IRB Reviewer Questionnaire for Initial and Continuing Review

Reviewer name: Signature

IRB Meeting Date: IRB Control #: PI:

***This form is to be completed and turned in by the assigned primary reviewer(s).*** *Respond to each of the following questions to the extent you deem necessary. Form should be typewritten, or legibly handwritten.*

### This checklist is organized around the regulatory criteria at 45 CFR 46.111 and 21 CFR 56.111 for approval of human research. The regulatory criteria appear in larger type, with the “food for thought” questions in smaller type included as part of the considerations for each regulatory criterion. In order to approve research covered by this policy the IRB shall determine that all of the following regulatory requirements are satisfied.

Do you have a financial or other conflict of interest regarding this protocol? \_\_\_\_Yes \_\_\_\_No

If “Yes” please contact Kyle Conner at 3-8966 or Walter Kraft at 3-0203 ASAP so a new reviewer can be assigned.

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| **Criteria for All Reviews** | | **Reviewer Comments** |
| Physical, psychological, social, legal, and economic risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.       Would an alternative scientific design reduce the likelihood or magnitude of harm, but still answer the scientific question?       Would alternative procedures reduce the likelihood or magnitude of harm, but still answer the scientific question?       Would an alternative participant population reduce the likelihood or magnitude of harm, but still answer the scientific question?       Would fewer procedures answer the scientific question?       Would fewer participants answer the scientific question?       Are the research staff members qualified to conduct the procedures?       Does the investigator have adequate numbers of qualified staff?       Does the investigator have adequate facilities to conduct the research?       Does the investigator have a process to ensure that persons assisting with the research are adequately informed about the protocol and their research-related duties and functions?       Are medical or psychological resources available that participants might require as a consequence of the research? | |  |
| Physical, psychological, social, legal, and economic risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.       Are procedures that will answer the scientific question being done anyway?       If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm? | |  |
| Physical, psychological, social, legal, and economic risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.       Does the investigator have access to a population that will allow recruitment of the necessary number of participants?       Does the investigator have sufficient time to conduct and complete the research?       Is the research feasible?       Is the research likely to answer its proposed question?       Does the knowledge expected to result have importance? | |  |
| Selection of participants is equitable.       Consider the purpose of the research.       Consider the setting in which the research will be conducted.       Consider the involvement of populations vulnerable to coercion or undue influence.       Consider inclusion and exclusion criteria.       Consider recruitment and payment methods. | |  |
| The informed consent process will be waived or altered. *(See separate checklist)* **This option does not apply to FDA-regulated research.** OR Informed consent will be sought from each prospective participant or the participant’s representative in accordance with the regulations as follows: | |  |
|  | The investigator will obtain the legally effective informed consent of the participant or the participant’s legally authorized representative.       Has the investigator indicated whether consent will be obtained from the participant, from a legally authorized representative, or both?       If a legally authorized representative will be used, do the individuals to be used meet the regulatory definition?       Will the participants or representatives understand the facts?       Will the participants or representatives appreciate the implications of their decision?       Will the participants or representatives be able to decide?       Will the participants or representatives be able to communicate a decision? |  |
| The circumstances of consent provide the prospective participant or the representative sufficient opportunity to discuss and consider whether or not to participate.       How much time will be devoted to the consent discussion?       How much time will be allowed for a decision? |  |
| The circumstances of consent minimize the possibility of coercion or undue influence.       Is there a power differential?       Are there communication issues?       Are there issues regarding the capacity to make a decision?       Are there excessive motivating factors?       Is the recruitment process acceptable?       Are advertisements acceptable?       Are payment arrangements acceptable? |  |
| The information that will be given to the participant or the representative will be in language understandable to the participant or the representative.       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? |  |
| The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether or not to participate, and an opportunity to discuss that information. |  |
| Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative 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 prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. |  |
| No information will be provided to the participant or the representative that waives or appears to waive any of the participant’s legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.       Is the information factual? (E.g., the policy, plan, expectation, or law)       Does the information avoid stating an outcome? (E.g., something will or will not happen) |  |
| All required and appropriate additional disclosures will be provided to the participant or the participant’s representative. *(See Elements of Informed Consent below)* |  |
| If the study will involve decisionally-impaired individuals, is there an adequate plan for the assessment of capacity of the individual to consent?  Will assent of decisionally-impaired individuals be required, and if so, is the plan for assent adequate? | |  |
| The informed consent process will be waived. *(See separate checklist)* **This option does not apply to FDA-regulated research.** OR The requirement for written documentation will be waived*. (See separate checklist)* **This option does not apply to FDA-regulated research.** | |  |
| Does information to be disclosed meet regulatory requirements for elements of informed consent?  (see section below) | |  |
| Should the investigator provide participants with a written statement regarding the research? | |  |
