

**Continuing Review Checklist – Convened IRB Review**

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| --- | --- |
| **PI Name:** | **WMed IRB #:**  (for IRB office use only) |
| **Protocol Title:** | **Approval Date: Click or tap to enter a date.** |
| **Reviewer:** | **Review Date: Click or tap to enter a date.** |

**Guidance:**

When conducting continuing review, the IRB should start with the assumption that the research, as previously approved, satisfied all of the criteria under [45 CFR 46.111](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111) or [21 CFR 56.111](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111). The IRB should focus on any new information provided by the investigator or sponsor, or otherwise available to the IRB, that may alter the IRB’s prior determinations, particularly with respect to the IRB’s prior evaluation of the potential benefits or risks to the subjects. The IRB also should assess whether there is any new information that would necessitate revision of the protocol and/or the informed consent document. If the IRB determines that a research activity no longer meets the criteria for approval, the IRB is not permitted to reapprove it, but may either disapprove it or require modifications in order to secure re-approval.

For additional guidance on continuing review, please see the following:

<http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html>

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf>

1. **REVIEWER CONFLICT OF INTEREST**

As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the study; do you have a financial interest in the study; or do you have any other conflict of interest with this study?

Yes  No

If yes, please do not perform the review and contact the IRB Office at 269.337.4345.

1. **RISK EVALUATION**

Given the information provided in the Continuing Review, including any previously unreported information, does each of the following remain true?

* 1. Risks to subjects are minimized

Yes  No  Unable to determine

* 1. Risks to subjects are reasonable in relation to anticipated benefits

Yes  No  Unable to determine

**Comments or Concerns:**

1. **ADEQUACY OF INFORMED CONSENT**

Consent was waived (skip ahead to Section IV)

* 1. Does the consent document, script, or information sheet contain accurate, up-to-date information about the study?

Yes  No  NA – Enrollment is permanently closed

* 1. Is there new risk information available?

Yes  No

* 1. Are there significant new findings that may impact subjects’ willingness to continue participation?  Yes  No
  2. If yes to question b and/or c, should the researcher be asked to provide a plan for conveying the information to existing subjects?

Yes  No

* 1. If yes to question b and/or c, does the current consent need to be updated?

Yes  No  NA – Enrollment is permanently closed

* 1. If yes to question e, do you need to re-consent subjects?

Yes  No

**Comments or Concerns:**

1. **LOCAL ISSUES**
   1. Are there any local issues, such as the following, that need to be addressed?  Yes  No

* Changes in the investigator’s situation or qualifications (e.g., suspension of hospital privileges, medical license; involvement in numerous clinical trials);
* Changes in COI or prior COI management plans
* Expired trainings
* Evaluation, investigation, and resolution of complaints related to the research;
* Volume of, or pattern in, protocol deviations, adverse events, or unanticipated problems;
* Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable state and local law, or standards of professional conduct or practice;
* Reports from third party observation of the research;
* Concerns expressed by the investigator or others

**Comments or Concerns:**

1. **RESEARCH PROGRESS**
   1. Are the information and documents provided in the continuing review consistent with the IRB’s prior approval of the study?

Yes  No

* 1. Has enrollment in the study proceeded as expected?

Yes  No  NA

* 1. Is the number of, and reasons for, subject withdrawals reasonable?

Yes  No  NA

* 1. Is selection of subjects equitable?

Yes  No  Unable to evaluate, demographics not captured

**Comments or Concerns:**

1. **REGULATORY CRITERIA FOR APPROVAL**

Please note below whether each of the following criteria continue to be satisfied**:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** |
| 1. 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. |  |  |  |
| 1. 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. |  |  |  |
| 1. 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, students and economically or educationally disadvantaged persons. |  |  |  |
| 1. 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 [§46.116](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116#46.116) or [Part 50](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.20.4). |  |  | (waived) |
| 1. Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117#46.117) or [§50.27](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.27) |  |  | (waived) |
| 1. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. |  |  |  |
| 1. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. |  |  |  |
| 1. 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, students and economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. |  |  |  |

**Comments or Concerns:**

1. **SUBPART DETERMINATIONS**
   1. Do any of the subparts apply (children (FDA & Common Rule), prisoners (Common Rule), or pregnant women, fetuses, or neonates (Common Rule)?

Yes  No (skip ahead to VIII)

* 1. Are any changes recommended to prior subpart determinations (for example, because the remaining research activities are minimal risk)?

Yes (note changes below)  No

**Comments or Concerns:**

1. **REVIEWER’S RECOMMENDATIONS**
2. **Level of Risk** *(the risk determination should reflect the level of risk associated with the remaining research activities)***:**

**Minimal risk** (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)

**Greater than minimal risk**

1. **Independent Verification of No Material Changes Since Previous IRB Review** *(check one)***:**

Not Recommended  Recommended *(please comment)*:

1. **Continuing Review Frequency** *(check one)***:**

12 months  6 months  Other:

1. **Action**

Approve as submitted

Conditions required for approval\*

Partial approval

Defer\* for the reasons described below

Disapprove for the reasons described below

\*For Conditional Approval or Deferral, note your recommendations regarding ongoing study activities and enrollment of new subjects. Check all that apply.

Research activities for already enrolled subjects  should***(or)***  should not continue for existing subjects while the requirements are addressed.

Enrollment of new subjects should be held until the IRB reviews and approves the response. [*option for open to enrollment, expired studies*]

Enrollment of new subjects  should ***(or)***  should not continue up until the date of expiration. [*options for open to enrollment, un-expired studies*]

**Comments:**