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| Study ID |       | PI |       | Review Category |       |

Reviewer:

[ ]  I feel I am qualified to review this study.

[ ]  I do not feel I am qualified to review this study. *Notify IRB staff immediately.*

[ ]  I cannot review this study because of a potential conflict of interest. *Notify IRB staff immediately. (See Section 10-1, “Conflict of Interest”).*

*[ ]* I believe that additional expertise is needed in order to conduct an in-depth review of this study. *Notify IRB staff immediately. (See HRPP Manual 5-4, Additional Expertise)*

**Review Category:**

[ ]  Study is in the appropriate review category.

[ ]  Expedited review appropriate – meets applicability criteria and represents one or more approvable categories of research. *See HRP-313 - Worksheet - Expedited Review – Pre-2018.*

[ ]  Study is not in the appropriate review category. The review category should be     . *Notify IRB staff immediately.*

# For ALL Studies

[ ]  No [ ]  Yes **Risks to subjects are minimized**: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

 *Comments:*

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[ ]  No [ ]  Yes **Risks to subjects are reasonable in relation to anticipated benefits**, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

 *Comments:*

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 [ ] No [ ] Yes Did the investigator sufficiently discuss the range of risks? *Risks*: probability of harm or injury (physical, psychological, legal, social or economic) occurring as a result of participation in the study; *Benefit*: a valued or desired outcome; an advantage.

 *Comments:*

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[ ]  No [ ]  Yes **Selection of subjects is equitable**. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

 *Comments:*

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[ ]  No [ ]  Yes **Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 / 21 CFR 50.25.

 If **informed consent will be sought,** has the investigator adequately explained the consent process (not just the use of the form)? [ ]  No [ ]  Yes

 *Comments:*

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 [ ]  No [ ]  Yes Investigator will obtain the legally effective consent of participant or participant’s legally authorized representative.

 [ ]  No [ ]  Yes Circumstances of consent process provide the prospective participant or legally authorized representative sufficient opportunity to consider whether to participate.

 [ ]  No [ ]  Yes Circumstances of consent process minimize possibility of coercion or undue influence.

 [ ]  No [ ]  Yes Individuals communicating information to participant or legally authorized representative during consent process provide that information in language understandable to participant or representative.

 [ ]  No [ ]  Yes Information to be communicated to participant or representative during consent process does not include exculpatory language through which participant or legally authorized representative is made to appear to waive any of participant’s legal rights, or releases or appears to release investigator, sponsor, organization, or its agents from liability for negligence.

 If **informed consent will not be sought**, has the study met the waiver of consent criteria or a waiver of elements of consent criteria (s*ee HRP-410 - Checklist - Waiver of Alteration of Consent Process –Pre-2018 for additional criteria*)? [ ]  No [ ]  Yes

 *Comments:*

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[ ]  No [ ]  Yes **Informed consent will be appropriately documented**, in accordance with, and to the extent required by 45 CFR 46.117/ 21 CFR 50.27.

 If informed consent will be documented:

 [ ]  A written consent document that embodies the elements of informed consent required by *[§46.116 or §50.25]*. The subject or the subject’s legally authorized representative will sign (and date for FDA-regulated research) the form. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed. A copy shall be given to the person signing the form.

OR

[ ]  A *short form* written consent document stating that the elements of informed consent required by [§*46.116 or § 50.25]* have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed (and dated for FDA-regulated research) by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

 If **no**, has the study met the waiver of documentation criteria (*see HRP-411 - Checklist - Waiver of Written Documentation of Consent – Pre-2018 for additional criteria*)? [ ]  No [ ]  Yes

 *Comments:*

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[ ]  No [ ]  Yes When appropriate, the research plan makes **adequate provision for monitoring the data collected to ensure the safety** **of subjects.** *If appropriate, has a data and safety monitoring plan been submitted?* [ ]  No [ ]  Yes

 *Comments:*

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[ ]  No [ ]  Yes When appropriate, there are **adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

 *Comments:*

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[ ] No [ ]  Yes Study involves **children**. *See HRP-416 - Checklist – Children – Pre-2018 for additional criteria.*

 If **yes**, additional criteria for approval have been met (HHS – 45 CFR 46 Subpart D, FDA – 21 CFR 50 Subpart D)

 [ ]  No [ ]  Yes

 *Comments:*

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[ ]  No [ ]  Yes Study involves **pregnant women, human fetuses or neonates.** *See HRP-412 - Checklist - Pregnant Women, HRP-413 - Checklist - Non-Viable Neonates, and HRP-414 - Checklist - Neonates of Uncertain Viability for additional criteria.*

 If **yes**, additional criteria for approval have been met (HHS – 45 CFR 46 Subpart B) [ ]  No [ ]  Yes

 *Comments:*

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[ ]  No [ ]  Yes Study involves **prisoners**. *See HRP-415 - Checklist – Prisoners for additional criteria.*

 If **yes**, additional criteria for approval have been met (HHS – 45 CFR 46 Subpart C) [ ]  No [ ]  Yes

 *Comments:*

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# When Applicable

[ ]  No [ ]  Yes When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

 *Comments:*

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[ ]  No [ ]  Yes Study involves incomplete disclosure/deception. Debriefing form included and judged to be adequate. Consent form reviewed and waiver of elements of consent has been documented (if applicable).

 *Comments:*

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[ ]  No [ ]  Yes Study involves individuals with diminished capacity / adults unable to consent. Study should be brought to full committee for discussion. *See HRP-417 - Checklist - Cognitively Impaired Adults for additional criteria.* *Notify IRB staff.*

[ ]  No [ ]  Yes Study involves MSU units not under control or supervision of investigator. Communication with units is adequate to protect participants.

 *Comments:*

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[ ]  No [ ]  Yes Study involves investigator who is the lead of a multi-site study. Management of information relevant to the protection of participants is adequate to protect participants.

 *Comments:*

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[ ]  No [ ]  Yes Investigator indicates that there is a potential for conflict. *Notify IRB staff.*

# Reviewer’s Decision

[ ]  This protocol has been reviewed and approved. *If you would like continuing review more often than annually, notify IRB staff.*

[ ]  This protocol has been reviewed and lacking for the following reasons:

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[ ]  This protocol has been reviewed and cannot be adequately judged without the following information:

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| Name |       | Date |       |

Follow-Up. Upon receipt of a revised protocol or additional information:

[ ]  This protocol has been reviewed and approved. *If you would like continuing review more often than annually, notify IRB staff.*

[ ]  This protocol has been reviewed and judged to be lacking for the following reasons: