**IRB**

Name:

IRB File No.:

Date Received:

 **Full Board Review Checklist**

**Protocol Information**

**Title of Project:**

**Principal Investigator:**   **Co-PI / Faculty Sponsor:**

**Department:**  **IRB Review Date:**

|  |
| --- |
| **Risk / Benefit Assessment** |
| **Level of Risk*****A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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(i)]******Also consider risk related to invasion of privacy and breach of confidentiality, if identification of the subjects******and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the******subject’s financial standing employability, insurability, reputation, or be stigmatizing, unless reasonable and******appropriate protections will be implemented. [63 FR 60364]*** **[ ]  No more than minimal risk to subjects** **[ ]  Greater than minimal risk**  |
| **Benefit*****A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.*** **[ ]  Prospect of direct benefit to individual subjects** **[ ]  No prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge** **about the subjects’ disorder or condition** |
| **Review Recommendation Summary** |
|  **IRB Action (*check one*):** **[ ]  Approved** * **Continuing Review Frequency (*check one*):** [ ]  **12 months** [ ]  **Other: \_\_\_\_\_\_\_\_\_\_\_\_**
* **Continuing Review may be conducted by:** [ ]  **Expedited Review** [ ]  **Full Board**

 **[ ]  Modifications required to secure approval (*see comments on following pages)*****[ ]  Modifications to be reviewed by designated reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****[ ]  Modifications to be reviewed at IRB meeting** **[ ]  Research not approved (*see comments below*)** **Comments:** |
| **Signature of IRB Chair:** | **Date:** |
|  **Regulatory Criteria for Review and Approval** |
| **1. Risks to subjects are minimized**  (45 CFR 46.111a(1)) | [ ]  **Yes** [ ]  **No** |
| *Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation**in a research study.***Considerations:**□ Risks are minimized using procedures which are consistent with sound research design and which do not  unnecessarily expose subjects to risk□ Adequate provisions are in place to minimize research risk, especially for those with any special physiological,  psychological, or social characteristics that could pose special risk □ Research personnel are qualifiedCOMMENTS: |
| **2. Risks are reasonable in relation to anticipated benefits, if any, to subjects,** **and the importance of the knowledge that may reasonably be expected to** **result** (45 CFR 46.111a(2)) | [ ]  **Yes** [ ]  **No** |
| *Benefit: Something of health-related, psychological, or other value to an individual research subject, or something that**will contribute to the acquisition of generalizable knowledge.***Considerations:**□ Consider only those risks and benefits that may result from the research, not risks and benefits of therapies subjects would receive even if not participating in the research□ The research involves the prospect of direct benefit to individual subjects, and/or, is likely to contribute to the acquisition of generalizable knowledge□ Foreseeable risks and anticipated benefits to subjects and the knowledge researchers expect to gain are accurately and clearly identified and considered□ The proposed research population’s perception of risks and benefits are taken into accountCOMMENTS: |
|  **3. Selection of subjects is equitable**  (45 CFR 46.111a(3)) | [ ]  **Yes** [ ]  **No** |
| **Considerations:**□ Take into account the purposes of the research, the setting in which the research will be conducted, and if it requires  or justifies using the proposed subject population□ Will the solicitation of subjects avoid placing a disproportionate share of the burdens of research on any single group?□ To the extent that risks and benefits to the subjects are anticipated, are they distributed fairly?□ Are inclusion / exclusion criteria appropriate?□ Participant recruitment and enrollment procedures are appropriate and not based solely on the convenience of the  researcher□ Influence of incentives on participants COMMENTS: |
| **4. Informed consent will be sought from each prospective subject or the****subject’s legally authorized representative**  (45 CFR 46.111a(4)) ***If informed consent is waived, complete section 4a, Waiver of Informed Consent*** | [ ]  **Yes** [ ]  **No**[ ]  **Waived** **(see section 4a)** |
| **Considerations:**□ Informed consent process is adequately described□ Circumstances of the consent process (e.g., timing, place, person obtaining consent) minimize coercion or undue influence□ Circumstances of the consent process provide sufficient opportunity for the subject or subject’s representative to consider whether or not to participate□ Informed consent does not include exculpatory language (i.e., waiving or appearing to waive any of the subject’s legal rights or releasing or appearing to release the investigator, the sponsor, the institution or its agents from liability for  negligence)□ Information given to the subject or subject representative is in language understandable to the subject or the  representative and does not include undefined technical terms**Additional Considerations:**□ Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.□ Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the  subject’s or LAR’s understanding of the reasons why one might or might not want to participate.**The following required 8 basic elements of informed consent are included:** □ (1) A statement that the study involves research; □ an explanation of the purposes of the research; □ the expected duration of the subject’s participation; □ a description of the procedures to be followed; □ identification of any procedures which are experimental □ (2) A description of any reasonably foreseeable risks or discomforts to the subject *Note: If there are no foreseeable risks to subjects, this must be stated* □ (3) A description of any benefits to subjects or others  *Note: If there are no direct benefits to subjects, this must be stated* □ (4) Disclosure of appropriate alternative procedures or courses of treatment, *if any*, that might be advantageous to the subjects □ (5) Description of the extent to which confidentiality of records will be maintained *Note: If research records contain identifying information, it should be stated who will* *have access to records, how they will be secured, and if and when they will be*  *destroyed.* □ (6) *For research involving more than minimal risk*, an explanation as to whether any compensation and an  explanation as to whether any medical treatments are available if injury occurs, and if so, what they consist of,  or where further information may be obtained □ (7) Three contacts: study information (PI or faculty sponsor name and email address or phone number);  subject’s rights (IRB); and research related injury (if applicable) □ (8) A statement that participation is voluntary; □ refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; □ the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is  otherwise entitled □ (9) One of the following statements about any research that involves the collection of identifiable private  information or identifiable biospecimens: a) That identifiers might be removed from the identifiable private information or biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another PI for future research studies without additional informed consent from the subject or LAR, IF this might be a possibility, or b) The subject’s information or biospecimens collected as part of the research even if identifiers are removed, will not be used or distributed for future research. **The following additional elements may be provided, when appropriate:** □ (1) A statement that the particular treatment or procedure may involve risks to the subject which are currently  unforeseeable  □ (2) Investigator-initiated termination of participation without regard to subject’s consent □ (3) Additional costs to subjects that may result from participation in the study □ (4) Consequences of subject withdrawal and procedures for orderly termination □ (5) Significant new findings that may relate to a subject’s willingness to continue participation will be provided to  the subject □ (6) Approximate number of subjects involved in the study □ (7) A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit □ (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to the subjects, and if so, under what conditions □ (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.COMMENTS: |
| **4a. Waiver of Informed Consent (or Permission or Assent)**  (45 CFR 46.116d)  | [ ]  **Yes** [ ]  **No** [ ]  **N/A** |
|  **All of the following 4 criteria have been satisfied for waiver of informed consent (or waiver of parental** **permission, or waiver of child assent) – See Form I :**□ The research involves no more than minimal risks to subjects; **AND**□ The research could not be practicably carried out without the waiver or alteration; **AND**□ If the research involves using identifiable private information or biospecimens, the research could not be practicably carried out without using such information or biospecimens in an identifiable format; **AND**□ The waiver or alteration will not adversely affect the rights and welfare of subjects; **AND**□ Whenever appropriate, the subjects or LAR will be provided with additional pertinent information after participationCOMMENTS: |
|  **5. Informed consent will be appropriately documented**  (45 CFR 46.111a(5)) ***If documentation of consent is waived, complete section 5a, Waiver of Documentation of Consent*** | [ ]  **Yes** [ ]  **No**[ ]  **Waived** **(see section 5a)** |
| Informed consent shall be documented by the use of a written consent form and signed by the subject or the subject’s legally authorized representative. COMMENTS:  |
|  **5a. Waiver of Documentation of Consent (or Parental Permission)** (45 CFR 46.117c)  | [ ]  **Yes** [ ]  **No** [ ]  **N/A** |
|  **At least one of the following 2 criteria have been satisfied to waive the requirement of the investigator to obtain****a signed consent form (or parent permission form) – See Form I :**□ The only record linking the subject and the research would be the consent document and the principle risk would be  potential harm resulting from a breach of confidentiality; **OR**□ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written  consent is normally required outside of the research context; **OR**□ The subjects or LAR are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is a mechanism for documenting that informed consent was obtained.COMMENTS: |
| **6. Data and Safety Monitoring**  (45 CFR 46.111a(6)) | [ ]  **Yes** [ ]  **No** [ ]  **N/A** |
| *Monitoring: The collection and analysis of data as the project progresses to assure the appropriateness of the research,* *its design, and subject protections.**When appropriate*, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. *NOTE: The presence of a data and safety monitoring plan is not required for research that is deemed no more**than minimal risk***Considerations:**□ Does the researcher need to monitor the data frequently to determine if there needs to be a change in the research design, a change in the information presented to subjects, or even termination of the study before the end date?□ Would the use of a research oversight process enhance subject safety?COMMENTS: |
|  **7. Privacy & Confidentiality**  (45 CFR 46.111a(7)) | [ ]  **Yes** [ ]  **No** |
| When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain confidentiality ofdata. Consider the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research.**Considerations:**□ Procedures are in place to protect the privacy of subjects, if necessary□ If sensitive information is collected, there are adequate provisions for protecting the confidentiality of the data through anonymizing techniques, coding systems, destruction of identifying information, limiting access to the data, or  whatever methods may be appropriate to the study□ Investigator’s disclosures to subjects about confidentiality are adequate□ Procedures for sharing data are described and satisfactory□ Plans for storage and retention of records are described and satisfactory□ Plans for future use of data are adequate and satisfactoryCOMMENTS: |
| **8. Vulnerable populations and additional safeguards**  (45 CFR 46.111b) | [ ]  **Yes** [ ]  **No** [ ]  **N/A** |
| When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant persons, mentally disabled persons, or economically or educationally disadvantaged persons, additionalsafeguards have been included in the study to protect the rights and welfare of these subjects.**Considerations:**□ Procedures to address subjects’ vulnerabilities are included appropriate and adequate□ Procedures to assess subjects’ decisional capacity and understanding of the research are adequate□ If applicable, procedures for obtaining consent from legally authorized representative are adequateCOMMENTS: |

**Are there any potential concerns in this study regarding inclusivity or potential points of tension with exclusivity?** [ ]  **Yes** [ ]  **No**

**Additional Comments:**