| OR Informed consent will be documented in writing in accordance with the regulations.       **Long form**  o   The consent document embodies the basic and appropriate additional elements of disclosure. *(See below)*  o  The participant or the participant’s legally authorized representative will sign and date the consent document.  o   A copy of the signed and dated consent document will be given to the person signing the consent document.   * The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed. * The consent form clearly documents all the information potential participants need to make an informed decision        **Short form**  o   The consent document states that the elements of disclosure required by regulations had been presented orally to the participant or the participant’s legally authorized representative.  o   A written summary embodies the basic and appropriate additional elements of disclosure.  o   There will be a witness to the oral presentation.  o   For participants who do not speak English, the witness is conversant in both English and the language of the participant.  o   The participant or the participant’s legally authorized representative will sign and date the consent document.  o   The witness will sign and date both the short form and a copy of the summary.  o   The person actually obtaining consent will sign and date a copy of the summary.  o   A copy of signed and dated short form will be given to the participant or the representative.  o  A copy of the signed and dated summary will be given to the participant or the representative. | |  |
| The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants. *(Not applicable if the research involves no more than minimal risk.)*       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?       Will unexpected harms be detected promptly?       Will an increased frequency or severity of unexpected harms be detected promptly?       Will the protocol be stopped once benefits are proven to outweigh harms?       Will the protocol be stopped once harms are proven to outweigh benefits? | |  |
| There are adequate provisions to protect the privacy of participants.       Will participants have an expectation of privacy?       Will participants think that the information sought is any of the researcher’s business?       Will participants be comfortable in the research setting?       Will participants be comfortable with the research procedures? | |  |
| There are adequate provisions to maintain the confidentiality of the data.       Is confidentiality assured in the consent form?       Are there legal/ethical requirements?       Will data release cause risk of harm?       Are appropriate techniques being used to protect confidentiality?  o   Use of alphanumeric codes  o   Statistical strategies  o   Restricted public use data  o   Restricted access  o   Certificates of Confidentiality  o   Data brokering  o   Other methods | |  |
| Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence. | |  |
| **Considerations For All Reviews** | | **Reviewer Comments** |
| Does the IRB have the scientific or scholarly expertise, the representational experience, knowledge of the local context, and other expertise needed to review this research? *(If not, obtain consultation or review by another IRB.)* | |  |
| **Considerations For Research Being Done In States Other Than Or In Addition To Pennsylvania** | | **Reviewer Comments** |
| * Sufficient information has been provided to the IRB (see OHR-2, part H, #2,)   YES  NO   * If insufficient information, the reviewer recommends that the PI contact the Legal Office. | |  |
| **Considerations For Initial Review** | | **Reviewer Comments** |
| For expedited studies: As per 45 CFR 46.109(f)(1), continuing review is not required for studies that meet expedited criteria.  However, if you feel that Continuing Review is still warranted, **please provide your written rationale**.  Note: This cannot be applied to FDA-Regulated Studies  **For Full Review Studies:**  Should review be obtained more often than annually? | |  |
| If the investigator is the lead investigator or TJU is the lead site in a multi-site study:  Is the proposed management plan for information that is relevant to participant safety (i.e., adverse events, unanticipated problems, interim reports, etc.) adequate?  If the submission is part of a cooperative single IRB submission to Jefferson IRB, is there documentation of approval by the Federal department or agency supporting or conducting the research or lead institution?  Regarding Investigator Initiated Trials, the physicians and scientists on the IRB also serve as the scientific review subcommittee and should address in writing the following two questions:  1. Does the research use procedures consistent with sound research?  2. Is the research design sound enough to yield the expected results?   |  | | --- | | **INVESTIGATIONAL DEVICES/INVESTIGATIONAL DRUGS (if applicable)** | | Does the study involve the testing of safety and/or efficacy of a device (“investigational device”)?  Does the device have an IDE#? Is there documentation to validate?  ***(See OHR-2, Part C.III, to answer the following questions.)***  If not, does the device meet one of the FDA exemption categories?  If not, does the device meet requirements for a non-significant risk device?  ***(See OHR-28)***  Is device an in vitro diagnostic device?  If applicable, does in vitro diagnostic device study meet criteria allowing research to be conducted using leftover specimens obtained without informed consent? | | Does this study involve the use of an experimental drug (i.e., a drug being tested for safety and/or efficacy)?  Is there an IND# for this drug?  Does study meet one of the FDA criteria for exemption from IND requirement?  Is there a letter from the FDA exempting the drug from an IND? | | |  |
| **Considerations For Continuing Review** | | **Reviewer Comments** |
| Unless the IRB determines otherwise, it shall conduct continuing review of research at intervals appropriate to the degree of risk, the degree of uncertainty regarding the risk, the vulnerability of the subject population, and the experience of the Investigator, not less than once per year; however.  Continuing review of research is not required if the following criteria are met:   1. The study is not FDA regulated.   **FDA-regulated studies involve investigational drugs, devices, or biologic products, or products approved by FDA that are used in a study in an off-label manner. These products may or may not be associated with an IND#, IDE#, or HDE# (***see table in Part C of OHR-2***).**  AND, either #2 or #3 below:  2. Research is eligible for expedited review  3. When research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:  a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, and/or;  b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.  However, if you feel that Continuing Review is still warranted, **please provide your written rationale**. | |  |
| **For Full Review Studies:**  Should review be obtained more often than annually?  Should verification be obtained from sources other than the investigator that no material changes have taken place since prior IRB review?  Is the consent document accurate and complete?  If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?  Were any subjects enrolled before initial approval date?  Have more subjects been enrolled than were approved for the study?  Does the Certification section of the OHR-9 indicate that every subject signed and received a copy of the consent form?  Do the demographics of the subjects enrolled match those stated in the OHR-2? | |  |

