

**Modification and Protocol Exceptions Review Checklist**

**Expedited Review**

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

**Instructions**: This form is intended to be used by the reviewer to ensure that all required determinations and findings are made. The IRB minutes serve as the official IRB record of final determinations; this checklist serves as the official record as this is an expedited review and no minutes will be recorded.

1. **Conflict of Interest**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Comments** |
| As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study? |  |  |  |
| If yes, please do not perform the review and contact the HRPP/IRB Office at 269.337.4345. | | | |

1. **Eligibility for Expedited Review**

Expedited review may be used for (1) some or all of the research appearing on the list of eligible categories and found by the reviewer(s) to involve no more than minimal risk, and/or (2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

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| --- | --- | --- | --- |
| 1. **Minor Changes in Research Approved by the Convened IRB**  NA, research was approved by expedited review (skip to section B) | **Yes** | **No** | **Comments** |
| Do the changes proposed make substantial alteration in: |  |  |  |
| 1. The acceptability of the risk-to-benefit analysis or increases the level of risks to subjects (unless the overall risk of the study remains minimal or the increase in risks is so minor that it does not negatively impact overall risk-to-benefit) |  |  |  |
| 1. The research design or methods (adding procedures that are not eligible for expedited review would not be considered a minor change) |  |  |  |
| 1. The total number of local subjects to be enrolled in greater than minimal risk research (usually not greater than 10% of the previously approved total) |  |  | NA, the research is minimal risk |
| 1. The qualifications of the research team |  |  |  |
| 1. The facilities available to support safe conduct of the research |  |  |  |
| 1. Any other factor which would warrant review of the proposed changes by the convened IRB |  |  |  |
| **If the answer to any of the above is Yes, then the modification is not eligible for expedited review. Go to Section VI Determination.** |  |  |  |
| 1. **Modifications in Research Approved by under Expedited Review**  NA, research was approved by the convened IRB (If NA, skip ahead to Section III) |  |  |  |
| 1. Is the research more than minimal risk? |  |  |  |
| 1. Is the research classified? |  |  |  |
| 1. Would identification of the subjects and/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? |  |  |  |
| 1. Does the research include prisoners? |  |  |  |
| * 1. If yes, is the modification eligible for expedited review? (see section 12.6.4.2 of the HRPP and IRB Handbook) If No, go to Section VI Determination |  |  |  |

1. **Review of Modification**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Research Plan:** | **Yes** | **No** | **Comments** |
| 1. Is the purpose of the change summarized on modification request form? |  |  |  |
| 1. Has the initial submission documentation been revised, updated and submitted? |  |  |  |
| 1. Does this change affect the purpose of the study? |  |  |  |
| 1. Does this change affect the procedures of the study? |  |  |  |
| 1. Does this change affect the Expedited Review category/ies for the protocol? |  |  |  |
| * 1. If so, please refer to ***Expedited Review Criteria*** located at the end of this documentand insert expedited category(ies) here. |  |  |  |
| 1. Is there justification for the change(s)? |  |  |  |
| 1. Does this change create the need for the study to be reviewed more frequently? (If yes please note the duration and reasons in the comments section.) |  |  |  |
| 1. Does the change affect the original determination for any of the criteria for approval under 45 CFR 46.111? |  |  |  |
|  |  |  |  |
| 1. **Risk/Benefit:** |  |  |  |
| 1. Does this change affect the risk to subjects? |  |  |  |
| * 1. If so, do the risks of the research remain no more than minimal[[1]](#footnote-1)? |  |  |  |
| **For research approved under Expedited Review, if the risks are more than minimal, the modification is no longer eligible for Expedited Review. Go to Section VI Determination.** |  |  |  |
| 1. Does this change affect the benefits to subjects or others? |  |  |  |
| 1. Does this change affect the risk/benefit relationship? |  |  |  |
| 1. Does the proposed modification add any procedures, which will unnecessarily expose subjects to risk? |  |  |  |
|  |  |  |  |
| 1. **Consent:** |  |  |  |
| **If the modifications include the addition of new consent documents, please complete the *“Elements of Consent Review Checklist” for each additional consent.*** |  |  |  |
| 1. Could the change impact the subjects’ willingness to continue participation? |  |  |  |
| 1. For research with a waiver of consent or documentation of consent, does the modification affect the eligibility for a waiver? If so, explain. |  |  |  |
| 1. Does the change impact any of the elements of consent? (If yes please note the specific elements and reasons in the comments section.) |  |  |  |
| 1. Does the change otherwise provide or alter information that may be important to subjects? |  |  |  |
| 1. Does the change affect the consent process? |  |  |  |
| * 1. If so, is the consent process still appropriate? |  |  |  |
| 1. Is the change reflected in the revised consent document(s), if applicable |  |  |  |
| 1. Should subjects be re-consented? |  |  |  |
| * 1. Should **all** (both active and inactive) subjects be re-consented? |  |  |  |
| * 1. Should **only** **still active** subjects be re-consented? |  |  |  |
| * 1. If so, has the PI provided an adequate plan for re-consenting subjects already enrolled? |  |  |  |
|  |  |  |  |
| 1. **Other Concerns:** |  |  |  |
| 1. Does the change affect the recruitment process? |  |  |  |
| * 1. If so, is the recruitment process still appropriate? |  |  |  |
| 1. Does the change affect the privacy or confidentiality of subjects? |  |  |  |
| 1. If so, are the procedures to protect privacy and confidentiality still appropriate |  |  |  |
| 1. Does the change include the addition of any vulnerable populations? |  |  |  |
| * 1. If so, are the vulnerable populations appropriately safeguarded? *If the change includes the addition of Children, Pregnant Women, Fetuses and Neonates or Prisoners please fill out the appropriate Review Checklist Supplement.* |  |  |  |
| 1. Does the change affect the protection of vulnerable subjects? |  |  |  |
| 1. If so, are the protections for vulnerable subjects still adequate? |  |  |  |

