**Initial Submission Review Checklist**

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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. |

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| **Type of Review (check one):** | **Action** *(or recommendation for convened studies)* |
| Full Board  \*Expedited Initial Review, Category(ies):  \**For Expedited Review, please also complete the “Expedited Review Determination” located in Section XIII.* | Approval  Conditions Required for Approval  \*Partial Approval  Approval in principle  \*Defer  \*Disapprove (*Convened board action only)*  *\* Explain partial approval or basis for deferral or disapproval:* |
| **Complete the following for approvals** *(including approvals with conditions)* | |
| **Risk Level (check one):** | **Period of Approval:** |
| Minimal risk  Greater than minimal risk  *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.* | 12 Months  \*6 Months  \*Other  *\*If continuing review should be more often than annually, indicate the reason:* |
| **Waivers & Alterations (check all that apply):** | **Vulnerable Populations (check all that apply):** |
| Full waiver of consent  \*Partial waiver of consent  Waiver of documentation of consent  \*Alteration of consent  Full HIPAA waiver  \*Partial HIPAA waiver  \*Alteration of HIPAA  \**Explain:* | Children, category(ies):  Pregnant women, fetuses, or neonates  Prisoners  Adults with impaired decision-making capacity  Employees  Students  Other: |

**Changes, Modifications, and Clarifications**

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| Please list any required changes, modifications, or clarifications. Please word as you would like the information to appear on the letter to the researcher. |

**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** | **NA** |
| 1. Is the research adequately described? |  |  |  |
| Resources. Has the investigator indicated: | | | |
| 1. Sufficient time to conduct and complete the research? |  |  |  |
| 1. Appropriate expertise to conduct the study (or is supplemented by sub-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. |  |  |  |

**Comments:**

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| **II. Research Setting** | **Yes** | **No** | **NA** |
| 1. External Sites/Investigators. |  |  |  |
| Has the investigator indicated: | | | |
| 1. Whether the external site has granted permission for the research to be conducted? |  |  |  |
| 1. Whether the site or investigator is under the jurisdiction of another IRB? |  |  |  |
| 1. If the site or investigator is under the jurisdiction of another IRB: |  |  |  |
| * 1. Has the IRB approved the research? |  |  |  |
| * 1. Does the IRB plan to cede review to the WMed IRB? |  |  |  |
| 1. If the investigator is the lead investigator of a multi-site study, or the organization is the lead site or coordinating center in a multi-site study, is the plan for dissemination of information among sites sufficient to ensure the protection of subjects? (See Supplement L) |  |  |  |

**Comments:**

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| **III. Selection of Subjects** | **Yes** | **No** | **NA** | |
| 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) |  |  |  |

**Comments:**

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| **IV. Vulnerable Populations** | **Yes** | **No** | **NA** |
| 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 adults with impaired decision-making capacity   **NOTE:** *If adults with impaired decision-making capacity are involved, 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? |  |  |  |

**Comments:**

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| **V. Subject Recruitment** | **Yes** | **No** | **NA** |
| 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. For studies with multiple interactions, credit for payment accrues as the study progresses and is not 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. 5. Investigators, research staff, or participants will not receive payment, bonuses, finder’s fees or anything similar in exchange for referring participants or accelerating enrollment. |  |  |  |
| 1. Are there any advertising materials being used for this study? If yes, complete Section O in the special determinations section. |  |  |  |

**Comments:**

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| **VI. Risks to Subjects Minimized** | **Yes** | **No** | **NA** |
| 1. Is there a clear and accurate identification of risks? |  |  |  |
| 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. For greater than minimal risk studies, an appropriate plan for data and safety monitoring |  |  |  |
| 1. Precautions to decrease the likelihood of harm |  |  |  |
| 1. Contingencies to deal with harms if they occur |  |  |  |
| 1. Qualifications of investigators and study personnel |  |  |  |
| 1. Incidental Findings: |  |  |  |
| 1. Is there a plan for handling incidental findings, if applicable (i.e. communicating findings with subjects and/or providers)? |  |  |  |
| 1. If there is a plan, is it adequate? |  |  |  |
| 1. Is the plan described in the consent document? |  |  |  |

**Comments:**

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| **VII. Risk-Benefit Ratio** | **Yes** | **No** | **NA** |
| 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 subjects, short- and long-term |  |  |  |
| 1. Risks to others (e.g., risks related to disclosure of genetic information) |  |  |  |
| 1. Psychological effects (e.g., feeling sad, depressed, or suicidal) |  |  |  |

**Comments:**

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| **VIII. Obtaining Informed Consent**  **Note:** If theinvestigator is requesting a full waiver of consent, please complete Section XIV.E and, within this main form, skip forward to Section X “Privacy &Confidentiality”  **NA** | | | |
| 1. Informed Consent Process | **Yes** | **No** | **NA** |
| Indicate whether the process to obtain informed consent is adequate by considering the following elements of the protocol: | | | |
| 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. |  |  |  |

**Comments:**

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| 1. Process for special populations | **Yes** | **No** | **NA** |
| 1. Minors: Is assent needed? *If yes,* *please complete Section XIV.A, question 2 “Other IRB Determinations.”* |  |  |  |
| 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)? |  |  |  |

**Comments:**

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| 1. Basic Elements of Informed Consent  **NA** | **Yes** | **No** | **NA** |
| 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 an alteration of consent, please skip C & D in this section and complete Section XIV.E in the Other IRB Determinations section.*  **NOTE 2:** *If there is more than one consent form, please fill out the “Elements of Consent Review Checklist” for each additional consent form.* | | | |
| * 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 |  |  |  |
| * A description of reasonably foreseeable risks or discomforts. |  |  |  |
| * A description of any benefits to subjects or to others which may be reasonably be expected from the research. |  |  |  |
| * A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to subjects. |  |  |  |
| * A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained |  |  |  |
| * For research involving more than minimal risk: * an explanation as to whether any compensation and an explanation as to whether any medical treatments are available, if injury occurs **and**, if so:   + an explanation as to what it consists of or where further information can be obtained. |  |  |  |
| * 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 |  |  |  |
| * 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 (as applicable)  **NA** | **Yes** | **No** | **NA** |
| If appropriate to the research, indicate whether the consent includes 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 |  |  |  |

**Comments:**

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| 1. FDA-Regulated Studies | **Yes** | **No** | **NA** |
| 1. A statement that notes the possibility that the FDA might inspect and copy 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. |  |  |  |
| 1. If the trial must be registered on clinicaltrials.gov under [FDAAA801](https://clinicaltrials.gov/ct2/manage-recs/fdaaa), 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. |  |  |  |

**Comments:**

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| 1. Genetics | **Yes** | **No** | **NA** |
| 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 opt-in 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. |  |  |  |

**Comments:**

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| 1. Additional Considerations  **NA** | **Yes** | **No** | **NA** |
| 1. Is the level of language appropriate for the subject population? |  |  |  |
| 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 opt-in 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, or research subject to [ICH-GCP E6](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf) requirements, does the consent capture the name of the person who provided the consent information and the date the form was signed? |  |  |  |

