken to help the participants or representatives understand the research and the associated ramifications? * Does the investigator adequately address how he/she will determine that a subject understands the research prior to providing consent/assent? * Is adequate time devoted to the consent discussion and decision-making process? * Do the circumstances of consent minimize the possibility of coercion or undue influence? * Have all issues regarding the capacity to decide been addressed? * Are consent procedures well defined? * Is the timing, location, and setting of obtaining consent acceptable? * Are payment arrangements acceptable? |  |  |  |
| Will the language of informed consent information and/or documents be provided in a language and format understandable to the subject or the subject’s legal representative (e.g., reading level, formatting, etc.)? *Source: 45 CFR Part 46.116(a)(3)*  Points to Consider**:**   * What language do the participants or representatives speak? * Can the research team communicate in understandable language to the participants or representatives? * Will written information be in the language understandable to the participants or representatives? |  |  |  |
| Will the informed consent information and/or documents include the information that a reasonable person would want to have to make an informed decision about whether to participate?  *Source: 45 CFR Part 46.116(a)(4)* |  |  |  |
| Will the informed consent information and/or documents present information in a manner that begins with key information and includes information in sufficient detail that a reasonable person would want to have to make an informed decision about whether to participate?  *Source: 45 CFR Part 46.116(a)(5)* |  |  |  |
| Will informed consent information and/or documents be free of exculpatory language through which the subject or subject’s representative waives or appears to waive legal rights or releases investigators, sponsors, or institutions from liability for negligence?  *Source: 45 CFR Part 46.116(a)(6)* |  |  |  |
| Will informed consent information and/or documents include a statement that the study involves research, provide an explanation of the purposes of the research, describe the estimated duration of the subject’s participation, provide a description of the procedures to be followed, and identify procedures (if any) that are experimental?  *Source: 45 CFR Part 46.116(b)(1)* |  |  |  |
| Will informed consent information and/or documents include a description of foreseeable risks or discomforts to the subject?  *Source: 45 CFR Part 46.116(b)(2)* |  |  |  |
| Will informed consent information and/or documents include a description of benefits to the subject that may be reasonably anticipated?  *Source: 45 CFR Part 46.116(b)(3)* |  |  |  |
| Will informed consent information and/or documents include a disclosure of alternative procedures / treatment (if any) that might be advantageous to the subject?  *Source: 45 CFR Part 46.116(b)(4)* |  |  |  |
| Will informed consent information and/or documents include a description of the extent to which confidentiality of records identifying the subject will be maintained?  *Source: 45 CFR Part 46.116(b)(5)* |  |  |  |
| *If the study will involve more than minimal risk*, will informed consent information and/or documents include an explanation as to whether any compensation will be provided and an explanation as to whether treatments are available if injury occurs, and if so, what they consist of and where further information may be obtained?  *Source: 45 CFR Part 46.116(b)(6)* |  |  |  |
| Will informed consent information and/or documents include information on whom to contact for questions about the study, subjects’ rights, and where to report research-related injuries or concerns?  *Source: 45 CFR Part 46.116(b)(7)* |  |  |  |
| Will informed consent information and/or documents include a statement that participation is voluntary, that refusal to participate will incur no penalties or loss of benefits to which the subject is otherwise entitled, and that the subject may withdraw at any time without penalty or loss of benefits to which the subject is otherwise entitled?  *Source: 45 CFR Part 46.116(b)(8)* |  |  |  |
| For research involving the collection of identifiable private information or identifiable biospecimens, does the informed consent information include one of the following statements?   1. A statement that once identifiers are removed from information or biospecimens, information or biospecimens *may* be used for future research or sent to other researchers without additional informed consent; or 2. A statement that the subject’s information or biospecimens, even with identifiers removed, will *not* be used or distributed for further research.   *Source: 45 CFR Part 46.116(b)(9)* |  |  |  |
| *If appropriate*, will informed consent information and/or documents include a statement that particular treatments or procedures may involve risks to the subject (or to the embryo or fetus if the subject becomes pregnant) that are currently unforeseeable?  *Source: 45 CFR Part 46.116(c)(1)* |  |  |  |
| *If appropriate*, will informed consent information and/or documents include a statement of any unanticipated circumstances under which the subject’s participation may be terminated by the investigator without the subject’s consent?  *Source: 45 CFR Part 46.116(c)(2)* |  |  |  |
| *If appropriate*, will informed consent information and/or documents include information about costs to the subject as a result of participation?  *Source: 45 CFR Part 46.116(c)(3)* |  |  |  |
| *If appropriate*, will informed consent information and/or documents include a discussion of the consequences for withdrawal from the study and procedures for orderly termination of participation?  *Source: 45 CFR Part 46.116(c)(4)* |  |  |  |
| *If appropriate*, will informed consent information and/or documents include a statement that should new findings develop during the course of the study that might influence a subject’s willingness to continue participation will be provided to the subjects?  *Source: 45 CFR Part 46.116(c)(5)* |  |  |  |
| *If appropriate*, will informed consent information and/or documents include the approximate number of subjects involved in the study?  *Source: 45 CFR Part 46.116(c)(6)* |  |  |  |
| *If appropriate*, will informed consent information and/or documents include a statement that biospecimens (even with identifiers removed) may be used for commercial profit and whether or not subjects will share in the commercial profit?  *Source: 45 CFR Part 46.116(c)(7)* |  |  |  |
| *If appropriate*, will informed consent information and/or documents include a statement as to whether clinically relevant research results will be disclosed to subjects, and if so, under what circumstances?  *Source: 45 CFR Part 46.116(c)(8)* |  |  |  |
| *For research involving biospecimens*, will informed consent information and/or documents include a statement as to whether whole-genome sequencing will occur?  *Source: 45 CFR Part 46.116(c)(9)* |  |  |  |
| Will a copy of informed consent information and/or documents be provided (or available online) to the subject or the subject’s legal representative?  *Source: 45 CFR Part 46.117(a)* |  |  |  |
| **Comments**: | | | |
| **Criteria for Waiver of Documentation of Signed Informed Consent** | **Yes** | **No** | **N/A** |
| Has the investigator requested a waiver for the *documentation* of signed informed consent? (If “NO”, proceed to the next section.) |  |  |  |
| If “Yes”…  Would a signed informed consent form be the only record linking the subject’s identity to the study; AND would the principal risk for potential harm be the breach of confidentiality? (Each subject or legal representative will be asked whether he or she wants documentation linking him or her to the research. The subject’s wishes will govern as to whether a signed informed consent form is obtained.)  -or-  Does the study present with no more than minimal risk AND involve no procedures for which written informed consent is normally required outside the research context?  -or-  Does the subject belong to a distinct cultural group or community in which signing forms is not the norm (as identified by the investigator), AND the research presents no more than minimal risk of harm to subjects, AND subjects will be provided an appropriate alternative mechanism for documenting that informed consent was obtained? |  |  |  |
| If “Yes” to any of the above pairs of statements, a waiver for the requirement for documentation of informed consent may be provided.  *Source: 45 CFR Part 46.117(c)(1)* |  |  |  |
| If the waiver for documentation of signed informed consent is granted, will subjects or their legal representatives receive written information about the research?  *Source: 45 CFR Part 46.117(c)(2)* |  |  |  |
| Is the request for waiver of documentation of signed informed consent approved? |  |  |  |
| **Comments**: | | | |
| **Risks and Benefits** | **Yes** | **No** | **N/A** |
| Are risks to subjects minimized by using either a) procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk and, b) when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes?  *Source: 45 CFR Part 46.111(a)(1)*  Points to Consider:   |  |  | | --- | --- | | * Are the aims and objectives clearly defined? * Are there adequate preliminary data and/ or is there appropriate justification for the research? * Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question? * Are there qualified staff and resources to conduct the research? * Is there appropriate monitoring of the subject during and after the research? * Are medical or psychological resources available that participants might require because of the research?  |  | | --- | | * Are procedures that will answer the scientific question being performed anyway? If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm? * Is there a clear differentiation between research and standard of care procedures? * Are adequate references provided? | | |  |  |  |
