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| **PI:**        **Meeting Date:**        **Reviewer:**  **Instructions:** Use the  [DHHS Continuing Review Guidance](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjlg4fw7fTSAhVF6iYKHZB-Cn8QFggfMAA&url=https%3A%2F%2Fwww.hhs.gov%2Fohrp%2Fregulations-and-policy%2Fguidance%2Fguidance-on-continuing-review-2010%2F&usg=AFQjCNFDMJFE1VDRqKjGUcSkN3KN8qmf4g)  to assist in addressing the approval criteria  If conditions are not met for any of the Approval Criteria, list the requirements to be communicated to the study team under the applicable condition(s) AND complete each drop down menu option that is highlighted in yellow.  **Refer to Appendices at the end of this document for assistance with determining approval criteria** | | |
| **Study Status:**  Open to Enrollment  Closed to Enrollment (subjects in treatment)  **Populations requiring additional protections:**  NONE  Children  Impaired Decision Making Capacity  Economically and Educationally Challenged.  Fetuses  Neonates  Prisoners  Pregnant Women | | |
| |  | | --- | | The reviewer gave an overview of the research project stating that **the purpose of this study is to**       .  The protocol Choose an item.  The protocol is FDA Regulated  YES  NO (see 1st page of Status Report)  The protocol is being conducted under Choose an item.       .  The protocol is regulated by the Department of Defense (DOD)  YES  NO (see Appendix D)  If Yes, the IRB Choose an item. received information that would lead to concerns that the protections found in Appendix D are not being carried out.  The study was initially approved to enroll in     . The study team has enrolled       out of       subjects approved to enroll.       subjects were enrolled during this review period. | | | |
| **Approval Criteria per Federal Regulations (45CFR46.116/21CFR56.111/32CFR219)** | **YES** | **NO** |
| **(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:** | | |
| ***Pre 2018 Common Rule***  (1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.  ***2018 Common Rule***  (1) Risks to subjects are minimized: (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. |  |  |
| ***If NO, list conditions that must be met to meet this criterion:***   * Required Conditions: | | |
| The reviewer Choose an item.    The study team Choose an item. expressed concerns about the availability of resources required to complete the study (personnel, equipment, etc.)  The reviewer Choose an item. have any concerns regarding the feasibility to continue to conduct the study.  There Choose an item. complaints against the study team, or about the research, that would raise concerns.  There have been Choose an item. changes in terms of new significant financial interest in the sponsor or a direct competitor of the sponsor (COI)(see: Status Report Form, question #17)  If there have been changes: The COI management plan Choose an item. continue to be appropriate.  The reviewer shared that Choose an item.  Optional: The following key changes will be made:  If applicable: The reviewer shared that a Waiver of Age of Majority Consent Choose an item. requested with this continuation.  **Points to Consider if there have been modifications since the last continuation review:**   * If procedures have been added since the last review:   + Can less risky procedures answer the question? Can fewer procedures answer the question? Are the procedures needed at all? Can different exclusion criteria reduce risk?   + Can the data from procedures performed for clinical care be used to reduce the likelihood or magnitude of harm or be used to answer the hypothesis?   + Does there continue to be a clear differentiation between research and usual practice? * Do the hypothesis and objectives remain clear following any modifications? * Is there a plan in place to manage any potential conflict of interest created by a change in personnel? | | |

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|  | **YES** | **NO** |
| ***Pre 2018 Common Rule***  (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.  ***2018 Common Rule***  (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. |  |  |
| ***If NO, list conditions that must be met to meet this criterion:***   * Required Conditions: | | |
| The study team Choose an item. changes to equipoise, risks associated with research, risk-benefit analysis, alternative to participation, participant’s willingness to continue participation(see Status Report Form question #6):  There were       withdrawals. Withdrawal(s) was/were due to      .  The reviewer stated that there were *complete both sentences below*        internal SAEs were reported during this review period.       Unanticipated Problems were reported during this review period.  ***IF SAE’S WERE REPORTED ANSWER THE FOLLOWING QUESTION:***  Choose an item.  ***Points to consider (see Status Report Form questions #11, #12 and event report)***   * Has the IRB learned any new information that affects the risk benefit ratio? (e.g. a new drug has received FDA approval to treat the same condition that has fewer side effects than the drug currently under study) * Has the study been put on hold by the FDA or any other regulatory agency? * Has the FDA changed labeling or withdrawn the study drug/device from distribution? If yes do any of these affect the risk –benefit ratio such that would affect the subject’s willingness to continue in the study or that would require the study to be modified or closed? * Are reasons for study withdrawals expected/reasonable given the study? If not, could the withdrawals affect the risk benefit ratio of the study? | | |

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|  | **YES** | **NO** |
| ***Pre 2018 Common Rule***  (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.  ***2018 Common Rule***  (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. |  |  |
| ***If NO, list conditions that must be met to meet this criterion:***   * Required Conditions: | | |
| This study Choose an item. enroll populations requiring additional protections. (per Regulatory page of IRB online).    ***IF POPULATIONS REQUIRING ADDITIONAL PROTECTIONS ARE ENROLLED COMPLETE THE FOLLOWING:***  This study continues to enroll the following populations requiring additional protections:  Children  Impaired Decision Making Capacity  Economically or Educationally Challenged  Fetuses/Neonates  Pregnant Women  Prisoners  All applicable approval criteria have been appropriately noted by the IRB.  **AND** Choose ***applicable option below****:*  Choose an item. added groups requiring additional protections during this review period:  Children  Impaired Decision Making Capacity  Economically or Educationally Challenged  Fetuses/Neonates  Pregnant Women  Prisoners  All applicable approval criteria have been appropriately noted by the IRB.  *(****See Event Report. The comment section of the approval events should include language that the populations requiring additional protection have been approved to be enrolled)***  Points to Consider if any Modifications have occurred since the last continuation review:  Be particularly cognizant of the special problems of research involving populations requiring additional protections. Have any modifications affected the equitable selection of subjects?   * Do the burdens and benefits of the research continue to be distributed fairly? * Does the nature of the research continue to justify using the subject population? * Do the methods of recruitment continue to be appropriate? * If there has been a change to the amount of compensation and the proposed timing of disbursement, do they present the potential for undue influence? * Do the inclusion and exclusion criteria continue to be justified by science, adequately defined and equitable? * If new study populations were excluded (women, minorities or populations requiring additional protections) is their exclusion justified? * Does the setting, location and timing of recruitment continue to be appropriate for this study? * Do the recruitment methods continue to be appropriate for this study? | | |

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|  | **YES** | | **NO** | |
| ***Pre 2018 AND 2018 Common Rule***  (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, §46.116.  ***NA Study is closed to enrollment (no consent) or subjects are enrolled under waiver criteria*.** |  | |  | |
| ***If NO, list conditions that must be met to meet this criterion:***   * Required Conditions: | | | | |
| **Enrolling under WAIVER OF CONSENT, WAIVER OF DOCUMENTATION OF CONSENT (verbal consent), WAIVER OF HIPAA AUTHORIZATION (access to protected health information) (see status form, page 1)**  The protocol has not been granted waivers. (**skip to question 5)**  The protocol has previously been granted the following waivers to enroll subjects and access protected health information (HIPAA Authorization) check all that apply  **Waiver of consent:**  main study  study involves deception  **Waiver of consent/HIPAA Authorization:**  age of majority  **Waiver of HIPAA Authorization:** screening log  **Waiver of documentation of consent:** prescreening questions minimal risk prescreening procedures  **Waiver of documentation of consent/HIPAA Authorization:** questionnaires main study  **If waivers granted, check appropriate response below:**  *See appendix C as a reference when completing the below items.*  The protocol continues to meet the waiver criteria.  The protocol does not continue to meet waiver criteria for the following reasons:  With the Continuation Review, the following NEW waiver should be granted because of the justifications noted below:  **Waiver of consent/HIPAA Authorization:**  age of majority  The remaining research involving use of data collected while the subjects were a minor is minimal risk because the information will be protected according to the Data Security Plan and Privacy Plan of this study.  The waiver or alterations will not adversely affect the rights and welfare of the subjects because the information will be protected according to the Data Security Plan and Privacy Plan of this study  The research could not practicably be carried out without the waiver because the study team no longer has contact with the subjects. | | | | |
|  | | **YES** | | **NO** |
| ***Pre 2018 Common Rule***  (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117  ***2018 Common Rule***  (5) Informed consent will be appropriately documented or appropriately waived in accordance with §46.117 | |  | |  |
| ***If NO, list conditions that must be met to meet this criterion:***   * Required Conditions: | | | | |
| The IRB Choose an item. received information that would raise concerns regarding informed consent being appropriately documented or obtained. (i.e. PAM report) | | | | |
| ***Points to Consider:***   * Did the study team submit the most current version(s) of the approved consent form(s)? * Does the consent include the most up to date information? * Are the alternative treatments current per usual practice?   + Have significant new findings been shared with subjects | | | | |
|  | | YES | | NO |
| ***Pre 2018 AND 2018 Common Rule***  (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. | |  | |  |
| ***If NO, list conditions that must be met to meet this criterion:***   * Required Conditions: | | | | |
| The reviewer indicated there Choose an item. major protocol deviations/enrollment exceptions reported during this review period.  The reviewer shared that Choose an item.  The reviewer shared that there Choose an item. been articles published describing  The reviewer shared that Choose an item.  The reviewer shared that Choose an item.  *If there was an audit pick one of the following options:* Choose an item.       ***Points to Consider***   * Has the IRB received MedWatch reports? * Have subjects been provided with all information regarding significant changes/ results that would affect their willingness to participate? (recent consent addendums) * If there have been any changes to the Data and Safety Monitoring Plan does it continue to provide adequate oversight? | | | | |

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|  | **YES** | **NO** |
| ***Pre 2018 Common Rule***  (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.  ***2018 Common Rule***  (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data. |  |  |
| *If NO, list conditions that must be met to meet this criterion:*   * Required Conditions: |  |  |
| ***Points to Consider:***   * Privacy refers to persons and their interest in controlling access of others to themselves. * Confidentiality refers to how a persons’ information will be protected. | | |

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|  | **YES** | **NO** | **NA** |
| ***Pre 2018 Common Rule***  (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.  ***2018 Common Rule***  (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.  *IRB note: This should also include additional populations such as pregnant women that may require additional protections.* |  |  |  |
| *If NO, list conditions that must be met to meet this criterion:*   * Required Conditions: | | | |
| **If study enrolls populations requiring additional protections OR during the reviewing period, populations requiring additional protections were added, complete the following:**  The protocol and/or IRB application include:  *check all that apply*  appendices for each targeted population requiring additional protections identified  information that identifies the protective measures  **(If not present, DEFER the study until the appendix has been added/ completed and reviewed by the IRB.**  This study includes the following provisions to protect the rights and welfare of participants:  N/A  (**see Event Report, Receipt of New Protocol Event in order to complete)**  consent observation (do not tick unless determined by full board-see event report)  two parent signatures  ward of the state advocate  prisoner representative  use of a LAR  other:  The IRB Choose an item. received any information that would raise concerns that the study team is not protecting the privacy of the subject or the confidentiality of their information. | | | |

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| **Minimal Risk Determination** |
| **IRB determined the study is Minimal Risk and does not have an IND or IDE Number** Yes No  Note to Continuation Admin: If yes, change TYPE to Expedited in IRB Online Main Page  Regulatory page: check Expedited Category# 9.  Add the following to the existing Approval Comments:  The board determined that the study is no more than minimal risk to subjects and that future continuations may be reviewed by an expedited review process under Expedited Review Category # 9. |

**The reviewer stated that: *Pick one of the following options:***

Research appears to be proceeding in accordance with the IRB-approved protocol and continues to meet the federal criteria for approval per federal regulations.

Research does not appear to be proceeding in accordance with the IRB-approved protocol and/or do not meet the federal criteria for approval per federal regulations.

***(e.g. terminated or disapproved, no study activities may continue)***

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| 1. **Motion** |
| **Approve for one year- Approval criteria continue to be met** |
| **Approve for period of less than 1 year due to**        **- Approval criteria continue to be met**  Designate time frame: 3 months/ 6 months/       *See Appendix B for additional information.* |
| **Approve for one year with suggestions - Approval criteria continue to be met** *(e.g. typographical errors that do not affect the understanding of the study etc. List SUGGESTIONS in the Suggestions Section on the next page.* |
| **Approvable with conditions: conditions must be submitted to the IRB-HSR office staff for review and approval within 30 days.** |
| **Deferred** -*PI will need to re-submit the protocol continuation and modification for review at a future IRB-HSR meeting. (Additional continuation review required) PI may be asked to attend future meeting to answer questions. See Appendix A for examples of items that may require a deferral.*  **Justification for deferral:** *(specify)*  ***Specify below if the IRB requires any activity to be suspended:*** *See HRPP SOP section 7.1 & 8 for additional information.*  **Study will be closed to enrollment until the requested modifications are approved at a future IRB meeting.**  *(Check if not already closed to enrollment)*  **NOTE:** IRB staff will report this action to institutional officials and to OHRP, FDA (if applicable) per AG-2-7.  **Study treatment/interventions will be held until modifications are approved at a future IRB meeting. Justification for closing to enrollment or treatment:**  *(e.g. concerns related to subject safety, issues of serious/continuing noncompliance etc.*)  **NOTE:** IRB staff will report this action to institutional officials and to OHRP, FDA (if applicable) per AG-2-7. |
| **Termination (Disapproved): No study activities may continue.**  *Risks to the participants outweigh the possible benefit of the research and the research will no longer meet the federal criteria for IRB approval even after substantial modification.*  **Justification for termination**       *(e.g. concerns related to subject safety, suspected serious/continuing noncompliance, suspected research misconduct) If research misconduct is suspected, IRB Staff will notify the UVA Research Integrity Officer at 434-924-3606.*  **NOTE:** IRB staff will report this action to institutional officials and to OHRP, FDA (if applicable) per AG-2-7.  Change status in IRB online to CLOSED /inactive  Enter event type: Termination |

