

**Initial Study Review Checklist**

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

**Reviewer: Please check the following sections and detail all changes to be made below.**

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| **Type of Review (check one):** | **Risk Level (check one)** |
| Full Board Initial Review | Minimal risk\* |
| \*Expedited Initial Review | Greater than minimal risk |
| \**For* ***Expedited Review****, please also complete the “****Expedited Review Determination”*** *located in Section XIII.* | *\*Minimal risk means that the probability and magnitude of harm or discomfort anticipated 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 (45 CFR 46.102(i)).* |
| **Continuing Review Frequency (check one)** | **Recommendation (check one):** |
| 12 Months | Approval  Conditions Required for Approval |
| \*6 Months \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \*Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *\*If continuing review should be more often than annually, indicate the reason*  Does the protocol need verification from sources other than the investigators that no material changes have occurred since previous IRB review?  Yes  No If so, indicate reason: | Partial Approval  Approval in principle  \*Deferred  \*Disapproved  *\*Only the convened board can disapprove research.*  *\*For* ***deferral*** *or* ***disapproval****, list reasons in the “Changes, Modifications, or Clarifications” section.* |
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**Changes, Modifications, and Clarifications**

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| Please list any changes, modifications, or clarifications required (Changes to the research protocol, informed consent form, questionnaires, IRB application, etc.) If recommendation is for deferral or disapproval, please describe the basis for the determination. |

**PROTOCOL REVIEW CHECKLIST**

**Please check whether the following elements are adequately addressed in the materials submitted to the IRB and make comments, if necessary. Where noted, make the necessary additional determinations in Section XIV “Other IRB Determinations.”**

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| **I. Research Description** | **Yes** | **No** | **Comments** |
| 1. Is the research adequately described? |  |  |  |
| 1. Resources. Has the investigator indicated: |  |  |  |
| 1. Sufficient time to conduct and complete the research? |  |  |  |
| 1. He/She has the appropriate expertise to conduct the study (or is supplemented by sub/co-investigator expertise)? |  |  |  |
| 1. Availability of medical or psychological resources that subjects might require as a consequence of the research? |  |  |  |
| 1. Adequate psychological, social or medical monitoring, ancillary care, equipment, or other resources needed to protect participants |  |  |  |
| 1. Access to a population that would allow recruitment of the required number of subjects. |  |  |  |

**Research Description: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

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| **II. Research Setting** | **Yes** | **No** | **Comments** |
| 1. External Sites. Has the investigator indicated:   If no external sites, skip to Section III. |  |  |  |
| 1. Whether the site has an IRB? |  |  |  |
| 1. Whether the site has granted permission for the research to be conducted? |  |  |  |
| 1. Contact information for the site? |  |  |  |
| 1. If the site has an IRB, whether the IRB has approved the research or plans to defer review to the organization’s IRB? |  |  |  |
| 1. If the investigator is the lead investigator of a multi-site study, or the organization is the lead site in a multi-site study, is the plan for dissemination of information (e.g. protocol, modifications, unanticipated problems, etc.) among sites sufficient to ensure the protection of subjects? (*See Supplement L*) |  |  |  |

**Research Setting: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

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| **III. Selection of Subjects** | **Yes** | **No** | **Comments** |
| Indicate whether the selection of subjects is reasonable and equitable by considering the following elements of the protocol: |  |  |  |
| 1. Inclusion and exclusion criteria |  |  |  |
| 1. Minority and ethnic representation |  |  |  |
| 1. Representation of women and children |  |  |  |
| 1. The purposes of the research |  |  |  |
| 1. The setting in which the research will be conducted |  |  |  |
| 1. Recruitment and enrollment procedures (see below) |  |  |  |
| 1. Whether participants will be vulnerable to coercion or undue influence (see below) |  |  |  |

**Selection of Subjects: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

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| **IV. Vulnerable Populations** | **Yes** | **No** | **Comments** |
| Indicate whether vulnerable subjects are included in the research: |  |  |  |
| 1. Inclusion of pregnant women, fetuses or neonates (Subpart B)   **NOTE:** *If pregnant women, fetuses or neonates are involved, please complete section XIV.C, “Other IRB Determinations.”* |  |  |  |
| 1. Inclusion of prisoners (Subpart C)   **NOTE:** *If prisoners are involved, please complete section XIV.B, “Other IRB Determinations.”* |  |  |  |
| 1. Inclusion of children (Subpart D)   **NOTE:** *If children are involved, please complete Section XIV.A, “Other IRB Determinations.”* |  |  |  |
| 1. Inclusion of Cognitively Impaired Subjects   **NOTE:** *If cognitively impaired subjects, please complete Section XIV.D, “Other IRB Determinations.”* |  |  |  |
| 1. If other vulnerable populations (e.g., students) are included, have additional safeguards been included in the study to protect the rights and welfare of these subjects? |  |  |  |

**Vulnerable Populations: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

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| **V. Subject Recruitment** | **Yes** | **No** | **Comments** |
| 1. Indicate whether the recruitment of subjects is reasonable and equitable |  |  |  |
| 1. Are the subjects being compensated? |  |  |  |
| 1. Is the compensation plan reasonable? (See a-e) |  |  |  |
| 1. The amount of payment and the proposed method and timing of disbursement is neither coercive nor presents undue influence. 2. Credit for payment accrues as the study progresses and not be contingent upon the participant completing the entire study. 3. Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn. 4. All information concerning payment, including the amount and schedule of payments, is set forth in the consent document. 5. Neither investigators, research staff, or participants will receive payment, recruitment bonuses, finders fees or anything similar in exchange for referring participants? |  |  |  |
| 1. Are there any advertising materials being used for this study? If yes, do the materials comply with section 7.5.10 of the handbook? |  |  |  |

**Subject Recruitment: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

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| **VI. Risks to Subjects Minimized** | **Yes** | **No** | **Comments** |
| 1. Is there a clear and accurate identification of risks? |  |  |  |
| 1. Indicate whether risks to subjects are minimized by considering the following elements of the protocol: |  |  |  |
| 1. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk. |  |  |  |
| 1. Risks to subjects are minimized, when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. |  |  |  |
| 1. Data and Safety monitoring |  |  |  |
| 1. Precautions to decrease the likelihood of harm |  |  |  |
| 1. Contingencies to deal with harms if they occur |  |  |  |
| 1. Qualifications of personnel |  |  |  |
| 1. Incidental Findings: |  |  |  |
| 1. Is there a plan for handling incidental findings, if applicable (i.e. communicating findings with the subjects and/or physicians)? |  |  |  |
| 1. If there is a plan, is it adequate? |  |  |  |
| 1. Is the plan described in the consent document? |  |  |  |

**Risks to Subjects Minimized: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

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| **VII. Risk-Benefit Ratio** | **Yes** | **No** | **Comments** |
| Indicate whether the risks of the research are reasonable in relation to the benefits by considering the following elements in the protocol: |  |  |  |
| 1. Potential benefits, if any, to subjects |  |  |  |
| 1. The importance of the knowledge that might reasonably be expected to result. |  |  |  |
| 1. Risks to others (e.g., risks related to disclosure of genetic information) |  |  |  |
| 1. Short-term effects |  |  |  |
| 1. Long-term effects |  |  |  |
| 1. Psychological effects (e.g., feeling sad, depressed, or suicidal following the research) |  |  |  |

**Risk-Benefit Ratio: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

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| **VIII. Obtaining Informed Consent** | **Yes** | **No** | **Comments** |
| 1. Informed Consent Process |  |  |  |
| Indicate whether the process to obtain informed consent is adequate by considering the following elements of the protocol.  **NOTE 1:** *If investigator is requesting a waiver and/or alteration of the informed consent process, please complete Section XIV.E, “Other IRB Determinations.”*  **NOTE 2:** *If the investigator is requesting an alteration of informed consent, questions regarding informed consent process still need to be answered.* |  |  |  |
| 1. The investigator will obtain the legally effective informed consent of the subject or the subject’s legally authorized representative. |  |  |  |
| 1. The circumstances of the consent process provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether to participate. |  |  |  |
| 1. The circumstances of the consent process minimize the possibility of coercion or undue influence. |  |  |  |
| 1. The individuals communicating information to the subject or the legally authorized representative during the consent process will provide that information in language understandable to the subject or the representative. |  |  |  |
| 1. The information being communicated to the subject or the representative during the consent process will not include 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. |  |  |  |

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|  | **Yes** | **No** | **Comments** |
| 1. Process for special populations |  |  |  |
| 1. Minors: Is assent needed? *If yes,* *please complete Section XIV.A, question 2 “Other IRB Determinations.”* |  |  |  |
| 1. Adults with impaired decision-making capacity:    1. Are there mechanisms for obtaining informed consent from legally authorized representative?    2. Are there mechanisms to assess capacity and to consent if capacity is regained?    3. Is assent of the participants a requirement, and, if so whether the plan for assent is adequate? |  |  |  |
| 1. Subjects with limited-English fluency: Is there an adequate plan to ensure that subjects are provided with information in a language they understand and able to ask questions and have them answered (e.g., research personnel fluent in the anticipated language(s), use of interpreters, translation)? |  |  |  |

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| 1. Basic Elements of Informed Consent |  |  |  |
| Indicate whether the informed consent is adequate by considering whether it provides the required basic elements of information to subjects.  **NOTE 1:** *If the investigator is requesting alteration/waiver of informed consent, please skip this section.*  **NOTE 2:** *If there is more than one consent form, please fill out the “Elements of Consent Review Checklist” for each additional informed consent.* |  |  |  |
| 1. Each of the following:    * + - A statement that the study involves research  * An explanation of the purposes of the research * The expected duration of subject’s participation * A description of the procedures to be followed * Identification of any procedures which are experimental |  |  |  |
| 1. A description of reasonably foreseeable risks or discomforts. |  |  |  |
| 1. A description of any benefits to subjects or to others which may be reasonably be expected from the research. |  |  |  |
| 1. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to subjects. |  |  |  |
| 1. For FDA-regulated research, a statement that notes the possibility that the FDA might inspect the records. |  |  |  |
| 1. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained |  |  |  |

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|  | **Yes** | **No** | **Comments** |
| 1. An explanation of whom to contact:  * for answers to questions about the research. * for answers about research subjects’ rights * In the event of a research-related injury |  |  |  |
| 1. A statement that:  * participation is voluntary, * that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and * that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. |  |  |  |

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| 1. Additional Elements of Consent (if applicable) | **Yes** | **No** | **Comments** |
| If appropriate to the research, indicate whether the informed consent process provides the following additional elements of information |  |  |  |
| 1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable. |  |  |  |
| 1. Anticipated circumstances under which a subject’s participation may be terminated by the investigator without regard to subject’s consent. |  |  |  |
| 1. Any additional costs to the subject that may result from participation in the research. |  |  |  |
| 1. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject. |  |  |  |
| 1. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject |  |  |  |
| 1. The approximate number of subjects involved in the study |  |  |  |

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| 1. FDA-Regulated Studies | **Yes** | **No** | **Comments** |
| 1. If a trial involves FDA regulated materials, the consent form must contain a statement disclosing that the FDA has access to review and copy all relevant records. |  |  |  |
| 1. The consent discloses that when subjects withdraw that the data collected on them up until the point of their withdrawal remains part of the study database and may not be removed. |  |  |  |

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|  | **Yes** | **No** | **Comments** |
| 1. For applicable clinical trials[[1]](#footnote-1), as defined in 42 USC 282 (j)(1)(A), the following statement verbatim:   “A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.” |  |  |  |
| 1. The consent form captures both signature and date by the subject or legally authorized representative. |  |  |  |

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| 1. Genetics | **Yes** | **No** | **Comments** |
| 1. For research involving genetic tests or information, a disclosure of the protections provided by [GINA](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html) and the limitations of these protections. |  |  |  |
| 1. For studies subject to the [NIH Genomic Data Sharing Policy](https://gds.nih.gov/03policy2.html), the consent includes an option for subjects to provide consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly. The consent should include an explanation about whether participants’ individual-level data will be shared through unrestricted – or controlled-access repositories. |  |  |  |

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| 1. Additional Considerations | **Yes** | **No** | **Comments** |
| 1. Are complex or technical terms explained? |  |  |  |
| 1. Is the consent provided in the anticipated language(s) of the subject population? |  |  |  |
| 1. Does the consent contain exculpatory language through which the subject or the 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? |  |  |  |
| 1. When applicable, does the consent disclose that a [Certificate of Confidentiality](https://humansubjects.nih.gov/coc/background) is in place, describe the protections it affords, and any limitations or exceptions to those protections? |  |  |  |
| 1. When appropriate, and the research is not FDA regulated, does the consent describe whether and how subjects may withdraw data and/or specimens? |  |  |  |
| 1. When applicable, does the consent include an option to provide consent for future or secondary research using the data and/or specimens obtained for this research? |  |  |  |
| 1. For organizations subject to Joint Commission requirements, does the consent capture the name of the person who provided the consent information and the date the form was signed? |  |  |  |

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| **IX. Consent Form** | **Yes** | **No** | **Comments** |
| 1. Indicate whether informed consent will be documented by obtaining a signed informed consent form.   **NOTE:** *If investigator is requesting a waiver of the determination, please complete Section XIV.E, question 1, “Other IRB Determinations.”* |  |  |  |
| 1. Indicate whether the informed consent form is written at an appropriate reading level. |  |  |  |
| 1. Indicate whether: |  |  |  |
| 1. The consent document embodies the basic and required additional elements of disclosure. |  |  |  |
| 1. The subject or the subject’s legally authorized representative sign and date the consent document. |  |  |  |
| 1. A copy of the consent document is given to the person signing the form. |  |  |  |
| 1. The investigator will give either the subject or the legally authorized representative adequate opportunity to read the consent document before it is signed. |  |  |  |
| D. Is the research using a Short Form Consent Process? If so, *(****Note****: FDA expects that short form will only be used when inclusion of non-English speaking subjects is not anticipated and that subjects consented using the short form will be provide a copy of the fully translated consent ASAP.)* |  |  |  |
| 1. The short form states that the elements of disclosure required by regulations have been presented orally to the subject or the subject’s legally authorized representative. |  |  |  |
| 1. The written summary embodies the basic and required additional elements of disclosure. |  |  |  |
| 1. There will be a witness (\*Please note the witness must be impartial (e.g., can’t be a part of the research team) to the oral presentation. |  |  |  |
| 1. For subjects who do not speak English, the witness is conversant in both English and the language of the subject |  |  |  |
| 1. The subject or the subject’s legally authorized representative will sign and date the short form. |  |  |  |
| 1. The witness will sign and date both the short form and a copy of the summary. |  |  |  |
| 1. The person actually obtaining consent shall sign a copy of the summary |  |  |  |
| 1. A copy of the short form will be given to the subject or their representative. |  |  |  |
| 1. A copy of the summary will be given to the subject or their representative. |  |  |  |

**Consent Form: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

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| **X. Privacy and Confidentiality of Data and Records** | **Yes** | **No** | **Comments** |
| 1. Does the research make adequate provisions to protect the privacy interests of subjects such as: |  |  |  |
| 1. Ensuring that recruitment discussions take place in a private setting when appropriate? |  |  |  |
| 1. Ensuring that consent discussions take place in a private setting when appropriate? |  |  |  |
| 1. Provisions to ensure privacy during research exams or procedures (e.g., if subjects are required to disrobe, that they are provided with a private area to disrobe). |  |  |  |
| 1. Provisions to ensure privacy when soliciting information from subjects (e.g., when children will be asked to provide sensitive information that they may not wish to disclose to their parents). |  |  |  |
| 1. Indicate if provisions to maintain confidentiality of data and research records are adequate by considering the following elements: |  |  |  |
| 1. Obtaining or accessing data |  |  |  |
| 1. Recording and coding of data |  |  |  |
| 1. Identifiability of data |  |  |  |
| 1. Sensitivity of data |  |  |  |
| 1. Storage of data |  |  |  |
| 1. Transport or transmission of data |  |  |  |
| 1. Sharing of data |  |  |  |
| 1. Plans for future or secondary uses of data |  |  |  |
| 1. Plans for destruction of data |  |  |  |
| 1. Technological procedures to obtain, secure, and transfer data when applicable. *\*Refer to relevant statement from WMed Policy on Data Management and organization’s Information Security standards.* |  |  |  |

**Privacy and Confidentiality of Data and Records: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

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| **XI. Data Safety Monitoring** | **Yes** | **No** | **Comments** |
| For more than minimal risk research, indicate the following: |  |  |  |
| 1. Has a plan to monitor data to ensure the safety of subjects been included? If so, consider:  * Does the plan clearly identify what data will be monitored for safety purposes? * Does the plan identify whom will be responsible for evaluating safety data (e.g., the researcher, an independent medical monitor, a DSMB or DMC) and is this appropriate given the risks and other characteristics of the research? * Does the plan describe the methods that will be used to evaluate the safety data? * Does the plan describe the actions to be taken based on the occurrence of certain events or the outcome of an interim analysis (e.g., study holds, stopping rules)? * Does the plan describe how findings will be communicated to investigators and IRBs? |  |  |  |
| 1. Is this plan appropriate given the design and the risks of the research? |  |  |  |

**Data Safety Monitoring: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

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| **XII. Investigator Conflict of Interest**  **(See Supplement N)** | **Yes** | **No** | **Comments** |
| Has the investigator indicated:   * Source of funding * Relationships of investigator which may represent potential conflicts of interest or might give the appearance of a conflict of interest * Were any conflicts identified? * Was a conflict management plan (CMP) provided? * If a CMP was provided, is it acceptable as written? * Should the IRB place additional requirements or restrictions? * Is the conflict such that research cannot be adequately modified to protect human subjects (Note: only the convened IRB can disapprove research.) |  |  |  |

**Investigator Conflict of Interest: Changes, Modifications, and Clarifications**

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| Please list any recommended changes, modifications, or clarifications to the research protocol, informed consent form, or IRB application. |

**XIII. Expedited Review Determination**

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.

1. **The research is no more than minimal risk.**

Yes

No. If the research is more than minimal risk, it is not eligible for expedited review.

1. **The research involves Prisoners as subjects**

Yes. If the research involves Prisoners as subjects, it is not eligible for expedited review.

No.

1. **The research is classified.**

Yes (If the research is classified, it is not eligible for expedited review)

No.

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.**

Yes.

If yes, have reasonable and appropriate protections implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal?  
 Yes  No (If No, the research is not eligible for expedited review).

No

**ELIGIBLE CATEGORIES**

|  |  |
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| 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** |

**Note:** *Expedited Review categories 8 and 9 only apply to continuing reviews and thus are not included in this document.*

**XIV. OTHER IRB DETERMINATIONS**

**Please complete the sections that apply in order to make determinations as required.**

* 1. **RESEARCH WITH CHILDREN (refer to Supplement A submission)**

1. **If research involves children, which of the following conditions applies? The research is:**

**45 CFR 46.404/21 CFR 50.51 – Research not involving greater than minimal risk**

Research in which the IRB finds that:

No greater than minimal risk to children is presented,

Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians

The permission of one parent is sufficient **OR**

The permission of both parents is necessary, if the IRB finds it appropriate **OR**

Parental permission and the assent can be waived using the criteria for waiver of informed consent (refer to Supplement E submission)

**Justify:**

**45 CFR 46.405/21 CFR 50.52** **– Research involving greater than minimal risk, but presenting the prospect of direct benefit to individual subjects.**

Research in which the IRB finds that:

More than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject’s well-being, only if the IRB finds that:

The risk is justified by the anticipated benefit to the subjects;

The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

The permission of one parent is sufficient **OR**

The permission of both parents is necessary, if the IRB finds it appropriate

**Justify:**

**45 CFR 46.406/21 CFR 50.52 – Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition.**

Research in which the IRB finds that:

More than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB must find that

The risk represents a minor increase over minimal risk;

The intervention or procedure represents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

The research is likely to yield generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the subjects’ disorder or condition; and

Adequate provisions are made for soliciting the assent of the children and permission of both parents or guardians.

**Note:** *Where research is covered by* [*§§46.406*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.406) *and* [*46.407*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.407) *and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*

**Justify:**

**45 CFR 46.407/21 CFR 50.53 – Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.**

Research that the IRB does not believe meets the requirements of 46.404, 46.405 or 46.406 only if:

The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

**For HHS-funded research**, the Secretary (of DHHS) or FDA Commissioner after consultation with a panel of experts in pertinent disciplines (for example, science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

the research in fact satisfies the conditions of previous categories, as applicable, or

the following:

the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

the research will be conducted in accordance with sound ethical principles; and

adequate provisions are made for soliciting the assent of the children and permission of both parents or guardians.

For **non-HHS-**funded or **FDA-regulated** research, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). the IRB has determined either:

the research in fact satisfies the conditions of the previous categories, as applicable; or

the following:

the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

the research will be conducted in accord with sound ethical principles; and

adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in Section 12.7.2.

**Note:** *Where research is covered by* [*§§46.406*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.406) *and* [*46.407*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.407) *and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*

**Justify**:

1. **Assent (45 CFR 46.408/21 CFR 50.55)**

Yes  No - Is assent required of **all** children? If no, please justify:

Yes  No - Is documentation of assent required?

Yes  No – Are the procedures for documenting assent appropriate for the age and ability of the children?

Yes  No - Is assent required for **some** of the children? Whom:

If assent is not required for some or all children, please indicate why:

The children are not capable of providing assent based on the age, maturity, or psychological state.

The capability of the children is so limited that they could not reasonably be consulted or that the intervention.

The research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research (Please note that under state law, child assent may be required).

The assent can be waived using the criteria for waiver of informed consent.

Other:

**Comments:**

1. **Parental Permission**

Yes No - Will parental permission be obtained?

Yes  No - If yes to the question above are procedures for obtaining parental permission adequate?

Yes  No - Is a waiver of parental permission being requested?

If yes to the question above the research must meet one of the following:

Research meets the criteria for a waiver of consent (See Section E.1 below),

**OR**

The research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects and an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted,

**AND**

The research is **NOT** subject to FDA regulation.

**Comments:**

1. **Wards (45 CFR 46.409/21 CFR 50.56) NA**

Yes  No – Does this research involve children who are wards of the state or any other agency, institution, or entity?

If yes, is the research category 45 CFR 46.406 or 45 CFR 46.407 (see above)  Yes  No

If so, indicate whether:

Yes  No – The research is related to their status as wards; or

Yes  No – The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

Indicate whether the following requirements are satisfied:

Yes  No – There will be an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis.

Yes  No – The advocate is an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child’s participation in the research.

Yes  No – The advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator (s), or the guardian.

**Comments:**

* 1. **RESEARCH WITH PRISONERS (refer to Supplement B submission)**

1. **Indicate which category(ies) of permissible research the research falls within (45 CFR 46.306):**

Study on the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects; **OR**

Study on prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk[[2]](#footnote-2) and no more than inconvenience to the subjects; **OR**

Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults), provided that the study may proceed only after the Secretary (of DHHS) has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice, in the Federal Register, of his intent to approve such research; **OR**

Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subjects. If so, select one below:

For **HHS-funded research**, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research, such research may only proceed after the Secretary (of DHHS) has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice in the Federal Register, of the intent to approve such research.

For **non-HHS-funded research**, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research, such research may only proceed, after consultation with appropriate experts, including experts in penology, medicine, and ethics, and published notice in the Federal Register, of the intent to approve such research. **OR**

The research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease.

**Justify:**

1. **Are the criteria that allow research involving prisoners to be approved satisfied? (ALL MUST BE SATISFIED)** (**45 CFR 46.305**)

Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired; **AND**

The risks involved in the research are commensurate with risks that would be accepted by non-prisoners; **AND**

Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners; **AND**

Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project; **AND**

The information is presented in an understandable language to the subject population; **AND**

Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; **AND**

Where the Board find there may a need for follow-up examination or care of participants after the end of their participation, adequate provisions are made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing participants of this fact.

**Comments:**

1. **Consent for Research Involving Prisoners**

Yes  No - Is the language being presented to prisoners during the consent process and in the consent document understandable to prisoners?

Yes  No - Will each prisoner be informed in advance that participation in the research will have no effect on his or her parole?

Yes  No – A waiver of consent has been requested. See section E below.

**Comments:**

1. **RESEARCH INVOLVING PREGNANT WOMEN, FETUSES OR NEONATES (45 CFR 46 Subpart B)**

**(refer to Supplement C submission)**

1. **If research involves pregnant women or fetuses, the following determinations must be made:**

Yes  No  NA - Where scientifically appropriate, preclinical studies including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

Yes  No - The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the women or the fetus; **OR** if there is no prospect for benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means

Yes  No - Any risk is the least possible for achieving the objectives of the research;

Yes  No – If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the father must also be obtained unless he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulting from a rape or incest.

Yes  No – There are adequate provisions to ensure that he individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

Yes  No - There are no inducements, monetary or otherwise, will be offered to terminate a pregnancy.

Yes  No - Individuals engaged in the research have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

Yes  No - Individuals engaged in the research have no part in determining the viability of a neonate.

Yes  No  NA – If federally funded, the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means.

**Comments:**

**Consent for Research Involving Pregnant Women and Fetuses**

Yes  No - For children who are pregnant, assent and permission are obtained in accordance with the regulations. (Note: please consider state law when making this determination (i.e. is a pregnant child considered a minor, do they have rights to consent for themselves?)

Yes  No - If the research holds out the prospect of direct benefit to the pregnant woman, **OR** the prospect of a direct benefit both to the pregnant woman and the fetus, **OR** no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, then the **consent of the pregnant woman** is obtained in accord with the provisions for informed consent.

Yes  No - If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman **AND** the father is obtained in accord with the provisions for informed consent (except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest).