1. **Regulatory Criteria for Approval (Section 111 Criteria)**

The following information is designed to assist the reviewer in determining that the federally required criteria for IRB approval codified at 45 CFR Part 46.111 and FDA regulations have not changed due to this modification.

Please note and comment below as to whether the following elements continue to be met**:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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, or 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 has previously been waived by the IRB) |  |  |  |
| 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 has previously been waived by the IRB) |  |  |  |
| 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, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. |  |  |  |

**Comments:**

1. **Protocol Exceptions**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Comments** |
| 1. Is there any increase of harm to subjects as a result of the exception? |  |  |  |
| 1. Will the exception impact the integrity of the data? |  |  |  |
| 1. If so, please explain how. |  |  |  |

1. **Determination** *(See section 7.6 of the WMed HRPP and IRB Handbook for information on IRB actions)*

Based on the information in the protocol, I have made the following determination:

The modification is **not eligible for expedited review** and must be reviewed by the full IRB.

The modification is **eligible for expedited review** and is:

Approved

Approved with Conditions

Deferred

Partially Approved

Review by the full IRB is recommended (note reason below)

|  |  |
| --- | --- |
| Please list any changes, modifications, or clarifications required to the research protocol, informed consent form, or IRB application. | |
|  | |
| **Signed** | **Dated** |

**EXPEDITED REVIEW CRITERIA**

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the allowable categories, may be reviewed by the IRB through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on the list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

**Minimal Risk.** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Eligible Categories**

|  |  |
| --- | --- |
| 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. 2. 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.) 3. 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. | **Yes**  **No** |
| 1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: 2. 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 3. from other adults and children2, 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. | **Yes** **No** |
| 1. Prospective collection of biological specimens for research purposes by noninvasive means.   Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization. | **Yes**  **No** |
| 1. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, **excluding procedures involving x-rays or microwaves.** Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) | **Yes**  **No** |
| 1. 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101(b)(4)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101). This listing refers only to research that is not exempt.) | **Yes**  **No** |
| 1. Collection of data from voice, video, digital, or image recordings made for research purposes. | **Yes**  **No** |
| 1. 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. (**NOTE:** *Some research in this category may be exempt from the HHS regulations for the protection of human subjects.* [*45 CFR 46.101*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)*(b)(2) and (b)(3). This listing refers only to research that is not exempt.)* | **Yes**  **No** |
| 1. Continuing review of research previously approved by the convened IRB as follows: 2. where : 3. the research is permanently closed to the enrollment of new subjects; 4. all subjects have completed all research-related interventions; and 5. the research remains active only for long-term follow-up of subjects; or, 6. where no subjects have been enrolled and no additional risks have been identified; or, 7. Where the remaining research activities are limited to data analysis. | **Yes**  **No** |
| 1. 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. | **Yes**  **No** |

1. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [↑](#footnote-ref-1)