**Comments:**

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| **IX. Consent Form  NA** | **Yes** | **No** | **NA** |
| 1. Indicate whether informed consent will be documented by obtaining a signed informed consent form.   **NOTE:** *If investigator is requesting a waiver of documentation of consent, please skip this section and complete Section XIV.E, “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 subjects not fluent in English 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. |  |  |  |

**Comments:**

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| **X. Privacy and Confidentiality of Data and Records** | **Yes** | **No** | **NA** |
| 1. Indicate if provisions to protect the privacy interests are adequate by considering the following: |  |  |  |
| 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.* |  |  |  |

**Comments:**

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| **XI. Data Safety Monitoring  NA** | **Yes** | **No** | **NA** |
| For greater 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: |  |  |  |
| * 1. Does the plan clearly identify what data will be monitored for safety purposes? |  |  |  |
| * 1. 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? |  |  |  |
| * 1. Does the plan describe the methods that will be used to evaluate the safety data? |  |  |  |
| * 1. 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)? |  |  |  |
| * 1. Does the plan describe communication of findings to investigators and IRBs? |  |  |  |
| 1. Is the plan appropriate given the design and the risks of the research? |  |  |  |

**Comments:**

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| **XII. Investigator Conflict of Interest** | **Yes** | **No** | **NA** |
| 1. Were any conflicts identified? |  |  |  |
| 1. Was a conflict management plan (CMP) provided? |  |  |  |
| 1. If a CMP was provided, is it acceptable as written? |  |  |  |
| 1. If No: |  |  |  |
| * 1. Should the IRB place additional requirements or restrictions? |  |  |  |
| * 1. Is the conflict such that the research cannot be adequately modified to protect human subjects (Note: only the convened IRB can disapprove research.) |  |  |  |

**Comments:**

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**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**

|  |  |
| --- | --- |
| 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 to make determinations (or recommendations for convened studies) as required.**

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

Research involving children must be reviewed by the IRB to determine if it fits within and is permissible under one or more federally-defined categories (OHRP/FDA). Each procedure or intervention that the child will undergo for the research must be taken into consideration, and, if the research includes more than one study group assignment (e.g., placebo vs. active, investigational agent vs. comparator), the category determination must be made for each group assignment ([component analysis](https://www.fda.gov/downloads/scienceresearch/specialtopics/pediatrictherapeuticsresearch/ucm331657.pdf)).

IRB documentation should include protocol-specific information justifying the pediatric determination(s).

1. **Pediatric Category:** Please indicate the pediatric category(ies) that apply to this research and make any additional determinations noted within the checklist.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Research not involving greater than minimal risk** (45 CFR 46.404/21 CFR 50.51) | | | | |
|  | No greater than minimal risk to children is presented; AND | | | |
|  | Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians. | | | |
|  |  | The requirement for parental permission may be waived (Complete Section E), OR | | |
|  |  | Permission of one parent is sufficient, OR | | |
|  |  | Permission of both parents is required, 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. | | |
|  | **Research involving greater than minimal risk, but presenting the prospect of direct benefit to individual subjects** (45 CFR 46.405/21 CFR 50.52) | | | | |
|  | 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; AND | | | |
|  | The risk is justified by the anticipated benefit to the subjects; AND | | | |
|  | 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 requirement for parental permission may be waived (Complete Section E); OR | | |
|  |  | Permission of one parent is sufficient; OR | | |
|  |  | Permission of both parents is required, 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. | | |
|  | **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 (**45 CFR 46.406/21 CFR 50.53) | | | | |
|  | 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; AND | | | |
|  | The risk represents a minor increase over minimal risk; AND | | | |
|  | 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; AND | | | |
|  | 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. | | | |
|  |  | The requirement for parental permission may be waived (Complete Section E), OR | | |
|  |  | Permission of both parents is required, 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. | | |
|  | **Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children** (45 CFR 46.407/21 CFR 50.54) | | | | |
|  | 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 | | | |
|  | The federal agency or FDA, 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 that either of the following is true:  (OR)  For non-federal, non-FDA research, the IRB has consulted with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the IRB may approve the research based on either: | | | |
|  | That the research in fact satisfies the conditions of 404/51, 405/52, 406/53, OR | | |
|  | That the following conditions are met: | | |
|  | 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 | |
|  | 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. | |
|  |  |  |  | Permission of both parents is required, 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. |

Please provide protocol-specific justification describing why the research is approvable under the selected category(ies):

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

Does this research involve children who are wards of the state or any other agency, institution, or entity?  Yes  No (skip ahead to question 3)

* 1. If yes, is the research category 406/53 or 407/54 (above)?

Yes – complete the table below to determine if inclusion of wards is permissible.

No (skip ahead to question 3)

|  |  |
| --- | --- |
| One of the following must be true: | |
|  | The research is related to the children’s status as wards; OR |
|  | The research will be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards |
| All of the following must be true: | |
|  | 1. The IRB shall require appointment of 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. Advocate: |
|  | The advocate 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 |
|  | 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 organization. |

1. **Waivers of Assent –** Complete this section if a waiver of assent is requested  NA
   1. Is the waiver for all children or some children?

All

Some, explain:

* 1. Based upon the following criteria and the information provided by the investigator, is the waiver approved?

Yes

No, explain:

|  |  |  |
| --- | --- | --- |
| One of the following must be true: | | |
|  | The children are not capable of providing assent because of age, maturity, or psychological state; OR | |
|  | The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research. | |
|  | The following criteria for a waiver of assent are satisfied: | |
|  |  | The research is minimal risk; AND |
|  |  | The waiver will not adversely affect the rights and welfare of the subjects; AND |
|  |  | The research could not practicably be carried out without the waiver; AND |
|  |  | Whenever appropriate, the subjects will be provided with additional pertinent information after participation.  NA |

1. **Assent –** Complete this section if assent will be obtained from some or all children  NA

a. Is the process to obtain assent (assent plan) appropriate?

Yes

No, explain:

b. Is the plan for documentation of assent appropriate?

Yes

No, documentation of assent is not required

No, documentation of assent is required but the presented plan or form is not sufficient. Explain:

*Note: Federal research regulations do not specify how child assent must be obtained or documented. IRBs have wide discretion to approve processes that are appropriate for the subject population and the research.*

**Comments:**

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1. **RESEARCH WITH PRISONERS (refer to Supplement B submission)  NA**
2. **Indicate which category(ies) of permissible research the research falls within (45 CFR 46.306):**

|  |  |  |
| --- | --- | --- |
|  | Research involving the study of the possible causes, effects, and processes of incarceration, and of criminal behavior, if both of the following are true: | |
|  | The study presents no more than minimal risk[[1]](#footnote-1) (see footnote – definition is different for research involving prisoners); AND |
|  | The study presents no more than inconvenience to the subjects. |
|  | Research involving the study of prisons as institutional structures or of prisoners as incarcerated persons, if both of the following are true: | |
|  | The study presents no more than minimal risk (see footnote – definition is different for research involving prisoners); AND |
|  | The study presents no more than inconvenience to the subjects. |
|  | Research on conditions particularly affecting prisoners as a class; the regulations list as examples 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, if one of following is true: | |
|  | For HHS-supported research, research in this category may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research; OR |
|  | For non-HHS research, research in this category may proceed only when the IRB review includes appropriate experts in penology, medicine, and ethics. |
|  | Research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.  If prisoners will be assigned to a control group[[2]](#footnote-2) and these prisoners may not benefit from their participation in the research, one of the following must be true:  NA – no control group | |
|  | For HHS-supported research, research in this category may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research; OR |
|  | For non-HHS research, research in this category may proceed only when the IRB review includes appropriate experts in penology, medicine, and ethics. |
|  | Epidemiological research that has 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. | |

Please provide protocol-specific justification describing why the research is approvable under the selected category(ies):

|  |
| --- |
|  |

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

|  |  |
| --- | --- |
| All of the following must be true: | |
|  | 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 receiving such advantages in the limited-choice prison environment is impaired; AND |
|  | The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers; 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. Unless the principal investigator provides the IRB with written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal; AND |
|  | Information is presented in language that is understandable 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 IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.  NA – no need for follow-up exams or care |

1. **Waiver or Alteration of Consent for Research Involving Prisoners**  **NA**

|  |  |
| --- | --- |
| All of the following must be true: | |
|  | The criteria for a waiver or alteration of consent are satisfied (Complete Section E), AND |
|  | The prisoner subjects will be clearly informed in advance that participation in the research will have no effect on their parole, if such notification is relevant: AND  NA – not relevant |
|  | The research is not planned emergency research. |

**Comments:**

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1. **RESEARCH INVOLVING PREGNANT WOMEN, FETUSES OR NEONATES  NA**

**(refer to Supplement C submission)**

**Note:** *For the purposes of this worksheet, once neonates have been determined viable they are considered children. Section A of this worksheet should be completed for research involving children.*

1. **Is the research conducted or supported by HHS?**

Yes – complete **section 3** below

No – compete **section 2** below

1. **Non-HHS Research**
   1. Are the risks presented by the research to the pregnant women, fetuses, and/or neonates no more than minimal?

Yes – no additional safeguards are required and there are no restrictions on the involvement of these populations in this research. The rest of this section is NA, skip ahead to Section D.

No – compete the remainder of this section.

* 1. Complete this table if the research involves pregnant women or fetuses  **NA**

Based on the information provided, indicate whether each of the following are true (‘Yes’)

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| Where scientifically appropriate, pre-clinical 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. |  |  |  |
| The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus. |  |  |  |
| Any risk is the least possible for achieving the objectives of the research |  |  |  |
| 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, then the consent of the pregnant woman is obtained in accord with the provisions for informed consent. |  |  |  |
| 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  *(NA = Consent is waived OR the research holds the prospect of direct benefit to the pregnant women)* |  |  |  |
| Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate  *(NA = Consent is waived)* |  |  |  |
| For children (as defined by state law) who are pregnant, assent and permission are obtained in accordance with applicable state law  *(NA = Consent is waived or state law permits pregnant children to provide consent without parental permission)* |  |  |  |
| No inducements, monetary or otherwise, will be offered to terminate a pregnancy |  |  |  |
| Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy |  |  |  |
| Individuals engaged in the research will have no part in determining the viability of a neonate; **or**, if their involvement in the determination of viability for an individual fetus cannot be avoided, confirmation of the determination regarding viability will be sought from a qualified individual who is not otherwise engaged in the research prior to beginning the research. The opinion of the independent qualified individual will be documented and made available upon request to the HRPP/IRB representative. When advance confirmation is not possible, the investigator will obtain it as soon as s/he can after enrollment, but in all cases within 3 business days. The circumstances that prohibited prospective confirmation of viability and the outcome of the subsequent consultation will be reported to the IRB within five (5) working days. |  |  |  |

* 1. Complete this table if the research involves neonates\* of uncertain viability or nonviable neonates  **NA**

*\* Neonate means a newborn. Nonviable neonate means a neonate after delivery that, although living, is not viable. Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. 45 CFR 46.202*

*Note: As used in Subpart B, neonate is meant to be a very temporary state. Viable neonates are considered “children” and the IRB should review as such (See Section A of this worksheet).*

Based on the information provided, indicate whether each of the following are true (‘Yes’)

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. |  |  |  |
| Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.  *(NA = Consent is waived)* |  |  |  |
| Individuals engaged in the research will have no part in determining the viability of a neonate; **or**, if their involvement in the determination of viability for an individual neonate cannot be avoided, confirmation of the determination regarding viability must be made by a qualified individual who is not otherwise engaged in the research whenever possible prior to beginning the research. The opinion of the independent qualified individual will be documented and made available upon request to the HRPP/IRB representative. When advance confirmation is not possible, the investigator will obtain it as soon as s/he can after enrollment, but in all cases within three (3) working days. The circumstances that prohibited prospective confirmation of viability and the outcome of the subsequent consultation will be reported to the IRB within five (5) working days. |  |  |  |
| Until it has been ascertained whether or not a neonate is viable, the neonate may not be involved in research unless the following additional conditions are met: | | | |
| Either: the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or the purpose of the research is the development of important knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research. |  |  |  |
| The legally effective informed consent of either parent of the neonate or, 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 is obtained in accord with the provisions of permission and assent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. |  |  |  |
| Nonviable neonates after delivery may not be involved in research unless all of the following additional conditions are met: | | |  |
| Vital functions of the neonate will not be artificially maintained. |  |  |  |
| The research will not terminate the heartbeat or respiration of the neonate. |  |  |  |
| There will be no added risk to the neonate resulting from the research. |  |  |  |
| The purpose of the research is the development of important knowledge that cannot be obtained by other means. |  |  |  |
| The legally effective informed consent of both parents of the neonate is obtained (waivers and alterations or consent are not permitted, consent by LARs of either parent is not permitted). However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. |  |  |  |

* 1. Complete this table if the research involves, after delivery, the placenta, the dead fetus, or fetal material  **NA**

Based on the information provided, indicate whether each of the following are true (‘Yes’)

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| The research has been referred to Legal and/or Research Compliance to provide guidance to the researchers on any applicable federal, state, or local laws and regulations. |  |  |  |
| The research includes information about living individuals (e.g. the parents, siblings, etc.), and their participation in the research has been evaluated for approvability using other sections of this worksheet. |  |  |  |

* 1. Complete this table if the research is not approvable per the criteria in the preceding sections **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| 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; and |  |  |  |
| The IRB has consulted with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the research may be approved because either:  the research in fact satisfies the criteria detailed above; or  All of the following are true:  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.  Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of the HRPP and IRB Handbook. |  |  |  |

**Comments:**

|  |
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|  |

1. **HHS Research**
   1. Complete this table if the research involves pregnant women or fetuses  **NA**

Based on the information provided, indicate whether each of the following are true (‘Yes’)

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| Where scientifically appropriate, pre-clinical 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. |  |  |  |
| The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; **or**,  if there is no such prospect of 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. |  |  |  |
| Any risk is the least possible for achieving the objectives of the research |  |  |  |
| If the research holds out the prospect of direct benefit to the pregnant woman, 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. |  |  |  |
| 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  *(NA = Consent is waived OR the research holds the prospect of direct benefit to the pregnant women)* |  |  |  |
| Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate  *(NA = Consent is waived)* |  |  |  |
| For children (as defined by state law) who are pregnant, assent and permission are obtained in accordance with applicable state law  *(NA = Consent is waived or state law permits pregnant children to provide consent without parental permission)* |  |  |  |
| No inducements, monetary or otherwise, will be offered to terminate a pregnancy |  |  |  |
| Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy |  |  |  |
| Individuals engaged in the research will have no part in determining the viability of a neonate |  |  |  |

* 1. Complete this table if the research involves neonates\* of uncertain viability or nonviable neonates  **NA**

*\* Neonate means a newborn. Nonviable neonate means a neonate after delivery that, although living, is not viable. Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. 45 CFR 46.202*

*Note: As used in Subpart B, neonate is meant to be a very temporary state. Viable neonates are considered “children” and the IRB should review as such (See Section A of this worksheet).*

Based on the information provided, indicate whether each of the following are true (‘Yes’)

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. |  |  |  |
| Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.  *(NA = Consent is waived)* |  |  |  |
| Individuals engaged in the research will have no part in determining the viability of a neonate |  |  |  |
| Until it has been ascertained whether or not a neonate is viable, the neonate may not be involved in research unless the following additional conditions are met: | | | |
| Either: the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means and there will be no added risk to the neonate resulting from the research. |  |  |  |
| The legally effective informed consent of either parent of the neonate or, 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 is obtained in accord with the provisions of permission and assent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. |  |  |  |
| Nonviable neonates after delivery may not be involved in research unless all of the following additional conditions are met: | | |  |
| Vital functions of the neonate will not be artificially maintained. |  |  |  |
| The research will not terminate the heartbeat or respiration of the neonate. |  |  |  |
| There will be no added risk to the neonate resulting from the research. |  |  |  |
| The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means. |  |  |  |
| The legally effective informed consent of both parents of the neonate is obtained (waivers and alterations or consent are not permitted, consent by LARs of either parent is not permitted). However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. |  |  |  |

* 1. Complete this table if the research involves, after delivery, the placenta, the dead fetus, or fetal material  **NA**

Based on the information provided, indicate whether each of the following are true (‘Yes’)

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| The research has been referred to Legal and/or Research Compliance to provide guidance to the researchers on any applicable federal, state, or local laws and regulations. |  |  |  |
| The research includes information about living individuals (e.g. the parents, siblings, etc.), and their participation in the research has been evaluated for approvability using other sections of this worksheet. |  |  |  |

1. Complete this table if the research is not approvable per the criteria in the preceding sections **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| 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; and |  |  |  |
| The research has been referred to OHRP for DHHS review and the research has been approved by the Secretary of Health and Human Services. |  |  |  |

**Comments:**

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1. **RESEARCH INVOLVING ADULTS WITH IMPAIRED DECISION-MAKING CAPACITY NA**

**(refer to Supplement D submission)**

1. Based on the information provided, indicate whether each of the following are true (‘Yes’)

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| The aims of the research cannot reasonably be achieved without the inclusion of adults with impaired decision-making capacity |  |  |  |
| If the research includes subjects who may have adequate decision-making capacity to provide consent, an appropriate plan for determining capacity has been provided |  |  |  |
| If the research includes subjects whose decision-making capacity may diminish or fluctuate, an appropriate plan for re-evaluating capacity, and, if necessary obtaining consent from a LAR, has been provided |  |  |  |
| If the research includes subjects who may regain decision-making capacity during the course of the research, an appropriate plan for obtaining consent for ongoing participation in the research has been provided |  |  |  |
| If the research involves greater than minimal risk, the following criteria must be considered, as applicable: **NA** | | | |
| Is the research is likely to improve the understanding of the condition, disease, or issue affecting the subject population? |  |  |  |
| Have any experimental procedures or interventions undergone pre-clinical testing or human testing on other populations? |  |  |  |
| If yes, does the data from that testing support its use in the proposed research? |  |  |  |
| If the procedures or interventions that the subject will undergo in the research place them at increased risk, have appropriate mechanisms been put in place to minimize risks, when possible? |  |  |  |
| Is the data and safety monitoring plan, including any stopping rules, appropriate given the risks of the research and the vulnerability of the population? |  |  |  |
| Are the procedures for withdrawing individual subjects from the research appropriate? |  |  |  |
| Do the recruitment procedures, consent process, and any plans for financial compensation support voluntariness and minimize the likelihood of undue influence or coercion? |  |  |  |
| Will the subjects will be exposed to financial or other risks that they might not consider acceptable if they had the capacity to provide consent? |  |  |  |
| If yes, have appropriate mechanisms been put in place to minimize these risks? |  |  |  |

1. Should assent from adults with impaired decision-making capacity be obtained?

Yes - for all subjects

Yes – for some subjects. Explain:

No

* 1. If Yes, has an appropriate plan to obtain assent been provided?

NA

Yes

No. Explain:

1. Should a research subject advocate or consent monitor be required?

Yes - for all subjects

Yes – for some subjects. Explain:

No

* 1. If Yes, has an appropriate plan for a RSA or consent monitor been provided?

NA

Yes

No. Explain:

**Comments:**

|  |
| --- |
|  |

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

**(refer to Supplement E submission)**

**Note:** *This checklist should not be used to evaluate waivers of consent for* [*planned emergency research*](http://www.hhs.gov/ohrp/policy/hsdc97-01.html)*, for research evaluating the safety or effectiveness of an* [*In Vitro Diagnostic (IVD)*](http://www.fda.gov/RegulatoryInformation/Guidances/ucm078384.htm)*, or federally-funded research using dried* [*Newborn Blood Spots*](http://www.quorumreview.com/act-creates-confusion-irbs-reviewing-newborn-dried-bloodspot-research/)*. If the researcher is seeking a waiver for such research, contact the IRB office for guidance.*

1. **Waiver of Consent/Parental Permission** – Complete this set of questions if the researcher is requesting a full or partial waiver of the requirement for informed consent or parental permission. **NA**
   1. Has a waiver of consent been requested for all or some subjects/activities?

All subjects

Some subjects (e.g., retrospective cohort) or activities (e.g., screening), explain:

* 1. **Select the category or categories of waivers** being requested and then fill out the applicable section.

General. Complete question c.

State or Local Public Benefit or Service Programs. Complete question d.

Parental Permission is not in the best interests of children. Complete question e.

The research is FDA-regulated and the researcher will review records prior to obtaining consent. In this case, the [FDA does not consider use of records for screening/recruitment to be part of the clinical investigation](http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm), therefore a consent waiver is not required unless the research is also HHS-supported (e.g., funded or staffed). Contact the IRB office if you have questions on this.

* 1. **General Waiver Criteria** - Based on the information provided, indicate whether each of the following are true (‘Yes’) **NA**

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| The research is minimal risk |  |  |  |
| The waiver will not adversely affect the rights and welfare of the subjects |  |  |  |
| The research could not practicably be carried out without the waiver |  |  |  |
| Whenever appropriate, the subjects will be provided with additional pertinent information after participation |  |  |  |
| The research is not FDA-regulated (i.e., is not a clinical investigation of a drug, device, or biologic) |  |  |  |

Based upon the information provided by the investigator, are the criteria for a general waiver of consent satisfied (‘Yes’ to all required criteria)?

Yes

No. Explain:

* 1. **State or Local Public Benefit or Service Program Criteria** - Based on the information provided, indicate whether each of the following are true (‘Yes’) **NA**

|  |  |  |
| --- | --- | --- |
| **Criteria** | **YES** | **NO** |
| The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. |  |  |
| The research is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. |  |  |
| The research could not practicably be carried out without the waiver |  |  |
| The research is not FDA-regulated (i.e., is not a clinical investigation of a drug, device, or biologic) |  |  |

Based upon the information provided by the investigator, are the criteria for a public benefit or service program waiver of consent satisfied (‘Yes’ to all criteria)?

Yes

No. Explain:

* 1. **Parental permission is not in the best interests of children waiver** - Based on the information provided, indicate whether each of the following are true (‘Yes’). Please note that parental permission may also be waived under ‘c’ or ‘d’ when appropriate. **NA**

|  |  |  |
| --- | --- | --- |
| **Criteria** | **YES** | **NO** |
| The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children). |  |  |
| An appropriate mechanism has been substituted for parental permission to ensure the protection of children. The mechanism (e.g., child advocate, witness, etc.) is in keeping with the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition. Mechanism: |  |  |
| The research is not FDA-regulated (i.e., is not a clinical investigation of a drug, device, or biologic) |  |  |

Based upon the information provided by the investigator, are the criteria for a waiver of parental permission for research when parental permission is not in the best interest of children satisfied (‘Yes’ to all criteria)?

Yes

No. Explain:

1. **Waiver of Documentation of Consent/Parental Permission** – Complete this set of questions if the researcher will obtain consent but it won’t be documented by signature on a consent form (e.g., oral consent, information sheet, or survey introduction without electronic signature) **NA**
   1. Has a waiver of documentation of consent been requested for all or some subjects/activities?

All subjects

Some subjects (e.g., prospective cohort) or activities (e.g., screening), explain:

* 1. **Waiver of Documentation of Consent Criteria** - Based on the information provided, indicate whether each of the following are true (‘Yes’). *To qualify for a waiver of documentation both criteria in the first boxed section below must be true* ***or*** *all four criteria in the second boxed section must be true.*

|  |  |  |
| --- | --- | --- |
| **Criteria** | **YES** | **NO** |
| The research is minimal risk |  |  |
| The research involves no procedures for which written consent is normally required outside of the research context |  |  |

OR

|  |  |  |
| --- | --- | --- |
| **Criteria** | **YES** | **NO** |
| The only record linking the subject and the research would be the consent document |  |  |
| The principal risk would be potential harm resulting from a breach of confidentiality |  |  |
| Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern |  |  |
| The research is not FDA-regulated (i.e., is not a clinical investigation of a drug, device, or biologic) |  |  |

Based upon the information provided by the investigator, are the criteria for a waiver of documentation of consent satisfied (‘Yes’ to all criteria)?

Yes

No. Explain:

* 1. Has a script, information sheet, or survey introduction been submitted? *Note: The IRB must review such to verify that the proposed consent process is appropriate and includes all required elements of consent.*

Yes

No

If yes:

Does it include all required elements of consent (see section 8.c in main worksheet)?

Yes

No. Explain:

Is it appropriate as is or are changes needed?

Yes

No. Explain:

1. **Alteration of Consent/Parental Permission** – Complete this set of questions if the researcher will obtain consent but wishes to omit or alter one or more of the elements of consent (see section 8.c in main worksheet). Alterations of consent can apply to both traditional written consent documents and alternative mechanisms to obtain consent (e.g. oral consent). **NA**
   1. Has an alteration of consent been requested for all or some subjects?

All subjects

Some subjects (e.g., prospective cohort), explain:

* 1. Element(s) of consent to be omitted or altered:

**Alteration Criteria** - Based on the information provided, indicate whether each of the following are true (‘Yes’)

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| The research is minimal risk |  |  |  |
| The alteration will not adversely affect the rights and welfare of the subjects |  |  |  |
| The research could not practicably be carried out without the alteration |  |  |  |
| Whenever appropriate, the subjects will be provided with additional pertinent information after participation |  |  |  |
| The research is not FDA-regulated (i.e., is not a clinical investigation of a drug, device, or biologic) |  |  |  |

Based upon the information provided by the investigator, are the criteria for a waiver of documentation of consent satisfied (‘Yes’ to all criteria)?

Yes

No. Explain:

**Comments:**

|  |
| --- |
|  |

1. **WAIVERS/ALTERATIONS OF REQUIREMENT FOR HIPAA AUTHORIZATION  NA**
2. **What is being requested?** *(check all that apply)*

a **full waiver** (all subjects and all uses or disclosures of PHI)?

a **partial waiver** (some subjects or some activities, e.g. screening)?

an **alteration** (removal or modification of one or more required element or statement)

1. **Waiver or Alteration of HIPAA Authorization Criteria** - Based on the information provided, indicate whether each of the following are true (‘Yes’).

|  |  |  |
| --- | --- | --- |
| **Criteria** | **YES** | **NO** |
| The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: |  |  |
| An adequate plan to protect the identifiers from improper use and disclosure. |  |  |
| An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. |  |  |
| Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA. |  |  |
| The research could not practicably be conducted without the waiver or alteration. |  |  |
| The research could not practicably be conducted without access to and use of the protected health information. |  |  |

1. Based upon the information provided by the investigator, are the criteria for a waiver of documentation of consent satisfied (‘Yes’ to all criteria)?

Yes

No. Explain:

**Comments:**

|  |
| --- |
|  |

1. **RESEARCH INVOLVING DRUGS OR BIOLOGICS (refer to Supplement H submission)  NA**

**Complete this section if the research involves the clinical investigation of one or more drugs or biologics classified as drugs.**

**A drug is defined as**:

*“A substance that is:*

* + *recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
  + *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*
  + *a substance (other than food) intended to affect the structure of any function of the body”*

**A biologic is defined as**:

*“A medical product that is:*

* + *made from a variety of natural sources (human, animal or microorganism),*
  + *like drugs, some biologics are intended to treat diseases and medical conditions,*
  + *others are utilized to prevent or diagnose diseases.*

**A clinical investigation of a drug or biologic is defined as:**

*“Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration (FDA) under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the FDA under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21CFR50.3(c), 21CFR56.102(c)]*

*Experiments that must meet the requirements for prior submission to FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act means any use of a drug [or biologic classified as a drug] other than the use of an approved drug in the course of medical practice.*

*Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21CFR50.3(c),21CFR56.102(c)]*

**Please refer to the following FDA guidance documents for helpful information:**

[Investigational New Drug Application (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)

[IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed, Guidance for IRBs, Clinical Investigators, and Sponsors](https://www.fda.gov/RegulatoryInformation/Guidances/ucm366335.htm)

[Off-Label and Investigational Use of Marketed Drugs, Biologics, and Medical Devices](https://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm)

1. This research involves the following types of test articles *(check all that apply):*

New investigational drug\* or biologics

Approved drug or biologic being used in accordance with its FDA-approved labeling

Investigational use of approved drug or biologic

*\*Dietary supplements, foods, and other substances may be considered drugs if they are being used to diagnose, cure, treat, mitigate, or prevent a disease or condition. Consult* [*FDA Guidance*](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf) *for more information*

1. Complete the following to evaluate the proposed use of the drug(s) or biologic(s).

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **Yes** | **No** | **NA** |
| The available data about the drug or biologic (pre-clinical, clinical) is sufficient to warrant the proposed phase of testing. |  |  |  |
| A pharmacy will manage the drugs or biologics used in the research or the investigator provided an appropriate plan for the storage, dispensing, and disposal of the drugs or biologics used in this study. |  |  |  |
| The sponsor of this research requires investigator compliance with ICH-GCP E6, and the investigator has attested that they will comply. |  |  |  |
| Based upon the information provided by the investigator, an IND is required for one or more of the drugs or biologics used in the research  Documentation of the IND(s) was included.  Documentation of the IND(s) was not included. |  |  |  |
| Based upon the information provided by the investigator, the research involves the use of a marketed drug and the available information supports that an IND is not required. |  |  |  |
| Indicate the category(ies) below that permit the research to be conducted without an IND:  **Category #1 General-Lawfully Marketed Drugs** [21 CFR 312.2(b)(1)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2) exemption for clinical investigations of a drug product that is lawfully marketed in the United States ([FDA Guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)).  **Category #2-In Vitro Diagnostic Biological** [21 CFR 312.2(b)(2)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2) exemption for clinical investigations involving defined (blood grouping serum, reagent red blood cells, or anti-human globulin) in vitro diagnostic biological products  **Category #3 Placebos** [(21 CFR 312.2(b)(5))](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2) exemption for clinical investigations involving the use of a placebo when the investigation does not otherwise require submission of an IND.  **Category #4 Bioavailability/Bioequivalence Studies** [21 CFR 320.31](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=320.31)(b) and (d) IND exemptions for Bioavailability or Bioequivalence (BA/BE) studies ([FDA Guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf))  **Category #5 Radioactive Drug**s [21 CFR 361.1](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=361.1) IND exemption for studies involving radioactive drugs ([FDA Guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf))  **Category #6 Cold Isotope**-IND exemption for studies involving cold isotopes ([FDA Guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf))  **Category #7 Cancer-** IND exemption for studies of marketed drugs to treat cancer ([FDA Guidance](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126837.pdf))\*Note- Planned studies may be considered exempt from the requirements of an IND if the studies involve a new use, dosage, schedule, route of administration, or new combination of marketed cancer products in a patient population with cancer | | | |

**Comments:**

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1. **RESEARCH INVOLVING MEDICAL DEVICES (refer to Supplement I submission)  NA**

**Complete this section if the research involves the evaluation of the safety and/or effectiveness of one or more medical devices in a clinical investigation.**

**Medical Devices** are defined by the FDA as:

*"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:*

* + *recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
  + *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*
  + *intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."*

[Combination Products](http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm) are products composed of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device, and a biological product. Combination products are assigned to a FDA Center for review and regulation in accordance with the products’ primary mode of action.

**A clinical investigation of a medical device is defined as:**

*“Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration (FDA) under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the FDA under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21CFR50.3(c), 21CFR56.102(c)]*

*Experiments that must meet the requirements for prior submission to FDA under section 520(g) of the Federal Food, Drug, and Cosmetic Act means any activity that evaluates the safety or effectiveness of a device. [21CFR812.2(a)]*

*Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21CFR50.3(c),21CFR56.102(c)]*

1. This research involves the following types of test articles *(check all that apply):*

New investigational medical device

Approved device being used in accordance with its FDA-approved labeling

Investigational use of a FDA-approved device

1. Does the available data (pre-clinical, clinical) support the proposed research and phase of testing?

Yes

No. Explain:

1. Has an appropriate plan been provided for the storage, dispensing, and disposal of the device(s) used in this study? If the device is not FDA-approved, the plan should include methods to segregate the device from other devices available for general use.

Yes

No. Explain:

1. **IDE Evaluation**

The Investigational Device Exemptions (IDE) regulation ([21 CFR 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812)) describes three classifications of device studies: **Significant risk (SR), Nonsignificant risk (NSR),** and **Exempt**. This section of the form is intended to identify the appropriate classification for this study if the FDA has not already made the classification.

**Exempt** device studies **(‘812-exempt’)** are exempt from the requirements describedin [21 CFR 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812)(with the exception of [812.119](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.119) (disqualification of a clinical investigator)), but are notexempt from the regulations at [21 CFR 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50) or [21 CFR 56](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56). Such studies include:

* Studies of an already cleared medical device in which the device is used or investigated in accordance with the indications in the cleared labeling.
* Studies of a PMA approved device if the device is being studied for the indications in the approved labeling.
* A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
* Diagnostic device studies (e.g., in vitro diagnostic studies) are exempt as long as the sponsor complies with the requirements at [21 CFR 809.10(c)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=809.10) for labeling, and if the testing: (i) is [noninvasive](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.3); (ii) does not require an invasive sampling procedure that presents significant risk; (iii) does not by design or intention introduce energy into a subject; and (iv) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

**Significant Risk Device,** under [21 CFR 812.3(m)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.3), means an investigational device that:

* Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
* Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
* Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
* Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

A SR device study is subject to the full requirements of [21 CFR 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812), including the need to submit an IDE application to FDA, and obtain approval, before the study can commence.

A **Nonsignificant Risk (NSR)** device study is a device study that does not meet the definition of significant risk and does not qualify as an 812**-**exempted investigation. NSR device studies are subject to [abbreviated requirements](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.2) under [21 CFR 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812). IRB approval of a NSR device study serves as the IDE approval.

Please refer to the following FDA guidance documents for helpful information and examples:

[Frequently Asked Questions About Medical Devices](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf)

[Significant Risk and Nonsignificant Risk Medical Device Studies](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf)

[In Vitro Diagnostic Device (IVD) Studies – Frequently Asked Questions](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071230.pdf)

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | **YES** | **NO** | **NA** |
| The FDA has classified the study as:  812-Exempt  NSR  SR |  |  |  |
| The FDA has approved the IDE (Only required for SR studys)  *\*Note: If the FDA has not yet approved the IDE, the study cannot be approved to begin until documentation of FDA IDE approval is received* |  |  |  |
| The FDA has not classified the proposed research, and the following classification is appropriate:  812-Exempt  NSR (Must be made by a convened IRB)  SR (Must be made by a convened IRB). An IDE application or request for risk classification must be submitted to the FDA and the results of the FDA review and any associated documentation must be provided to the IRB before the IRB can proceed with review.  Unable to determine  The study must be submitted to the FDA for a determination  More information is needed. Explain: |  |  |  |

**Comments:**

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1. **RESEARCH INVOLVING STORED DATA AND SPECIMENS FOR FUTURE USE (refer to Supplement J submission)  NA**

|  |  |  |
| --- | --- | --- |
| **I. Consider the following:** | **Yes** | **No** |
| 1. Does the consent sufficiently describe the potential future uses (so that subjects may make an informed choice)? |  |  |
| 1. Is the potential future use presented as optional\*? |  |  |
| * 1. If no, does the original research offer treatment or the prospect of benefit that isn’t readily accessible outside of the research? |  |  |
| 1. Does the consent describe if withdrawal of data/specimens is possible, any limitations, and how to withdraw consent? |  |  |
| 1. Are there appropriate plans to store and protect the data/specimens? |  |  |
| 1. If the data/specimens are identifiable or coded, are Newborn Blood Spots\*\*, or may be used for future FDA-regulated research (e.g., testing an in vitro diagnostic), does the research plan state that IRB approval or exemption will be sought for future research using the data/specimens? |  |  |

**\*** Use of data/specimens for future research [should be presented as optional whenever possible](http://wayback.archive-it.org/4657/20150826185216/http:/www.hhs.gov/ohrp/detrm_letrs/YR12/aug12a.pdf). This is especially important when the original research offers treatment or access to a potential benefit that isn’t readily accessible outside of the research. [NIH guidelines](https://gds.nih.gov/pdf/NIH_Guidance_on_Elements_of_Consent_under_the_GDS_Policy_07-13-2015.pdf) are consistent with this principle. When PHI is involved and the future research does not involve treatment or other circumstances that can be conditioned on use of PHI, [HIPAA](https://www.nationalacademies.org/hmd/~/media/Files/Activity%20Files/Disease/NCPF/2014-FEB-24/Bianchi.pdf) requires that future research is presented as an opt-in.

\*\* Under the [Newborn Screening Saves Live Reauthorization Act of 2014](http://www.quorumreview.com/act-creates-confusion-irbs-reviewing-newborn-dried-bloodspot-research/), any federally-funded research using dried Newborn Blood Spots is considered human subjects research and consent for such research is required.

**Comments:**

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|  |

1. **RESEARCH INVOLVING THE INTERNET (refer to Supplement K submission)  NA**

|  |  |  |  |
| --- | --- | --- | --- |
| **Is the proposed use of the internet appropriate taking into consideration the following factors (as applicable)?** | **Yes** | **No** | **NA** |
| 1. The Terms of Use or other rules or standards governing the use of the website or tool |  |  |  |
| 1. The mechanisms to ensure that only eligible subjects participate |  |  |  |
| 1. The privacy of subjects |  |  |  |
| 1. The mechanisms to protect the confidentiality of subject data |  |  |  |
| 1. The materials, information, messages, scripts, etc. that will be presented to or will guide interactions with subjects |  |  |  |
| 1. The technical expertise available on the research team or supplemented via consultation with experts |  |  |  |

**Comments:**

|  |
| --- |
|  |

1. **Collaborative Research (Refer to Supplement M Submission)  NA**

Complete this section for multicenter research when the local investigator is the lead PI or the local site is the coordinating center.

|  |  |  |  |
| --- | --- | --- | --- |
| **Consider the following:** | **Yes** | **No** | **NA** |
| 1. Has IRB approval been obtained for each outside site?   *(If no, consider whether approval at other sites is a pre-requisite for approval or if the research may commence independently at each site.)* |  |  |  |
| 1. If the WMed IRB is serving as the IRB of record for an outside site, does the WMed IRB need any additional information about local context or policies at the site (e.g., demographic information, who may serve as legally authorized representative, etc.)? |  |  |  |
| 1. If an external site or facility isn’t engaged in the research (e.g., their role is limited to providing data or specimens or analysis of de-identified data), has the site or facility provided permission for the research? |  |  |  |
| 1. Has an appropriate plan been provided to manage communication of information that is relevant to the conduct of the research and the protection of human subjects, such as reporting of unexpected problems, protocol modifications, and interim results? |  |  |  |
| * 1. For FDA-regulated clinical trials, does the plan address reporting serious adverse events or serious adverse device effects and significant new risk information? |  |  |  |
| 1. Has an appropriate plan been provided for oversight of research activities at other sites including verification of IRB approvals (initial, continuing, modifications, etc.), safety monitoring, and ensuring data quality and integrity? |  |  |  |
| * 1. For FDA-regulated clinical trials, does the plan include the use of trained and qualified monitors to oversee the progress of the research? |  |  |  |

**Comments:**

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1. **TRANSNATIONAL RESEARCH (refer to Supplement M submission)  NA**
2. Does the IRB have the necessary expertise, itself or through consultation, to review the research, including local law and context?

Yes

No. Explain:

1. Has the IRB been provided information about applicable laws pertaining to the protection of human subjects in the location where the research will be conducted?

Yes

No

1. Is there an IRB or EC in the location where the research will be conducted that will or has reviewed the study?

Yes. Has an approval letter been obtained? Yes No

No

1. Based on the available information, consider whether the proposed research is appropriate, taking into consideration the following factors (as applicable):

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** |
| Are the investigator and research staff qualified to conduct research in the location where it will take place, including knowledge of relevant laws, regulations, guidance, and customs? |  |  |  |
| Has the investigator obtained any necessary host country, locality, or facility permissions to conduct the research? |  |  |  |
| Is the recruitment plan appropriate for the location and subject population? |  |  |  |
| Is the consent process appropriate for the location and subject population? |  |  |  |
| Is the consent form or consent materials appropriate for the subject population, including the language used and readability for the population being recruited? |  |  |  |
| Are all written subject materials appropriate for the subject population, including the language used and readability for the population being recruited? |  |  |  |
| If the investigator and research staff are not fluent in the language of the subject population, is there an appropriate plan to ensure the ability to communicate? |  |  |  |
| If the investigator will not be present to supervise the conduct of the research, is there an appropriate plan in place to ensure that the research is conducted in accordance with the approved research plan? |  |  |  |
| Is there an appropriate plan in place to manage any modifications that need to be made to the approved research plan? |  |  |  |
| Is there an appropriate plan in place to identify and manage issues that may arise during the research such as complaints, noncompliance, protocol deviations, and unanticipated problems? |  |  |  |
| Is there an appropriate plan for data and safety monitoring, and for reporting and managing findings? |  |  |  |
| Is there an appropriate plan for protecting the confidentiality of data, taking into consideration any issues related to export control? |  |  |  |
| Is there an appropriate plan for disseminating the findings of the research to the community where it occurs? |  |  |  |

**Comments:**

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1. **FERPA/PPRA  NA**

**Complete this section if the research involves the use of student records protected under FERPA or activities involving students protected under PPRA.**

For more information, visit the following Department of Education websites:

