

### Full Board Amendment Reviewer Form

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| Reviewer |  | | | Assigned IRB | |  | Meeting Date | |  |
| Secondary Reviewer | **N/A** | | | | | | | | |
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| Investigator |  | Department |  | | | | | | |
| IRB# |  | Coeus # |  | | Expiration Date | | |  | |
| Study Title |  | | | | | | | | |
| Sponsor |  | | | | | | | | |

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| Reviewer’s Recommendation (Please complete after meeting discussion and decision is made) | | | |
| Approve | | | |
| 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:  Reviewer’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |

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| Current level of risk is:  Following your review of the submitted materials, is the risk to participants, *in your opinion*, *greater* than what was originally approved? | No  Yes - complete the risk section at the end of the form |

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|  | | | | Yes | | No | | | N/A | | **Reviewer’s Comments** | |
| **VA Research**  N/A | | | | | | | | | | | | |
|  | **Q#7**: If yes (research being conducted at VAMC), is the CIC memo attached? | | |  | |  | | |  |  | | |
|  | | | | | | | | | | | | |
|  | **Q#8a: If the study was previously determined to be eligible for flexible review and oversight**, select all items that are added with this amendment. If none of the items are selected, the study remains eligible for flexible review and oversight.  N/A  NOTE: Beginning March 15, 2016, studies that are minimal risk, do not have federal funding, are not FDA-regulated, and are not done at the VA may be determined to be eligible for flexible review and oversight. Addition of federal funding, FDA-regulated components, or VA sites are examples of changes that can affect eligibility for flexible review. See the “Flexible Review and Oversight of Research Not Covered by Federalwide Assurance” policy: <http://irb.wayne.edu/policies-human-research.php> | | Procedures that are more than minimal risk to participants  Federal funding/sponsorship  Food and Drug Administration (FDA) regulated components (drugs, biologics, medical devices, etc.)  Data will be used to support applications to the Food and Drug Administration (FDA)  Department of Veterans Affairs (VA) components  Prisoners targeted for participation  The study sponsor, outside collaborators, or other entities will require annual IRB review of the study  Contractual obligations with the study sponsor, outside collaborators, or other entities to adhere to federal research regulations | | | | | | | | | |
| **Recruiting and Advertising Materials**  N/A | | | | | | | | | | | | |
|  | **Q#14**: Are copies of all revised or new documents attached (advertisements, notice, flyer, participant information, brochure or pamphlet, press release)? | | |  | |  | | |  | |  | |
| **Protocol Revisions**  N/A | | | | | | | | | | | | |
|  | **Q#16**: Are the changes to the previously approved protocol described and is there sufficient information to make a determination? | | |  | |  | | |  | |  | |
|  | Are all of the appropriate Appendixes attached?  *Please complete any reviewer sheets for corresponding Appendix and attach*. | | |  | |  | | |  | |  | |
|  | Are vulnerable participants now included?  **If yes**, do you agree with the protocol-specific  justification provided for their inclusion? | | |  | |  | | |  | |  | |
|  | Has the sample size changed?  Has the enrollment criteria changed?  Has the research site changed?  Do the changes affect the risk/benefit ratio? | | |  | |  | | |  | |  | |
|  | Do the changes result in significant changes in the design, focus, or purpose of the research? | | |  | |  | | |  | |  | |
|  | Is there a change in treatment?  **If yes,** does this affect the risk/benefit ratio? | | |  | |  | | |  | |  | |
|  | If there is a *change in data collection*, does it protect the confidentiality and privacy of the participants? | | |  | |  | | |  | |  | |
| Consent Changes— see page p. 5 | | | | | | | | | | | | |
|  | | Yes | | | No | | | N/A | | | | **Reviewer’s Comments** |
| **Waiver of Consent (see 2nd part of Q #17)**  N/A | | | | | | | | | | | | |
|  | **Q #17 f – Waiver of Consent**  **a)** Do you agree with the protocol-specific justification for requesting the **waiver of consent**?  The consent process and the parental permission cannot be waived or altered for FDA-regulated research. | | |  | |  | | |  | |  | |
| **b)** Have all of the regulatory criteria been met? Please complete the following 2 forms and attach:  **1)** Waiver of Request for Written Documentation  of Informed Consent and  **2)** Waiver or Alteration of Requirements to Obtain  Informed Consent | | |  | |  | | |  | |  | |
| **C)** Do you concur that a waiver of consent should be granted? | | |  | |  | | |  | |  | |
|  | **Q #17 g – Waiver of documentation of consent**  **a)** Do you agree with the protocol-specific justification for requesting the **waiver of the documentation** of consent?  The consent process and the parental permission cannot be waived or altered for FDA-regulated research. | | |  | |  | | |  | |  | |
| **b)** Do you concur that a waiver of documentation of  consent should be granted?  Please complete the following form and attach:  ***Waiver of Request for Written Documentation***  ***of Informed Consent*** | | |  | |  | | |  | |  | |
|  | **Q #17 h – Alteration to the elements of consent**  **a)** Do you agree with the protocol-specific justification for requesting the **alteration to some or all of the elements of consent**?  The consent process and the parental permission cannot be waived or altered for FDA-regulated research. | | |  | |  | | |  | |  | |
| **b)** Have all of the regulatory criteria been met?  Please complete the following form and attach:  ***Waiver or Alteration of Requirements to***  ***Obtain Informed Consent*** | | |  | |  | | |  | |  | |
| **c)** Do you concur that an alteration to some or all of the required elements of consent should be granted? | | |  | |  | | |  | |  | |
| **HIPAA**  N/A | | | | | | | | | | | | |
|  | **Q#18** Are the HIPAA forms attached and completed appropriately? | |  | |  | |  | | |  | | |
|  | Do you agree with the HIPAA justification? | |  | |  | |  | | |  | | |
| **Drug Brochure and Package Insert**  N/A | | | | | | | | | | | | |
|  | **Q# 19** Has the risk/benefit ratio changed?  Note: a change in the Drug Brochure may or may not require a protocol revision. | |  | |  | |  | | |  | | |
| **Other**  N/A | | | | | | | | | | | | |
|  | **Q# 20** Do you agree with the justification provided for the additional changes? | |  | |  | |  | | |  | | |

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| **General Questions for ALL Reviewers** | | | | | |
|  | **a)** Are there any significant new findings that arose from the amendment that might relate to participants’ willingness to continue participation? |  |  |  |  |
| **If yes,** does this affect the risk/benefit ratio? |  |  |  |  |
| Should the change or new findings or information be provided to participants in a revised consent, assent, information sheet or other method for:  New participants  Current participants (re-consent or inform  them)  Are the revised documents attached?  *If yes, please complete the later consent section.* |  |  |  |  |

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| **Children**  N/A | | | | | | | | | |
|  | | Yes | | | No | | N/A | | **Reviewer’s Comments** |
|  | ***(Refer to Appendix C)***  **a)** In studies conducted outside of the local jurisdiction, have verification of the definition of *“child*” and any applicable laws regulations been submitted? | |  |  | |  | |  | |
| ***If yes,*** is a review and approval by an attorney  attached? | |  |  | |  | |  | |
| **b)** For risk level 1 and 2 research, is the signature of one parent sufficient? Must be consistent with laws/regulations in the jurisdiction in which the research is conducted. **(Appendix C Q# 2)** | |  |  | |  | |  | |
| ***If yes,*** do you agree with the justification  provided by the PI’s? | |  |  | |  | |  | |
| **c)** For risk level 3 research, will the signature of both parents be obtained, as is required? | |  |  | |  | |  | |
|  | ***If no,*** do you agree with the justification  provided by the PI’s?Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. Parental permission and the consent process cannot be waived or altered for FDA-regulated research. | |  |  | |  | |  | |
| **d)** If permission is to be obtained from a guardian, will the guardian be an individual who is authorized under applicable State or local law to consent on behalf of the child to general medical care? | |  |  | |  | |  | |
| **e)** Has the PI submitted an appropriate plan 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. | |  |  | |  | |  | |
| **f)** Is the capability of some or all of the children so limited that they cannot reasonably be consulted regarding assent or the intervention or procedure involved in the research? | |  |  | |  | |  | |
| **g)** If waiver of assent is permitted, have all of the regulatory criteria been met? | |  |  | |  | |  | |

| Consent, Assent, or Information Sheets Q# 17  N/A **Complete Reviewer Checklist for Consent or Assent form or Information Sheet:**   * ***Only* for any sections that were revised or added with the amendment *OR*** * **If the whole thing is new, the entire checklist must be completed.** * **Extra Reviewer Checklists are at:** [**http://irb.wayne.edu/irb-members.php**](http://irb.wayne.edu/irb-members.php) | | | | | |
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| *Complete only for the sections with changes* | | **Yes** | **No** | NA | Reviewer’s Comments |
| 1. 1 | A statement that the study involves research |  |  |  |  |
|  | An explanation of the purposes of the research. |  |  |  |  |
|  | An explanation of the expected duration of the participant’s participation. |  |  |  |  |
|  | A description of the procedures to be followed. |  |  |  |  |
|  | Identification of any procedures that are experimental. ***(May be omitted if there are none.)*** |  |  |  |  |
|  | A description of any reasonably foreseeable risks or discomforts to the participant. |  |  |  |  |
|  | A description of any benefits to the participant or to others, which may reasonably be expected from the research. |  |  |  |  |
|  | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. |  |  |  |  |
|  | A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. |  |  |  |  |
|  | A statement that notes the possibility that the FDA, &/or  OHRP, WSU, DMC, KCI may inspect the records.  **(May be “N/A” if Information Sheet is being used)** |  |  |  |  |
|  | An explanation as to whether compensation is available if injury occurs and if appropriate the WSU indemnification clause.  **IF N/A go to Q#31** |  |  |  |  |
|  | If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. |  |  |  |  |
|  | a) An explanation as to whether any medical treatments are available if injury occurs.  **IF N/A go to Q#32** |  |  |  |  |

