University of Virginia  
Office of the Vice President for Research  
Post-Approval Monitoring Report

Date:

Protocol #:

Title:

School/Department:

Principal Investigator:

Faculty Advisor: Project Manager:

IRB of Record:

Date of Review: Type of consent:

IRB Review type: Funding Source:

Initial Approval/Most Recent Approval: Subjects enrolled/subjects approved:

PAM Review Type:

Introduction of review:
<table>
<thead>
<tr>
<th>Findings:</th>
<th>Recommendations:</th>
<th>Resolution (to be completed by investigator/study team)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory documentation:</strong></td>
<td></td>
<td></td>
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<tr>
<td>Regulatory documentation, including IRB approvals, protocol and ancillary document versions, IRB correspondence, CITI training documentations are present in the study site files.</td>
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<tr>
<td><strong>Documentation of approved procedures for participant recruitment, screening, and informed consent:</strong></td>
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<tr>
<td>Approved recruitment materials and methods are used. Signed informed consent forms are present for all subjects enrolled and were the correct version. All consent forms were signed and dated by the subject, prior to any study procedures.</td>
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<tr>
<td><strong>Protocol Procedures</strong></td>
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<tr>
<td>Research conducted was consistent with description and procedures as approved by the IRB. Data collection tools used were approved by the IRB prior to use</td>
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</tbody>
</table>
Payment records are documented and stored appropriately.
Protocol modifications were approved prior to implementation.
Reportable events have been addressed as required by the IRB.

Privacy, Data Storage, and Confidentiality

Procedures to protect subject privacy and confidentiality have been implemented as approved by the IRB.

Data collection and storage are consistent with institutional policy and IRB approved protocol.

Study records are legible and organized.

Project continuation/Completion

General Comments:  The study team was available to discuss the study and answer questions throughout the review. This report will be copied to the IRB-SBS Post Approval Monitoring Advisory Committee. They will contact you if any further actions need to be taken.

IRB-SBS Research Compliance Monitor
Resources:
University of Virginia Human Research Protection Program Standard Operating Procedures
Office of the Vice President for Research:
https://research.virginia.edu/human-research-protection-program/hrpp-standard-operating-procedures

https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&p=20180719&pt=45.1.46&n=PART&ty=HTML

https://research.virginia.edu/irb-sbs/irb-sbs-citi-training

https://research.virginia.edu/irb-sbs/researcher-guide