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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)*

*Comments:*

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**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 – Revised Common Rule.*

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

*Comments:*

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# For ALL Studies

No  Yes **Risks to subjects are minimized**: (i) By using procedures that are consistent with sound research design and that 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 (e.g., 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. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, individuals with impaired decision-making capacity, 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 Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

No  Yes Circumstances provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate.

No  Yes Circumstances minimize the possibility of coercion or undue influence.

No  Yes The information that is given to the subject or the legally authorized representative is in language understandable to the subject or the legally authorized representative.

No  Yes The prospective subject or the legally authorized representative is provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

No  Yes Informed consent begins 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 is organized and presented in a way that facilitates comprehension.

No  Yes Informed consent as a whole presents information in sufficient detail relating to the research, and is 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  Yes No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

*Comments:*

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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 – Revised Common Rule for additional criteria*)?  No  Yes

*Comments:*

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No  Yes Study involves a research proposal in which an investigator will obtain information or biospecimens for the purpose of **screening, recruiting, or determining the eligibility of prospective subjects without the informed consent** of the prospective subject or the subject's legally authorized representative. *See HRP-442 - Checklist - Informed Consent Exception for Screening, Recruiting, or Determining Eligibility - Revised Common Rule for additional criteria. NOTE – this criteria cannot be used on FDA regulated research.*

*Comments:*

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No  Yes **Informed consent will be appropriately documented or appropriately waived** in accordance with 45 CFR 46.117 / 21 CFR 50.27.

No  Yes Informed consent will be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

*Comments:*

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If informed consent will be documented:

[FDA]  A written consent document that embodies the elements of informed consent required by §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.

[Common Rule]  A written informed consent form that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

OR

[FDA]  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.

[Common Rule]  A short form written informed consent form stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized 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 subject's legally authorized representative, in addition to a copy of the short form.

*Comments:*

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If **no**, has the study met the waiver of documentation criteria (*see HRP-411 - Checklist - Waiver of Written Documentation of Consent – Revised Common Rule 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 – Revised Common Rule 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 Viabilityt 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, individuals with impaired decision-making capacity, 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.*

*Comments:*

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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.*

**Continuing Review**

If the study does not require continuing review and the IRB member has required continuing review (or if continuing review is required because the study is FDA regulated or also subject to the DOJ requirements), *see the HRP-444 - Checklist - Determination that Continuing Review Required for Research Eligible for No Continuing Review - Revised Common Rule.*

*Comments:*

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**More than Minimal Risk or Full Board Review**

If the expedited reviewer determines the research is more than minimal risk or requires full board review even though the study qualifies for an expedited category, *see the HRP-443 - Checklist - Determination that Full Board Review Required for Research Eligible for Expedited Review.*

*Comments:*

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# 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: