# WSU_HIC_header

# Initial Submission Reviewer Form

|  |  |
| --- | --- |
| **PRIMARY REVIEWER:**       | **INVESTIGATOR:**   |
| **SECONDARY REVIEWER:**       | **IRB#:**   | **COEUS #:**   |
| **STUDY TITLE:**  |
| **MEETING DATE:**       | **ASSIGNED IRB:** B3 |

|  |
| --- |
| **Exempt Category #**       **or Expedited Category #**       |

|  |
| --- |
| Reviewer’s Recommendation(Please complete after meeting discussion and decision is made) |
| [ ]  Approve [ ]  12 months [ ]  36 months (flexible review only) [ ]  Other:   [ ]  Expedited Review not subject to FDA regulations\*  \*Provide justification for recommending continuing review for minimal risk research in the  comment section below.List reason for approval less than 12 months:  | [ ]  Eligible for flexible review and oversight |
| [ ]  Specific Minor Revisions  *(FB or Expedited; Response to issues can be reviewed by the Chair /designee)* | [ ]  Tabled *(****FB only****; Response to issues will be brought back to the Committee for review)* | [ ]  Disapprove *(****FB only****; Protocol as written is rejected. PI must address issues and resubmit as a new protocol)* | [ ]  Deferred *(Not reviewed due to internal error: not posted/given to reviewers, both reviewers unable to review, etc.)* |
| Comments:  |
| I am the: [ ]  Primary Reviewer [ ]  Secondary Reviewer |
| Reviewer’s Signature: Date: |

**Direction for Reviewers:**

* Please use this form to complete your review of the protocol; it becomes part of the original file and provides documentation for auditing purposes.
* Please contact the IRB Office immediately if **any** items are missing from your review packet (313) 577-1628.
* ***Secondary*** reviewers should contact the primary reviewer prior to the meeting with concerns regarding the research study.
* ***Primary*** reviewers should contact the investigator before the convened meeting with concerns raised by self and/or the secondary reviewer. If possible, obtain information/clarification for the research study from the investigator before the convened meeting to decrease the need for “tabling.”
* Please write a comment when information is checked in **shaded** box and as appropriate.
* Reviewer sheets can be typed. Computer based forms are available from the IRB website at [www.irb.wayne.edu](http://www.irb.wayne.edu). Legibility is important to ensure proper records are available for auditing by federal agencies and for information to be included in the correspondence to investigators. Reviewers should sign in ink.

**Section A: PI, Project Title, and Endorsements**

|  | **Questions** | **Yes** | **No** | **N/A** | **Reviewer’s Response/Comments** |
| --- | --- | --- | --- | --- | --- |
| 1 | **M1 and B3:** If this is a VA study, is the CIC approval letter attached?  | **[ ]**  | **[ ]**  | **[ ]**  | **If no,** contact the RCA at the IRB prior to reviewing. |
| 1. For the VA study, do you agree with the flagging status to protect the safety of the participant as determined by the VA? (refer to CIC approval letter and determine if you want to **add** flagging to an non-flagged record or **unflag** a flagged record).
 | **[ ]**  | **[ ]**  | **[ ]**  | Bring-up at IRB meeting,esp. if no. |
| 2 | Does this study meet the definition of human subject research? (see IRB website: “Human Participant Research – How is it Defined?”) | **[ ]**  | **[ ]**  |  |  |
| **For expedited submissions only:**Will knowledge of the research methods and/or results only be available to individuals who have U.S. government security clearances? | **[ ]**  | **[ ]**  | **[ ]**  | **If yes**, refer to the Full Board |
| 3 | **Q8**: Has the Dean/Chair certified that adequate resources and facilities are available to conduct the research in a way that protects human subjects and that the research design is sound and able to yield the expected knowledge? | **[ ]**  | **[ ]**  |  |  |
| 4 | **Q8-9**: Have all persons identified in questions 8 and 9 completed and signed Conflict of Interest statements?**If any key personnel have answered yes**, is the communication from the FCOI Committee attached?If there is a management plan, are there any additional conditions that you feel should be added to the management plan? | **[ ]** **[ ]** **[ ]**  | **[ ]** **[ ]** **[ ]**  | **[ ]** **[ ]** **[ ]**  | **If no,** contact your committee’s RCA**If no,** contact your committee’s RCA**If yes,** please describe: |
|  | **Q11:** Is this submission noted as a Clinical Trial?If yes, is the registration number provided?**Clinical Trail Determination:*** Does the study involve human participants?
* Are the participants prospectively assigned to an intervention?
* Is the study designed to evaluate the effect of the intervention on the participants?

Is the effect that will be evaluated a health-related biomedical or behavioral outcome? | **[ ]** **[ ]**  | **[ ]** **[ ]**  | **[ ]** **[ ]**  |  |
| 5 | **Q13** (Form Date 03/2016): **Flexible Review**Is the proposed study eligible for flexible review and oversight? | **[ ]**  | **[ ]**  | **[ ]**  | Select **N/A** if a form dated prior to 03/2016 is used |
| 6 | **Other Section A Comments:** |
| **Section B: Narrative Summary**  |
| 7 | **Q16: Narrative Description**Is the information concise and in **lay terms**, clearly stating the background, purpose, goals, inclusion/exclusion criteria, and procedures? | **[ ]**  | **[ ]**  |  |  |
| 8 | **Other Section B Comments:** |
| **Section C: Research Project Characteristics**  |
| 9 | **Q19: Sponsors**1. If sponsored by a component of the **Department of Defense (**DoD), is **Appendix I** completed appropriately?
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 1. If sponsored by the **Department of Energy** is the Checklist for IRBs to Use in Verifying that Human Subject Research Protocols are in Compliance with Department of Energy (DOE) Requirements attached*?*
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 10 | **Q21-22:** Letters of support are provided for the following:  |  |  |  |  |
| * A WSU-affiliated site outside of the PI’s department or practice plan
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
| * A Non-WSU site
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
| * An International site
* Is Appendix A attached and filled out appropriately
* Export Control review completed
 | **[ ]** **[ ]** **[ ]**  | **[ ]** **[ ]** **[ ]**  | **[ ]** **[ ]** **[ ]**  |  |
| 11 | **Q23**: If WSU is the **Coordinating Center** for this study, is the Coordinating Center Form attached for administrative review? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 12 | **Q25**: Is the data and safety monitoring plan adequate\* (DSMB or a local safety plan)? | **[ ]**  | **[ ]**  | **[ ]**  | \*If the DSMP is not adequate, the study must be tabled. |
| 13 | **Other Section C Comments:** |
| **Section D: Data Collection** |
| 14 | **Q28-30**: Are ALL data collection instruments, surveys and/or educational materials attached and in easy to understand language? If **audio/video** **taping**, is this and when the tapes will be destroyed listed in the consent document? | **[ ]** **[ ]**  | **[ ]** **[ ]**  | **[ ]** **[ ]**  | If FB, Table if all instruments given to participants are not included. |
| 15 | **Q28-30**: (Data Collection) If the internet is being used for data collection, is **Appendix B** attached and completed appropriately? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| **Q28-29**: If medical records will be accessed, or if a database or specimen bank will be created, are the HIPAA forms attached and completed appropriately? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 16 | **Q31**: Is the allotted time for research-related activities (active and follow-up) adequately addressed? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 17  | **Q32**: If there is potential for deception or experimental manipulation, is protocol-specific scientific justification adequate? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| **If yes,** is there an acceptable plan to debrief participants? | **[ ]**  | **[ ]**  |  |  |
| 18 | **Q34a:**  If pregnant women are excluded from this research, is appropriate scientific **justification provided**? | **[ ]**  | **[ ]**  | **[ ]**  | Appropriate justification is required. |
| **Q34b, c**: If research participants are based on gender and/or race/ethnicity, is there protocol specific justification? | **[ ]**  | **[ ]**  | **[ ]**  | Appropriate justification is required. |
| 19 | **Q35-37:** If participants who meet IRB criteria for one of the “vulnerable groups” are to be enrolled, does the research comply with the current IRB policy for inclusion of these participants?* Children
* Pregnant women
* Fetuses/neonates
* Non-consenting participants
* Terminal illness
* Cognitive impairment
 | **[ ]**  | **[ ]**  | **[ ]**  | Appropriate justification is required or it should be Tabled (if FB) |
| **If yes,** is the appropriate Appendix completed and attached? (Appendix C: children and viable neonates, Appendix D: participants with a cognitive impairment, Appendix E: prisoners, Appendix K: pregnant women, fetus and non-viable neonates)(**Complete additional reviewer forms for these appendices**) | **[ ]**  | **[ ]**  | **[ ]**  | If FB, Table if missing an appendix |
| **Q36:** If any of the above vulnerable participants are involved, has the PI provided adequate protocol specific justification for their use? | **[ ]**  | **[ ]**  | **[ ]**  | If FB, Table if missing. |
| 20 | **Q37 and 39d:** Is there potential for coercion or undue influence of potential participants? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| **If yes**, are sufficient safeguards in place? | **[ ]**  | **[ ]**  |  | If FB, Table if missing |
| 21 | **Q38 & 39**: (Recruitment) Are **all** flyers, notices, advertisements, verbatim scripts, etc. included and in the appropriate format? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 22 | **Q38**: If the **Internet** is being used for advertisement or recruitment, is **Appendix B** attached and appropriately completed? Note: SONA used for recruitment *only* does not need Appendix B | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 23 | **Q38-39: Recruitment/Consent**Are the recruitment procedures and the informed consent process clearly defined? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 24 | **Other Section D Comments:** |
| **Section E: Consent of Research Participants**  |
| 25 | **Q41:** Are the personnel who will be obtaining informed consent identified as key personnel in the response to Q#9? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 26 | **Q43 a-f:** Is the appropriate type of consent/assent/information sheet selected and included with the submission? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| Is the footer with version # and date added to the bottom and the short title at the top? | **[ ]**  | **[ ]**  | **[ ]**  | If FB, state this at the meeting |
| **Q43 b-e:** If there is an alternative to written consent requested, is the justification stated and is it appropriate?  | **[ ]**  | **[ ]**  | **[ ]**  | An appropriate justification is needed. |
| **Q43 e:** School-Parental Information Letter with Decline Participation Option: if this is used, did PI request waiver of consent with *appropriate justification* included (Q46)? This is required. See OHRP guidance: <http://answers.hhs.gov/ohrp/questions/7249> | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 27 | **Q45:** **MEDICAL RESEARCH ONLY**Is a waiver of consent for emergency situations being requested? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| **If yes,** has the PI justified rationale for the waiver of consent in emergency situation **and** has the consent process been described? | **[ ]**  | **[ ]**  |  |  |
| 28 | **Q46a-e:** If a **waiver of consent** is requested (e.g., secondary data, database, chart review, pre-screening), has the PI provided ***protocol specific justification*** and have all the regulatory criteria been met?**Complete the waiver of consent supplemental form** | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 29 | **Other Section E Comments:** |
| **Section F: Confidentiality**  |
| 30 | **Q47:** Are the measures to maintain confidentiality clearly stated, including: * An adequate plan for storage and disposal of data (i.e., audio- or video-tapes)?
* Adequate provisions to protect the personal privacy interests of the participant?
 | **[ ]**  | **[ ]**  |  | If FB and the confidentiality measures are missing, Table. |
| 31 | **Q50**: Are all activities that could potentially result in identification (i.e., abuse, reportable disease, criminal activities) addressed? **Note**: This information should also be listed in the informed consent. | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 32 | **Other Section F Comments:** |
| **Section G: Benefits and Risks to Research Participants**  |
| 33 | **Q51-52**: Are benefits described accurately and included on the informed consent? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 34 | **Q53-54:** Is the nature and degree of potential risks to participants (physical, psychological, legal, economic, social): * Minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk?
* Minimized when appropriate by using procedures already being performed on the participants for diagnostic procedures, treatment or educational purposes?
* Is the risk/benefit ratio acceptable?
* Are the risks reasonable in relationship to the potential benefits, if any, to participants and the importance of the knowledge that might be expected to result?
 | **[ ]** **[ ]** **[ ]** **[ ]**  | **[ ]** **[ ]** **[ ]** **[ ]**  | **[ ]** **[ ]** **[ ]** **[ ]**  | FB—Table if any of these are not met |
| Are the risks to participants more than minimal? | **[ ]**  | **[ ]**  |  |  |
| Are the risks described accurately? | **[ ]**  | **[ ]**  |  |  |
| **For expedited submissions only:**Would identification of participants and/or their responses reasonably place them at risk or harm their reputations?**If yes**, is there reasonable and appropriate measures to minimize risks to privacy and confidentiality? | **[ ]** **[ ]**  | **[ ]** **[ ]**  | **[ ]** **[ ]**  |  |
