

**Continuing Review Checklist – Expedited 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. \*Note: only the convened IRB can disapprove research, an expedited reviewer can recommend disapproval and refer the study for review by the convened IRB.

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. **EXPEDITED REVIEW ELIGIBILITY**
	1. Are the remaining research activities minimal risk ***or*** have no subjects ever been enrolled?

 [ ]  Yes [ ]  No (the research is not eligible for expedited review)

* 1. Is the research classified?

[ ]  Yes (the research is not eligible for expedited review). [ ]  No

* 1. Does the research include prisoners?

[ ]  Yes (the research is not eligible for expedited review). [ ]  No

* 1. Would identification of the subjects or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing?

[ ]  Yes [ ]  No

 If yes, are adequate precautions in place to minimize the risks related to invasion of privacy and breach of confidentiality? [ ]  Yes [ ]  No (the research is not eligible for expedited review)

* 1. To be eligible for expedited review, the above criteria (II.a-d) must be satisfied and all research activities must be in one or more of the categories below. Indicate which categories apply. If none apply ***or*** the criteria above aren’t satisfied, stop here and notify the IRB staff.

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| --- |
|[ ]  **Cat. 1**: Clinical studies of drugs and medical devices only when condition (a) or (b) is met.1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
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|[ ]  **Cat. 2**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
2. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
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|[ ]  **Cat. 3**: Prospective collection of biological specimens for research purposes by noninvasive means. |
|[ ]  **Cat. 4**: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. |
|[ ]  **Cat. 5**: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).  |
|[ ]  **Cat. 6**: Collection of data from voice, video, digital, or image recordings made for research purposes. |
|[ ]  **Cat. 7**: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. |
|[ ]  **Cat. 8**: Continuing review of research previously approved by the **convened IRB** as follows:1. where :
2. the research is permanently closed to the enrollment of new subjects;
3. all subjects have completed all research-related interventions; and
4. the research remains active only for long-term follow up of subjects; or,
5. where no subjects have been enrolled and no additional risks have been identified; or,
6. where the remaining research activities are limited to data analysis.
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|[ ]  **Cat. 9**: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a **convened meeting** that the research involves no greater than minimal risk and no additional risks have been identified. |

**Comments or Concerns:**

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 V)

* 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

* 1. 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, expired trainings);
* Changes in COI or prior COI management plans
* 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 observers or 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 IX)

* 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 DETERMINATIONS**
	1. **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

[ ]  Refer to the convened IRB for the reasons described below

\*For Conditional Approval or Deferral, note your determinations regarding ongoing study activities and enrollment of new subjects

[ ]  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:**