**The reviewer requests the following conditions:**

*See Appendix A for examples of items that may or may not be listed as Conditions:*

**The reviewer has the following suggestions that do not affect the approval criteria for continuation:**

**By placing my name below, I confirm I had no conflicts with this protocol.**

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Name Date

**Appendix A: *INSTRUCTIONS related to Motions***

1. **The IRB may require the following examples as conditions** **of approval.**

* Request for confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted *(e.g. It appears that those with impaired decision making capacity are excluded, however impaired decision making capacity is not listed as an exclusion. Please add impaired decision making capacity as an exclusion criteria. )*
* Changes to protocol or informed consent documents are requested with clear directions and using stated parameters that the changes must satisfy (*e.g. Consent procedures listed on page 5 state that blood will be drawn at Visit 3. The Protocol does not list a blood draw at Visit 3. Please modify the protocol or consent so that the information regarding blood draw at Visit 3 is consistent across study documents.)*
* The number of subjects to be enrolled at UVA does not match the number provided in the consent. *(e.g. Please modify the protocol or consent so that the information regarding number of subjects to be enrolled at UVA is consistent across study documents.)*

1. **The IRB may NOT require the following examples as conditions of approval.** **If issues such as these exist, the continuation review must be deferred until a modification is made. The following would be considered more than minor changes:**

* The procedures listed in the protocol do not match the consent. Please clarify. (There are no clear directions provided for this modification.)
* The DSMP Report dated (x) indicated that additional risk of cardiac arrhythmia, sudden death and liver failure will be added which are currently not listed in the protocol or consent as risks. Please add these risks. (The addition of these risks presents greater than minimal risk and would require full board review).
* A control group was added per modification dated x; however, it is not clear what study procedures are different between the control and the treatment group. Please clarify. (Requested change involved more than confirmation of specific study assumption and the IRB request does not provide specific enough directions.)
* Add an appendix for enrollment of children to the application/ protocol.

Appendix B: Factors to consider when determining which studies require review more frequently than on an annual basis

* The probability and magnitude of anticipated risks to subjects has increased since the initial review.
* The composition of the study team has changes such that the overall qualifications/expertise of the research team is now in question.
* The study team reports that they do not have enough staff or resources to perform the study as approved.
* The addition of populations requiring additional protections within the past year is likely to be subject to undue influence or coercion (e.g. terminally ill)
* Multiple issues of noncompliance were reported during the past year, which call into question study team or team member training/ability/competence.
  + Any other factors that the IRB deems relevant.

**Appendix C:**

**Waiver of Consent Approval Criteria: e.g. main study, deception, age of majority**

1. *The research (or part of the research for which the waiver was granted) involves no more than minimal risk to the subjects*
2. *The waiver will not adversely affect the rights and welfare of the subjects;*
3. *If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.*
4. *The research or the part of the research for which waiver of consent was granted, could not practicably be carried out without the waiver*
5. *Whenever appropriate, the subjects will be provided with additional pertinent information after participation.*

**WAIVER OF DOCUMENTATION OF CONSENT Approval Criteria: e.g. Pre-screening questions, minimal risk prescreening procedures**

* + *That the only record linking the subjects and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality OR*
  + *That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.*

**WAIVER OF HIPAA AUTHORIZATION-IDENTIFIABLE Data are collected without consent- approval criteria**

1. *The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based in, at least, the presence of the following elements:*
2. *An adequate plan to protect the identifiers from improper use and disclosure;*
3. *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; and*
4. *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 study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.*
5. *The research could not practicably be conducted without the waiver or alteration and*
6. *The research could not practicably be conducted without access to and use of the protected health information*

**ALTERATION OF HIPAA AUTHORIZATION FOR VERBAL AUTHORIZATION –Identifiable data-approval criteria**

1. *The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based in, at least, the presence of the following elements:*
2. *An adequate plan to protect the identifiers from improper use and disclosure;*
3. *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; and*
4. *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 study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.*
5. *The research could not practicably be conducted without the waiver or alteration and*
6. *The research could not practicably be conducted without access to and use of the protected health information*

**Appendix D:**

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| ***DoD (Department of Defense) Criteria***  *When research involves U.S. military personnel policies and procedures include additional protections for military research participants to minimize undue influence:*   * + - *Officers are not permitted to influence the decision of their subordinates.*     - *Officers and senior non-commissioned officers may not be present at the time of recruitment.*     - *Officers and senior non-commissioned officers have a separate opportunity to participate.*     - *When recruitment involves a percentage of a unit, an independent ombudsman is present.*   *When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:*   * + - *Prohibit an individual from receiving pay of compensation for research during duty hours.*     - *An individual may be compensated for research if the participant is involved in the research when not on duty.*     - *Federal employees while on duty and non- federal persons may be compensated for blood draws for research up to $50 for each blood draw.* * *Non-federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research* |