| Are risks to subjects reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result?  *Source: 45 CFR Part 46.111(a)(2)*   |  | | --- | | Points to Consider:   * Consider physical, psychological, social, legal, and economic risks. Are the risks and benefits adequately described? * Does the investigator have access to a population that will allow the recruitment of the necessary number of participants? * Does the investigator have sufficient time to conduct and complete the research? * Is the research and timeline for completion feasible? * Does the knowledge expected to result have importance? * Are there adequate plans to notify the subjects about the research results? | |  |  |  |
| Do the risks posed to potential subjects meet the definition of “minimal risk”?\* (If “No”, you must notify the IRB Administrator; studies involving more than minimal risk must be reviewed by the full IRB committee.)  \*“*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (45 CFR 46.102[j]) |  |  |  |
| If applicable, are compensation, incentives, rewards, gifts, or other benefits sufficiently low so as not to exert an undue influence on subjects’ participation? |  |  |  |
| If applicable, are any costs to subjects clearly delineated in information materials provided to subjects? |  |  |  |
| If applicable, (***not applicable if the research involves no more than minimal risk***) does the proposed study plan make adequate provision for monitoring the data of subjects to ensure the ***safety*** of subjects?  *Source: 45 CFR Part 46.111(a)(6)*  Points to Consider**:**  Does the protocol adequately specify?   * Who will monitor the data? * What data will be monitored? * How frequently will data be monitored? * What analyses will be performed on the data? * What decision rules (e.g., stopping rules) will be considered? * Is there a plan to promptly detect unexpected harms or an increase in frequency or severity of harms? * Is there an adequate plan to stop the protocol if benefits are proven to outweigh harms or harms are proven to outweigh benefits? |  |  |  |
| Will there be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data?  *Source: 45 CFR Part 46.111(a)(7)*  *Example considerations:*   * *Is the plan to secure data and information clearly articulated and appropriate to the study?* * *Are there clear rationales for each type of identifiable private information and/or biospecimens collected?* * *Will physical files be stored in a secure manner?* * *If the subject is required to download an app or software as part of the study, does the informed consent process include potential risks and terms and conditions associated with downloading the product(s)?* * *For data, information, and files that will be stored electronically:*   + *Will secure servers with password-only access be used for storage?*   + *If mobile devices will be used, will sensitive files and information be encrypted?*   + *Will sensitive data not be stored on a commercial cloud (i.e., non-private cloud or account)?*   + *Will identifiable private information linked to data not be sent via email, text, or social media post from subject to researcher?*   + *Will identifiable private information, such as a code list, be stored separately from the data?*   + *Is there a plan should mobile devices be lost or stolen?* |  |  |  |
| Will there be additional safeguards and protections to protect the rights and welfare of subjects vulnerable to coercion or undue influence?  (Children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons)  *Source: 45 CFR Part 46.111(b)*  Points to Consider**:**   * Will confidentiality be pledged? * Are there adequate provisions to protect the confidentiality of the data? * Are there legal/ethical requirements to breach confidentiality and is this well described and addressed? * Will data release cause risk of harm? * Are appropriate techniques being used to protect confidentiality (storage, coding, use of identifiers) * Does the protocol and consent specify where the data and consent form will be stored? |  |  |  |
| **Comments**: | | | |
| **Conflicts of Interest** | **Yes** | **No** | **N/A** |
| Are any conflicts of interest apparent and/ or reported? (If “Yes”, please contact the IRB Administrator.) |  |  |  |
| **Comments**: | | | |
| **Other Criteria/ Miscellaneous** | | | |
| **Comments**: | | | |

**Date Reviewer’s Review Submitted to IRB Chair:**