| 35 | **Other Section G Comments:** |
| **Section H: Study Design**  |
| 36 | **Q55**: Does the compensation meet IRB policy guidelines? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 37 | **Q56:** Are additional costs clearly stated? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 38 | **Q57:** Will any marketed or experimental investigational drugs or biological products or diagnostic agents be used in this study?If No – go to **Q#40** | **[ ]**  | **[ ]**  |  |  |
| 39 | **Appendix F (Section A – Drugs…)**Does this study require an IND? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| **If yes,** has the PI provided an IND#, date and letter from the FDA; ***or*** notification from the FDA that an IND# is not required? | **[ ]** **[ ]**  | **[ ]** **[ ]**  | **[ ]** **[ ]**  |  |
| 1. For **PI-initiated** studies, is a literature search attached that was used to justify use/dose?
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 1. Is a copy of the **Drug Brochure** or **Package Insert** required and included?
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 1. Is there an adequate drug plan that includes:
* storing,
* dispensing,
* final disposition, and
* accountability of the drugs?
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 40 | **Q57: a)** Will a medical device be studied to evaluate its effectiveness and/or its safety? If No – go to **Q#42** | **[ ]**  | **[ ]**  |  |  |
| **Appendix F (Section B – Devices…)**b) Does the device meet the criteria for a Significant Risk Device?See: <http://www.fda.gov/oc/ohrt/irbs/devices.html> | **[ ]**  | **[ ]**  | **[ ]**  |  |
| **If yes**, has the PI provided protocol specific rationale for its use? | **[ ]**  | **[ ]**  |  |  |
| **If yes,** has the PI provided:* an IDE#, or
* a letter from the FDA stating an IDE# is not required, or
* an exemption category?
 | **[ ]**  | **[ ]**  |  |  |
| c) Is there an adequate device plan that includes:* receiving
* storing
* dispensing
* final disposition
* accountability
 | **[ ]**  | **[ ]**  |  |  |
| 41 | Based on evaluation of the available nonclinical and clinical information on an investigational product, is the information adequate to support the proposed clinical trial? | **[ ]**  | **[ ]**  |  |  |
| 42 | **Q58:** If research participants will be exposed to imaging, MRI’s, PET scans, or diagnostic **radiation** (e.g., x-rays, CT scans, etc.), is **Appendix G** completed appropriately? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| * Is the frequency and amount of radiation for research purposes and the lay terms equivalent of this amount on App. G (Q 3 a & b, Q 4) stated consistently across all documents (PSF, consent, etc.)?
 | **[ ]**  | **[ ]**  | **[ ]**  |
| * Is the Radiation Safety Committee Memo or the Radioactive Drug Research Committee Memo attached?
 | **[ ]**  | **[ ]**  | **[ ]**  |
| 43 | **Q59**: Will biological specimens or standard of care laboratory results be used as part of this study?If no, go to **Q#44** | **[ ]**  | **[ ]**  |  |  |
| **Appendix H (Specimens)**: Are all the specimen procedures complete and justified? | **[ ]**  | **[ ]**  |  |  |
| 1. If genetic information will be collected, are there any concerns about safeguards?
 | **[ ]**  | **[ ]**  |  |  |
| 1. If specimens will be stored for the future, are there any concerns about the safeguards?
 | **[ ]**  | **[ ]**  |  |  |
| 44 | **Research Protocol:** Based on your review of the full descriptive research proposal, is the experimental design ethical? **If no**, clearly state your concerns.  | **[ ]**  | **[ ]**  |  | **If no**, state your concerns: |
| Are the literature references cogent and up-to-date as related to the protocol background, rationale, and methodology? | **[ ]**  | **[ ]**  |  |  |
| Are there any other concerns about the proposed research study? | **[ ]**  | **[ ]**  |  |  |
| 45 | Does this study meet the criteria necessary to require more than annual review? (See IRB policy “Criteria for determining frequency of IRB review”.**If yes,** state your reasons for this determination **and** what you suggest as an appropriate approval period. | **[ ]**  | **[ ]**  |  | **If yes,** state reasons for determination and suggested approval period: |
| 46 | If this is a multi-center study where the PI is the **Coordinating Center**, has the PI submitted an adequate plan to communicate information among the sites that may affect the health or safety of participants or their willingness to continue to participate in the study? (Examples include: unanticipated problems and adverse events, protocol modifications and interim study results)  | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 47 | **Other Section H Comments:** |

**CONSENT PROCESS (Extra Consent Reviewer Checklists are on the IRB website under “For IRB Members”)**

**[ ]** N/A - Waiver of informed consent (complete the **Waiver or Alteration to Informed Consent Checklist** and the **Waiver of Requirement for Written Documentation of Informed Consent Checklist**)

|  | **Questions** | **Yes** | **No** | **N/A** | **Reviewer’s Response/Comments** |
| --- | --- | --- | --- | --- | --- |
| 1 | Will children be enrolled as study participants? If no, go to **Q#2** | **[ ]**  | **[ ]**  |  |  |
| * In studies conducted outside of the local jurisdiction, has verification of the definition of “child” and any applicable laws/regulations been submitted?
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
| * If yes, has it been pre-reviewed by an attorney?
 | **[ ]**  | **[ ]**  |  |  |
| * For risk Category 1 and 2, is the signature of one parent sufficient? **If yes,** provide justification.
 | **[ ]**  | **[ ]**  | **[ ]**  | Justification:  |
| * For risk Category 3, will the signature of both parents be obtained?

**If not,** provide justification. | **[ ]**  | **[ ]**  | **[ ]**  | Justification: |
| * Is the appropriate Assent Form being used?
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
| * Has the PI submitted an appropriate plan (per Appendix C and/or D) to determine if the children are capable of assenting that is consistent with the medical/research area to be studied. Take into account the ages, maturity, and psychological state of the children to be recruited into this study.
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
|  | * If a waiver of Assent is permitted, have all of the regulatory criteria been met?
 | **[ ]**  | **[ ]**  | **[ ]**  |  |
|   | Consent document begins with a clear and concise presentation of “Key Information”  | **[ ]**  | **[ ]**  |  |  |
| 2 | A statement the study involves research | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 3 | An explanation of thepurposes of the research | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 4 | An explanation of the expected duration of the participant’s participation | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 5 | A statement of the approximate number of participants expected to be involved in the study. | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 6 | A description of the procedures to be followed. | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 7 | Identification of any procedures that are experimental (may be omitted if none). | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 8 | A description of any reasonably foreseeable risks or discomforts to the participant. | **[ ]**  | **[ ]**  | **[ ]**  |  |
| **Research involving collection of identifiable private information or identifiable bio-specimens** |
|  | A statement that the subject’s bio-specimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit | **[ ]**  | **[ ]**  | **[ ]**  |  |
|  | A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions | **[ ]**  | **[ ]**  | **[ ]**  |  |
|  | Whether the research will (if known) or might include whole genome sequencing of bio-specimens (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 9 | A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable **(Look for when research involves investigational drugs or devices, novel procedures involving risk, or where a goal of the research is to define safety.)** | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 10 | A statement that if the participant is, or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.**(Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.)** | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 11 | A description of any benefits to the participant or to others which may reasonably be expected from the research | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 12 | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant including their important potential benefits and risks (*may be omitted if there are none).* | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 13 | A statement describing any additional costs to the participant that may result from participation in the research (**look for when additional costs are expected.)** | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 14 | A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 15 | A statement that notes the possibility that the FDA and/or OHRP, WSU, DMC, KCI, etc., may inspect the records. This should also include the monitor, auditor, IRB, and any other applicable regulatory clause. May not be applicable if an Information Sheet is being used. | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 16 | An explanation of whether compensation is available if injury occurs and, if appropriate, the WSU indemnification clause.  | **[ ]**  | **[ ]**  | **[ ]**  |  |
| If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 17 | An explanation as to whether any medical treatments are available if injury occurs | **[ ]**  | **[ ]**  | **[ ]**  |  |
| *If medical treatments are available when injury occurs,* an explanation as to what it consists of or where further information may be obtained | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 18 | An explanation of whom to contact for answers to:* Pertinent questions about the research
* Pertinent questions about the research participants’ rights
 | **[ ]** **[ ]**  | **[ ]** **[ ]**  | **[ ]** **[ ]**  |  |
| 19a | An explanation of whom to contact (usually the PI) in the event of a research-related injury to the participant **(Note: May be omitted IF** the research involves **no more than minimal risk AND the reviewer concurs with the PI's rationale** for the omission—see q. below.) | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 19b | **Q. 40: *If*** *the Research-Related Injury* section is being **omitted** from the consent or the information sheet:* Is the study no more than minimal risk?
* Do you concur with the PIs justification?
 | **[ ]** **[ ]**  | **[ ]** **[ ]**  | **[ ]** **[ ]**  |  |
| 20 | A statement that participation is voluntary | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 21 | A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 22 | A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 23 | A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant. **(Look for in long-term clinical trials.)** | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 24 | A statement addressing the consequences of a participant’s decision to withdraw from the research **(Look for when withdrawal from the research will have adverse consequence.)** | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 25 | A statement describing anticipated circumstances under which the participant may be terminated by the investigator without regard to the participant’s consent. **(Look for when the protocol mentions this as a possibility.)** | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 26 | A description of procedures for orderly termination of participation by the participant. (**Look for when such procedures are part of the protocol.)** | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 27 | If a Clinical Trial, does consent contain the Clinical Trials.gov statement, as required by law? See below for more info. | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 28 | Have all the required elements of informed consent (above Q.s) been included in the documentation? | **[ ]**  | **[ ]**  | **[ ]**  |  |
| **REVIEWER’S COMMENTS:** (Typos, notes to PI, editing information) |
| Q.27, Clinical Trials.gov: [U.S. Public Law 110-85](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf) (Food and Drug Administration Amendments Act of 2007 or FDAAA), Title VIII, Section 801 mandates that a "responsible party" (i.e., the sponsor or designated principal investigator) register and report results of certain "applicable clinical trials": **Trials of Drugs and Biologics:** Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation; **Trials of Devices:** Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies. **"Applicable clinical trials"** generally include interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the U.S, involves a drug, biologic, or device that is manufactured in the US (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE). |

**REQUIREMENTS OF ASSENT (Extra Consent Reviewer Checklists are on the IRB website under “For IRB Members”)**

**[ ]** N/A

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Questions** | **Yes** | **No** | **N/A** | **Reviewer’s Response/Comments** |
| 1 | A statement that the study involves research | **[ ]**  | **[ ]**  |  |  |
| 2 | An explanation of the purposes of the research | **[ ]**  | **[ ]**  |  |  |
| 3 | An explanation of the expected duration of participation | **[ ]**  | **[ ]**  |  |  |
| 4 | A description of the procedures | **[ ]**  | **[ ]**  |  |  |
| 5 | Identification of any procedures that are experimental (May be omitted if there are none) | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 6 | A description of any reasonably foreseeable risks or discomforts to the participant | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 7 | A description of any benefits to the participant or to others which may reasonably be expected from the research | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 8 | A disclosure of alternative procedures or treatment, if any, that might be advantageous to the participant. | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 9 | An explanation as to whether compensation is available. | **[ ]**  | **[ ]**  | **[ ]**  |  |
| 10 | An explanation that parents or guardians are aware of the research. | **[ ]**  | **[ ]**  |  |  |
| 11 | A statement that includes contact information. | **[ ]**  | **[ ]**  |  |  |
| 12 | A statement that participation in the study is voluntary. | **[ ]**  | **[ ]**  |  |  |
| 13 | **REVIEWER’S COMMENTS:** (Typos, notes to PI, editing information) |

|  |  |  |
| --- | --- | --- |
|   | **RISK CATEGORY** – Reviewer must provide protocol specific examples to justify the selected risk level. If children are enrolled, examples are required to justify that the conditions are met. |  |
| 1 | **Level 1: Research not involving greater than minimal risk*****Justification:*** | **[ ]**  |
| IF CHILDREN ARE ENROLLED:The following condition must be met *for children* in order to qualify for risk Category 1:* Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.
 |
| 2 | **Level 2: Research involving greater than minimal risk but presenting the prospect of direct benefit to the participant.*****Justification:*** | **[ ]**  |
| IF CHILDREN ARE ENROLLED: All 3 of the following conditions must be met *for children* in order to qualify for risk Category 2:* The risk is justified by the anticipated benefit to the subjects;
* The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
* Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.
 |
| 3 | **Level 3: Research involving greater than minimal risk and NO prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s condition or disorder.** | **[ ]**  |
| ***Justification:*** |  |
| IF CHILDREN ARE ENROLLED: All 4 of the following conditions must be met *for children* in order to qualify for risk Category 3:* The risk represents a minor increase over minimal risk;
* The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
* The intervention of procedure is likely to yield generalizable knowledge about the participants’ disorder or condition which is of vital importance for the understanding or amelioration of the participants’ disorder or condition; and
* Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.
 |  |

***For your reference only:* 45 CFR 46.111 Criteria for IRB Approval or SMR** **of Research**

1. Is a plan for data safety and monitoring necessary?
2. Is the selection of participants equitable?
3. Is there any potential for coercion or undue influence of participants? If so what measures are taken?
4. Will informed consent be sought?
5. Will informed consent be documented, or a waiver of documentation w/info sheet granted?
6. Are confidentiality measures sufficient?
7. Have the risks to participants been minimized?
8. Are the risks reasonable in relation to the benefits and resulting knowledge?

**Advertising Policy:** **Criteria for advertisement review includes the following:**

* Advertisements may not imply a certainty of favorable outcome or benefits beyond what is outlined in the informed consent.
* No claims should be made that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.
* The terms "new treatment", "new medication" or "new drug" should not be used without explaining that the test article is investigational.
* Advertisements should not promise "free treatment", when the intent is only to say that participants will not be charged for taking part in the investigation.
* Advertisements may state that the participants will be paid, but should not emphasize the payment or the amount to be paid,by such means as larger or bold type. See the IRB policy on “Compensation for Research Participants” for guidelines on compensation.
* Advertisements should state that it is for a research study.
* Advertisements may not be coercive or imply undue pressure.
* Advertisements may be limited to the information the prospective participants need to determine their eligibility and interest.
* Advertisements may not include exculpatory language

**The following items may be included in advertisements (the inclusion of all of the listed items is not required):**

1. The name and address of the clinical investigator and the identity of the research facility.
2. The condition under study and/or the purpose of the research.
3. The criteria, in summary form, that will be used to determine eligibility for the study.
4. A brief list of the benefits or incentives of participation, if any.
5. The time or other commitment required of the participants.
6. The name of the person or office to contact for further information.

**For EXPEDIETED REVIEWERS ONLY:**

|  |  |
| --- | --- |
| Date of receipt of final version Medical Exemption Form: |   |
| Date of receipt of final version of HIPAA Summary Form: | [ ]  N/A  |
| Date final version of Research Protocol was received: |   |
| Date final versions of advertisements, brochures, surveys, scripts, assessments, etc. received: |   |