Yes  No – A waiver of consent has been requested. See section E below*.*

**Comments:**

1. **If research is directed toward fetuses after delivery-these are referred to as neonates.**

**FOR VIABLE NEONATES**

They are considered children and Subpart D applies. See determinations listed on section A above.

**FOR NEONATES OF UNCERTAIN VIABILITY, the following determinations must be made:**  **NA**

Yes  No  NA - Where scientifically appropriate, pre-clinical and clinical studies have been conducted and provided data for assessing potential risks to neonates?

Yes  No - There are no inducements, monetary or otherwise, will be offered to terminate a pregnancy.

Yes  No - Do individuals engaged in the research have no part in determining the viability of a neonate?

Yes  No - Does the research holds out the prospect of enhancing the probability of survival of the enrolled neonates to the point of viability?; and

Yes  No - Are the risks the least possible for achieving the objective of enhancing the probability of survival; **OR**

Yes  No – Is the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means **and** there is no added risk to the neonate from the research;

**Comments:**

**Consent for Research Involving Neonates of Uncertain Viability:**

Yes  No - Iseach individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate?

Yes  No - The legally effective informed consent of either parent of the neonate is obtained, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. **OR**

Yes  No - If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative will be obtained (except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest).

**Comments:**

**FOR NONVIABLE NEONATES, the following determinations must be made:**

Yes  No - Where scientifically appropriate, preclinical and clinical studies have been conducted and provided data for assessing potential risks to neonates?

Yes  No - Individuals engaged in the research have no part in determining the viability of a neonate?

Yes  No - (confirmation that) Vital functions will not be artificially maintained;

Yes  No - (confirmation that) The research will not terminate the heartbeat or respiration of the fetus;

Yes  No - The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means **and** there is no added risk to the neonate from the research?

**Comments:**

**Consent for Research Involving Nonviable Neonates:**

Yes  No - Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

Yes  No -The legally effective informed consent of either parent of the neonate is obtained, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

**Note:** Consent via an LAR is not permitted for research involving non-viable neonates.

**Comments:**

1. **For Research NOT Otherwise Approvable Under this section:**

**For HHS-funded research -** The IRB must determine that the research has the reasonable probability of providing important biomedical knowledge and the IRB determination must be forwarded to the Secretary of HHS who will consult with experts and determine whether the research should go forward. **OR**

**For non-HHS-funded research –** After consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law), the IRB has determined either:

the research has the reasonable probability of providing important biomedical knowledge or

the following:

the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

the research will be conducted in accord with sound ethical principles; and

informed consent will be obtained in accord with the provisions for informed consent

**Comments:**

1. **RESEARCH INVOLVING SUBJECTS WITH IMPAIRED DECISION-MAKING CAPACITY**

**(refer to Supplement D submission)**

1. **Yes**  **No - Is the use of cognitively impaired subjects justified?**
2. **Yes**  **No - Are the risks no more than minimal or, if they are more than minimal, is there the possibility for direct benefit to the subjects?**
3. **Yes**  **No - Is adequate consent or surrogate consent being obtained?**
4. **Yes**  **No - Are adequate procedures in place to determine the capacity of subjects to give consent?**
5. **Yes**  **No - Is assent from subjects being obtained and documented?**
6. **Yes**  **No – In the event that subjects regain capacity, is the process adequate: capacity assessment, re-consent process, etc.?**

**Comments:**

1. **WAIVERS OF INFORMED CONSENT/DOCUMENTATION OF CONSENT (45 CFR 46.116(c))**

**(refer to Supplement E submission)**

1. **Is a waiver or alteration of consent requested?**  Yes  No

Is it a request for a full waiver (all subjects all research activities)?  Yes  No

**OR**

Is it a request for a partial waiver (some subjects or some research activities, e.g. screening)?

Yes  No

**Is it appropriate? (ALL MUST APPLY)**

Research involves no more than minimal risk; **AND**

Waiver/alteration will not adversely affect rights and welfare of subjects; **AND**

Research could not practicably be conducted without waiver/alteration; **AND**

Whenever appropriate, subjects will be provided additional pertinent information after participation.

The research is **NOT** subject to FDA regulation

1. **Is PI requesting waiver of requirement to obtain signed consent form (documentation of consent)**

Yes  No

If yes, is it for  some or all  subjects?

**Is it appropriate? (Either may apply)**

The only record linking subject to research would be the consent form, and principal risk to subject would be potential harm resulting from breach of confidentiality and the research is **NOT** subject to FDA regulation**;** The individual obtaining consent will ask whether he or she wants documentation linking the participant with the research, and the participant’s wishes will govern.

**OR**

Research presents no more than minimal risk of harm to subject and involves no procedures for which written consent is normally required outside of research context.

**Note:** For both option one and two above, answer the following:

1. Yes  No - Has the investigator provided a written description or statement regarding the research other than the unsigned consent form?
2. Yes  No - Is an additional description or statement needed?

**Comments:**

1. **RESEARCH INVOLVING DRUGS OR BIOLOGICS (refer to Supplement H submission)**
2. **Is there an IND for all investigational drugs or biologics?**  **Yes**  **No**

Yes  No - If NO, is there adequate justification?

1. **Is the plan for the storage, dispensing, handling, and disposal of investigational and FDA-approved drugs, and biologics adequate?**  Yes  No

If NO, explain:

**Comments:**

1. **RESEARCH INVOLVING MEDICAL DEVICES (refer to Supplement I submission)**
2. **Is there an IDE for all investigational medical devices?**  YES  NO

If NO, is there adequate justification? YES  NO

1. **Is the plan for the storage, dispensing, handling, and disposal of investigational medical devices adequate?**  **Yes**  **No**

If NO, explain:

1. **Indicate the risk level of the devices:**

A non-significant risk device. (Provide documentation from the Sponsor)

A significant risk device.

If it is a NSR, is the determination justified? Yes  No

**Comments:**

1. **RESEARCH INVOLVING STORED DATA AND SPECIMENS FOR FUTURE USE (refer to Supplement J submission)**
2. **Yes**  **No - Are there adequate procedures in place to control the receipt, storage and release of data?**
3. **Yes**  **No - Are there adequate procedures in place for informed consent?**

**Comments:**

1. **RESEARCH INVOLVING THE INTERNET (refer to Supplement K submission)**
2. **Yes**  **No - Are there adequate procedures for protecting the privacy of subjects?**
3. **Yes**  **No - Are there adequate procedures for protecting the confidentiality of subjects?**
4. **Yes**  **No - Is there adequate technical expertise on the research team?**
5. **Yes**  **No - Have the tools (survey company or website host) been evaluated against WMed polices or the IT department?** Researchers must comply with all WMed requirements for information security. When the research involves other organizations, their standards must be adhered to.

**If yes, Explain:**

1. **Yes**  **No - If data is to be transported or transferred are appropriate procedures in place for physical and technological security?**

**Comments:**

1. **TRANSNATIONAL RESEARCH (refer to Supplement M submission)**
2. **Yes**  **No - Are there adequate procedures in place to obtain consent appropriate to the local context?**
3. **Yes**  **No - Does the research team have or will the research obtain adequate expertise in the local context?**
4. **Yes**  **No - Does the investigator and members of the research team have adequate credentials to conduct research in the respective international location?**
5. **Yes**  **No - Has the IRB been provided with the applicable local laws (national, state, provincial, etc.) pertaining to the protection of human subjects in the location where the research will be conducted?**

Yes  No - If Not, there must be a procedure in place for obtaining and reviewing this information prior to IRB approval.

1. **Yes**  **No - Is an IRB or EC in the location where the research will be conducted also reviewing the research? If so, has an approval letter been received from the local IRB or EC?**
2. **Yes**  **No - If a local IRB is also reviewing the research, is there a mechanism for coordinating review with the local IRB or EC?**
3. **Yes**  **No - Does the proposed consent process and informed consent document take into account any cultural and legal differences from the investigator’s home organization?**
4. **Yes**  **No - Will the same procedures that are applied to research domestically be applied to this international project?**

**NOTE:** *In order to approve this international research project, investigators must submit reports of unanticipated problems and non-compliance, continuing review, and monitoring reports in the same way as is required for any domestic research involving human subjects.*

1. **Yes**  **No - Does the IRB need to obtain outside consultation with regard to the local context?**

**Comments:**

1. **CONFLICT OF INTEREST (refer to Supplement N submission)**
2. **Yes**  **No - Are there adequate procedures in place to manage any conflict of interest?**

**Comments:**

1. Applicable clinical trial means an applicable device clinical trial or an applicable drug clinical trial. [↑](#footnote-ref-1)
2. Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons ([45 CFR 46.303(d)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.303)). [↑](#footnote-ref-2)