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|  | *Refer to Appendix C* | | **Yes** | **No** | NA | Reviewer’s Comments |
|  | b) If medical treatments are available when injury occurs, an explanation as to what it consists of or where further information may be obtained. | |  |  |  |  |
| 32 | An explanation of whom to contact for answers to pertinent questions about the research. | |  |  |  |  |
| 33 | An explanation of whom to contact for answers to pertinent questions about the research participants’ rights. | |  |  |  |  |
| 34 | An explanation of whom to contact (usually the PI) in the event of a research-related injury to the participant.    **If no,** does the research involve **no more** than minimal risk **AND** you **concur** with the PIs rationale for omitting? | |  |  |  |  |
| 35 | A statement that participation is voluntary. | |  |  |  |  |
| 36 | A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. | |  |  |  |  |
| 37 | A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. | |  |  |  |  |
| 38 | 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/devices, novel procedures involving risk, or where a goal of the research is to define safety.)*** | |  |  |  |  |
| 39 | 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.)*** | |  |  |  |  |
| 40 | Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent. **(*Look for when the protocol mentions this as a possibility.)*** | |  |  |  |  |
| 41 | Any additional costs to the participant that may result from participation in the research. **(*Look for when additional costs are expected.)*** | |  |  |  |  |
|  |  | | **Yes** | **No** | NA | Reviewer’s Comments |
| 42 | The consequences of a participant’s decision to withdraw from the research. **(*Look for when withdrawal from the research will have adverse consequence.)*** | |  |  |  |  |
| 43 | Procedures for orderly termination of participation by the participant. **(*Look for when such procedures are part of the protocol.)*** | |  |  |  |  |
| 44 | 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 on long-term clinical trials.)*** | |  |  |  |  |
| 45 | The approximate number of participants involved in the study, if this has changed. | |  |  |  |  |
| 46 | ***If compensation was offered and has now been removed*,** a statement was added similar to “*Compensation will not be provided*.” | |  |  |  |  |
| 47 | ***When research is now approved for*** *adults or children with a* ***cognitive impairment***, a signature line for the parents/guardians is added to the consent form (if the adult is not their own partial or full guardian)? | |  |  |  |  |
| 48 | VA Informed Consents:The VA informed consent must be used. Is the required statement included?: that in the event of a research-related injury the VA had to provide necessary medical treatment to a participant injured by participation.    Is the required statement included?: that a veteran-participant would not be required to pay for care received as a participant in a VA research project except in accordance with federal law and that certain veterans were required to pay co-payments for medical care and services provided by VA. | |  |  |  |  |
| 49 | Any Additional Reviewer comments on the Informed Consent? |  | | | | |

| 50. Additional Requirements for Assent Forms if applicable  * **Extra Reviewer Checklists are at:** [**http://irb.wayne.edu/irb-members.php**](http://irb.wayne.edu/irb-members.php) | N / A | | | | | Reviewer’s Comments |
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| **Yes** | **No** | | | **N/A** |
| A statement that the study involves research |  | |  |  | |  |
| An explanation of the purposes of the research |  | |  |  | |  |
| An explanation of the expected duration of participation |  | |  |  | |  |
| A description of the procedures |  | |  |  | |  |
| Identification of any procedures that are experimental |  | |  |  | |  |
| A description of any reasonably foreseeable risks or discomforts to the participant |  | |  |  | |  |
| A description of any benefits to the participant or to others, which may reasonably be expected from the research |  | |  |  | |  |
| A disclosure of appropriate alternative procedures or treatment, if any, that might be advantageous to the participant |  | |  |  | |  |
| An explanation as to whether compensation is available |  | |  |  | |  |
| An explanation that parents or guardians are aware of the research |  | |  |  | |  |
| A statement that includes contact information |  | |  |  | |  |
| A statement that the study is voluntary |  | |  |  | |  |

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| 51 | Any additional reviewer comments or areas of concern? |  |

***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?

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| **ONLY NEED TO COMPLETE IF the level of risk has increased:** | | | |
|  | | **RISK CATEGORY – Reviewer must provide protocol specific examples to justify the selected risk level and met the conditions, if children are enrolled.** |  |
| 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. |  |

**Examples of amendments that would require full board review**  Full board review is required when an additional risk to participants has been identified or the proposed change poses an increased risk or there is a change in the risk or safety information to participants that significantly affect the nature of the study.

* Addition of a **new risk**, increased risk, serious unexpected adverse event, safety information or other risks to the protocol, Investigator Brochure, packet insert or consent documents
* Investigational Brochures, protocols, or package inserts with **updated** risk or safety information that is not already in the consent and, if multiple studies are using the drug, that does pertain to this study (if WSU site is permanently closed to accrual and no one is receiving treatment/active, and no one is in follow-up, then it can be expedited).
* Changes to the consent or Investigator Brochure that are ***more*** than administrative changes
* Broadening the range of inclusion criteria
* Narrowing the range of exclusion criteria
* Significant changes to the aims or design of the protocol
* Alteration in the dosage or route of administration of an administered drug
* Substantially extending the duration of exposure to the test material or intervention
* Deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations
* Changes that, in the opinion of the IRB Chair or his/her designee, do not meet the criteria or intent of a “minor” modification