<https://ed.gov/policy/gen/guid/fpco/ferpa/index.html>

<http://familypolicy.ed.gov/ppra?src=ferpa>

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| **I. FERPA** | **Yes** | **No** | **NA** |
| 1. **Is the research activity conducted in an educational agency or institution that receives Department of Education funding?**   **\*If Yes**, FERPA regulations apply. **If No**, skip to Section II. | \* | \* |  |
| 1. **Will the research activity include the use of student educational records?**   **\*If Yes**, FERPA regulations apply. **If No**, skip to Section II.  *Education records are records that are directly related to a student and that are maintained by an educational agency or institution or a party acting for or on behalf of the agency or institution.  These records include but are not limited to grades, transcripts, class lists, student course schedules, health records (at the K-12 level), student financial information (at the postsecondary level), and student discipline files.  The information may be recorded in any way, including, but not limited to, handwriting, print, computer media, videotape, audiotape, film, microfilm, microfiche, and e-mail.* | \* | \* |  |
| 1. **Will all of the records/data be de-identified when released to the researchers? De-identifying excludes the following**:    1. Students name, social security number, or student number    2. Parents/family member’s names, student or family’s address, easily identifiable personal characteristics, date and place of birth, and mother’s maiden name    3. Biometric records including fingerprints, retina & iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting   **\*If Yes**, consent is not required under FERPA regulations. | \* |  |  |
| 1. **Does the research only include “Directory Information” as noted below?**    1. Name, address, phone and email address    2. Date and place of birth, photographs    3. Participation in officially recognized sports and other activities    4. Field of study    5. Height and weight of athletes    6. Enrollment status (grade level, full, part-time, undergraduate, graduate), dates of attendance, most recent school attended    7. Degrees and awards received   **\*If Yes**, consent is not required under FERPA regulations. | \* |  |  |
| 1. **Is the research conducted for, or on behalf of, educational agencies or institutions to develop, validate, or administer predictive tests; administer student aid programs; or improve instruction?**   **\*If No,** FERPA requires consent from the parent (until the student is 18) or student (18 or older) which must include the following:   1. Signed and dated written consent 2. Specify the records that may be disclosed 3. State the purpose of the disclosure 4. Identify to whom the disclosure may be made   **\*If Yes,** Under FERPA, consent may be waived if all of the following criteria are met (*Note: these criteria are in addition to the Common Rule criteria for waivers*):   1. The study is conducted in a manner that does not permit personal identification of parents and students by individuals other than school officials who have legitimate interests in the information; 2. The information is destroyed when no longer needed for the purposes for which the study was conducted; and 3. There is a written agreement with the school that:   Specifies the purpose, scope, and duration of the study or studies and the information to be disclosed;  Requires the researchers to use personally identifiable information from education records only to meet the purpose or purposes of the study as stated in the written agreement;  Requires the researchers to conduct the study in a manner that does not permit personal identification of parents and students, as defined in this part, by anyone other than representatives of the organization with legitimate interests; and  Requires the researchers to destroy all personally identifiable information when the information is no longer needed for the purposes for which the study was conducted and specifies the time period in which the information must be destroyed. | \* | \* |  |
| 1. **Has the school’s FERPA Officer, or leader responsible for FERPA, signed off on the research?** |  |  |  |

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| **II. PPRA** | **Yes** | **No** | **NA** |
| 1. **Is the research conducted by or on behalf of a state or local educational agency or will research records obtained for this project come from an institution that receives any Department of Education funding?** |  |  |  |
| 1. **Does the project involve survey, analysis, or evaluation that includes any of the following topics?**    1. Mental and psychological problems potentially embarrassing to the student and family    2. Sex behavior and attitudes    3. Illegal, antisocial self-incriminating and demeaning behavior    4. Critical appraisals of other individuals with whom respondents have close family relationships    5. Legally recognized privileged or analogous relationships such as lawyers, physicians and ministers,    6. Religious practices, affiliations or beliefs of the student or student’s parents    7. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program) |  |  |  |
| 1. **Has school leadership responsible signed off on the research?** |  |  |  |
| **If Yes to 1 and 2**, PPRA applies. If the survey, analysis, or evaluation is funded, in part or in full, by DOE written consent of a parent or guardian (or student if emancipated or 18 or older) is required. If not DOE-funded, an opt-out is permissible with parent notice (notice must be in accordance with the school policy for communication with parents).  Written consent will be obtained  An opt-out mechanism with appropriate notice will be used | | | |

**Comments:**

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1. **RESEARCH INVOLVING EXERCISE INTERVENTIONS, TESTING, OR TRAINING  NA**

**(Refer to Supplement G Submission)**

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| **I. Consider the following:** | **Yes** | **No** | **NA** |
| 1. Is the target population appropriate given the nature and risks of the exercise interventions, testing, or training? |  |  |  |
| 1. Are the screening procedures appropriate given the nature and risks of the exercise interventions, testing, or training? |  |  |  |
| 1. Are the safety monitoring procedures appropriate given the target population and the nature and risks of the exercise interventions, testing, or training? |  |  |  |
| 1. Are trained personnel and first aid or emergency equipment readily available while subjects are undergoing the exercise interventions, testing, or training? |  |  |  |
| 1. Are there appropriate mechanisms in place to monitor the overall safety of the study as it progresses? |  |  |  |
| 1. Do the exercise procedures or interventions being done for the research place subjects at increased risk? |  |  |  |
| 1. Do the exercise procedures or interventions being done for the research offer the prospect of direct benefit to individual subjects? |  |  |  |
| 1. Does the consent appropriately describe foreseeable the risks associated with the exercise interventions, testing, or training? |  |  |  |

**Comments:**

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1. **ADVERTISEMENTS  NA**

The purpose of this section is to assist reviewers evaluating advertisements or other recruitment materials meant to be seen or heard by subjects. Directory listings (see note below) and materials not intended for prospective subjects (e.g., communications intended to be seen or heard by health professionals, such as "dear doctor" letters (even when soliciting for study subjects), news stories, and publicity intended for other audiences, such as financial page ads) do not require IRB approval.

*Note: Directory listings of research such as ClinicalTrials.gov are not considered advertisements and therefore do not require IRB review and approval if the listing is limited to the following basic trial information: title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the study site for further information.*

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| --- | --- | --- | --- |
| **Criteria:** | **Yes** | **No** | **N/A** |
| 1. The advertisements DO clearly disclose that the activity is research. |  |  |  |
| 1. The advertisements DO NOT: | | | |
| * 1. Imply favorable outcome or other benefits beyond that outlined in the consent document and the protocol. |  |  |  |
| * 1. Place emphasis on payment or the amount to be paid, such as bolded typed words or larger font on printed media. |  |  |  |
| * 1. Promise “Free medical treatment” when the intent was only to say subjects will not be charged for taking part in the investigation. |  |  |  |
| * 1. Contain explicit or implicit claims that the drug, biologic or device is safe or effective for the purposes under investigation. |  |  |  |
| * 1. Contain explicit or implicit claims that the test article is known to be equivalent or superior to any other drug, biologic or device. |  |  |  |
| * 1. Use terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article is investigational. |  |  |  |
| * 1. Include exculpatory language. |  |  |  |
| * 1. Include compensation for participation in a trial offered by a sponsor to involve a coupon good for a discount on the purchase price of the product once it has been approved for marketing. |  |  |  |
| The advertisement is limited to the information prospective subjects need to determine their eligibility and interest, such as: | | | |
| 1. The name and address of the investigator or research facility |  |  |  |
| 1. The condition under study and/or the purpose of the research |  |  |  |
| 1. In summary form, the criteria that will be used to determine eligibility for the study |  |  |  |
| 1. A brief list of participation benefits, if any |  |  |  |
| 1. The time or other commitment required of the subjects |  |  |  |
| 1. The location of the research and the person or office to contact for further information |  |  |  |

**Comments:**

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1. 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-1)
2. OHRP interprets control groups which may not benefit from research to include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo. [↑](#footnote-ref-2)