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| **Elements of Informed Consent** | **Reviewer Comments** |
| The study involves research. |  |
| Purpose. |  |
| Duration. |  |
| Procedures including experimental procedures. |  |
| Risks. |  |
| Benefits. |  |
| Alternatives. |  |
| Confidentiality (HIPAA). |  |
| A statement that notes the possibility that the Food and Drug Administration may inspect the records. *(Not applicable if research is not FDA-regulated.)* |  |
| Compensation and treatment for research-related injury. |  |
| Contact information for questions about the research, the subject’s rights, and research related injury. |  |
| Participation is voluntary and the subject may choose not to participate or withdraw without penalty or loss of benefits to which the subject is otherwise entitled. |  |
| **One of the following statements** about any research that involves the collection of identifiable private information or identifiable biospecimens:  A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility.  OR  A statement that 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 studies. |  |
| Risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable. |  |
| Circumstances participation may be ended without the subject’s consent. |  |
| Procedures for ending the research early. |  |
| Cost. |  |
| Significant new findings that may relate to the subject’s willingness to continue participation will be provided to the subject. |  |
| The approximate number of subjects. |  |
| 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. |  |
| A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. |  |
| For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). |  |

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| **MCARE Signature Line for All Reviews** | **Reviewer Comments** |
| **Is the appropriate MCARE investigator signature line included in the consent form?**  Use the information in the MCARE investigator signature line sections of the OHR-2/OHR-9 and OHR-8 to make this determination. |  |

###     Federal regulations at 45 CFR §46.111 include a reference to consent process requirement in 45 CFR §116 and a reference to consent documentation requirements in 45 CFR §117. These are also part of the regulatory criteria that the IRB has to determine are true in order to approve research

    Federal regulations at 21 CFR §56.111 include a reference to consent process requirement in 21 CFR §50 and a reference to consent documentation requirements in 21 CFR §50.27. These are also part of the regulatory criteria that the IRB has to determine are true in order to approve research.

**REVIEWER RECOMMENDATIONS**

*(Please modify as needed)*

SUMMARY:

GENERAL ISSUES:

OHR-1:

OHR-2/2B:

OHR-8:

PROTOCOL:

RISK:

RECOMMENDATION: