University of Virginia

**Office of the Vice President for Research**

# Post-Approval Monitoring Report: IRB-HSR Records

**Protocol:**  IRB-HSR/UVA Study Tracking# **IRB of record:**  **Principal Investigator:**

**Title:**

**Initial Review Type:**  **Date of Review:**  **Current Status:**

|  |  |  |  |
| --- | --- | --- | --- |
| *Findings:* | *Regulations:* | *Recommendations:* | *Resolution**To be completed by IRB Staff:* |
| **Cooperative Research**  *Possible responses:*   * NA – This is a single site study being reviewed by a UVA IRB. * The research being conducted at UVA as part of a multi-site study is being overseen by the UVA IRB-HSR. No IRB Authorization/ Reliance Agreement required. * The research being conducted at UVA as part of a multi-site study is being overseen by the non UVA IRB. An IRB Authorization/ Reliance Agreement is on file. | [§46.114](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.114) Cooperative research. |  |  |
| **Criteria for Approval**  *Possible responses:*   * The IRB appropriately documented that the study met the criteria for approval.   + *For full board events:* This documentation was included in the minutes. The justification for the study being more than minimal risk is included in the IRB meeting minutes   + *For Expedited events:* This documentation was included in the IRB Member Review Checklist for Expedited Events. The justification for the study being not more than minimal risk is included in the IRB Member Review Checklist for Expedited Studies. * The IRB did NOT appropriately document that the study met the criteria for approval.   + *Insert additional info here.* * The IRB did NOT appropriately document the justification for the risk determination.   + *Insert additional info here.* | [§46.111](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111) Criteria for IRB approval of research.  (a) …IRB shall determine that all of the following requirements are satisfied:   1. Risks to subjects are minimized… 2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects… 3. Selection of subjects is equitable… 4. Informed consent will be sought… 5. Informed consent will be appropriately documented… 6. …monitoring the data collected to ensure the safety of subjects. 7. …protect the privacy of subjects and to maintain the confidentiality of data. |  |  |
| **Expedited Review Procedures- Initial Review**  *Possible responses:*   * NA: Initial study reviewed by a convened meeting of the full board. * The IRB used all applicable expedited criteria during the initial review of the study. * The IRB used INCORRECT expedited criteria during the initial review of the study   + *Insert additional info here.* | [§46.110](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.110) Expedited review procedures.  (a) The Secretary, HHS, has established, and published…[a list](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html) of categories of research that may be reviewed by the IRB through an expedited review procedure.  (b) An IRB may use the expedited review procedure to review:   1. some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk… |  |  |
| **Expedited Review Procedures- Modifications**  *Possible responses:*   * NA: No modifications submitted * NA: All modification reviewed by a convened meeting of the full board. * The IRB used the expedited review process to review all minor changes during the review of modifications. * The IRB INCORRECTLY used the expedited review process during the review of modifications which included more than minor changes:   + *Insert additional info here.* | [§46.110](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.110) Expedited review procedures.  (b) An IRB may use the expedited review procedure to review:   1. minor changes in previously approved research during the period (of one year or less) for which approval is authorized. |  |  |
| **Continuing Review**  *Possible responses:*   * NA: This study is not yet due for the first continuing review. * The IRB conducted the continuing review under the appropriate review procedures (e.g. full board or expedited) and at an appropriate review interval. * The IRB did NOT conduct the continuing review under the appropriate review procedures (e.g. full board or expedited) or at an appropriate review interval.   + *Insert additional info here.* | [§46.109](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.109) IRB review of research.  (e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year…  [§46.110](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.110) Expedited review procedures.  (b)…the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson… |  |  |
| **IRB-HSR Records**  *Possible responses:*   * The IRB-HSR is not the IRB of Record or the HIPAA Privacy Board for this study. All applicable non IRB compliance reviews/ approvals are on file. * The IRB-HSR is not the IRB of Record or the HIPAA Privacy Board for this study. All applicable non IRB compliance reviews/ approvals are NOT on file.   + *Insert additional info here.* * The IRB-HSR is the IRB of Record for this study. The IRB-HSR files include all applicable documents including protocols, consents, continuation status reports, SAE/Unanticipated problem reports and correspondence between the IRB and the researchers. * The IRB-HSR is the IRB of Record for this study. The IRB-HSR files do NOT include all applicable documents including protocols, consents, continuation status reports, SAE/Unanticipated problem reports and correspondence between the IRB and the researchers.   + *Insert additional info here.* * The IRB-HSR Assurance forms are complete and accurate for each event. * The IRB-HSR Assurance forms are NOT complete or accurate for each event.   + *Insert additional info here.* | [§46.115](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.115) IRB records. |  |  |
| **Consent Forms**  *Possible responses:*   * NA- Study granted a Waiver of Consent * The consent forms approved for this study include all of the required and applicable optional elements. * The consent forms approved for this study do NOT include all of the required and applicable optional elements.   + *Insert additional info here.* | [§46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) General requirements for informed consent.  (a) Basic elements of informed consent…  (1)…statement that the study involves research…  (2)…description of any reasonable foreseeable risks or discomforts…  (3)...description of any benefits to the subject…  (4)…disclosure of appropriate alternative procedures or courses of treatment, if any…  (5)...confidentiality of records identifying the subject…  (6)…whether any compensation…any medical treatments are available if injury occurs…  (7)…whom to contact for answers to pertinent questions about the research and research subjects’ rights…  (8)…statement that participation is voluntary… |  |  |
| **Waiver of Consent**  *Possible responses:*   * NA- Subjects will give consent. * The IRB appropriately granted and documented a Waiver of Consent. Documentation included study specific justifications for meeting the Waiver Criteria . * The IRB did NOT appropriately grant Waiver of Consent. Documentation did NOT include study specific justifications for meeting the Waiver Criteria.   + *Insert additional info here.* | [§46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) General requirement for informed consent.  (c) An IRB may approve a consent procedure which does not include…or waive the requirement to obtain informed consent… |  |  |
| **Documentation of Consent**  *Possible responses:*   * Informed consent will be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. * *If applicable add:* A short form written consent document stating that the elements of informed consent required by [§46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) will be presented to the subject or the subject's legally authorized representative. * The IRB appropriately waived the requirement to obtain written consent per 46.117 (c). The documentation includes study specific justification for granting the waiver to obtain written consent. * The IRB did NOT appropriately waive the requirement to obtain written consent per 46.117 (c). The documentation does NOT include study specific justification for granting the waiver to obtain written consent. | [§46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.117) Documentation of informed consent.  (a)…informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject’s legally authorized representative. A copy shall be given to the person signing this form. |  |  |
| **Enrollment of Pregnant Women, Human Fetuses and Neonates**  *Possible responses:*   * NA: This study does not enroll pregnant women, human fetuses or neonates. * This study will enroll pregnant women, human fetuses or neonates.   + *For full board events:* The justification that the study provides adequate protections to enroll this population is included in the IRB meeting minutes.   + *For Expedited events:* The justification that the study provides adequate protections to enroll this population is included in the IRB Member Review Checklist for Expedited Studies. * This study will enroll pregnant women, human fetuses or neonates.   + *For full board events:* The justification that the study provides adequate protections to enroll this population is NOT included in the IRB meeting minutes.   *For Expedited events:* The justification that the study provides adequate protections to enroll this population is NOT included in the IRB Member Review Checklist for Expedited Studies. | [**Subpart B.**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartb) **Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research.** |  |  |
| **Enrollment of Prisoners**  *Possible responses:*   * NA: This study does not enroll prisoners. * This study will enroll prisoners.   + *For full board events:* The justification that the study provides adequate protections to enroll this population is included in the IRB meeting minutes.   + *For Expedited events:* The justification that the study provides adequate protections to enroll this population is included in the IRB Member Review Checklist for Expedited Studies. * This study will enroll prisoners.   + *For full board events:* The justification that the study provides adequate protections to enroll this population is NOT included in the IRB meeting minutes.   *For Expedited events:* The justification that the study provides adequate protections to enroll this population is NOT included in the | [**Subpart C.**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartc) **Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.** |  |  |
| **Enrollment of Children**  *Possible responses:*   * NA: This study does not enroll children. * This study will enroll children.   + *For full board events:* The justification that the study provides adequate protections to enroll this population is included in the IRB meeting minutes.   + *For Expedited events:* The justification that the study provides adequate protections to enroll this population is included in the IRB Member Review Checklist for Expedited Studies. * This study will enroll children.   + *For full board events:* The justification that the study provides adequate protections to enroll this population is NOT included in the IRB meeting minutes.   *For Expedited events:* The justification that the study provides adequate protections to enroll this population is NOT included in the IRB Member Review Checklist for Expedited Studies. | [**Subpart D.**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd) **Additional Protections for Children Involved as Subjects in Research.** |  |  |

**General Comments**: *Overall, good organization of IRB-HSR file. No problems identified.*

Jane Lehmbeck, RN, CCRP, CIP

Research Compliance Monitor

Office of the Vice President for Research