IRB Final Report Form

Submit this Final Report (signed) with all required documents to the IRB Office for Expedited Review

<table>
<thead>
<tr>
<th>IRB Certification of Compliance with Regulatory Requirements:</th>
<th>IRB #:</th>
</tr>
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<tbody>
<tr>
<td>All Must be Checked:</td>
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<tr>
<td>☐ FCOI is current for all listed personnel</td>
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<tr>
<td>☐ No FCOI exists for any listed personnel</td>
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<td>☐ CITI training is current for all listed personnel</td>
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<tr>
<th>Attachments:</th>
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<tr>
<td>Check and include all that apply:</td>
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<tr>
<td>☐ Current Protocol</td>
<td>☐ Current IB/Device Brochure/Package Insert</td>
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<tr>
<td>☐ Copy of Current Stamped Consent</td>
<td>☐ AE and UAP Spreadsheets since last review</td>
</tr>
<tr>
<td>☐ Off-Site INDSR Spreadsheet since last review</td>
<td>☐ Audit/Monitoring Visit Reports</td>
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<tr>
<td>☐ DSMB Reports</td>
<td>☐ FDA Correspondence/Annual Report</td>
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<tr>
<td>☐ Publications/Presentations</td>
<td>☐ Other: ______________________________</td>
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PROTOCOL TITLE: 

DEPARTMENT: 

SECTION A: Current Study Personnel

(Include the Principal Investigator, all Sub-Investigators, Research Nurses and Coordinators, Data personnel, Regulatory personnel, and any other personnel directly involved in the conduct of the research)

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<tr>
<th>Name</th>
<th>Address</th>
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SECTION B: Enrollment Information

1. Period of previous approval: □ 1 year  □ 6 months  □ Other

2. Date of first **on-site** subject enrollment:

3. Date of most recent **on-site** subject enrollment:

4. IRB-approved enrollment number:

5. If the study does not involve interaction with subjects (e.g. database or chart review), indicate the number of subjects entered or charts reviewed to date:  
   *(Skip to Section D, Progress Report.)*

6. If the study is a collection of pre-existing (stored) biological specimens, indicate the number of specimens collected to date:  
   *(Skip to Section D, Progress Report.)*

   ***All other studies, please complete the chart below***

<table>
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<tr>
<th>Since Last Approval</th>
<th>Total to Date</th>
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7. Total number of subjects enrolled **at SLUHN**:
   
   *Note: for the purposes of the Final Report, “subjects enrolled” is defined as subjects who have signed a consent form, successfully screened and been randomized or allocated or begun study procedures.*

   *Note: Do not respond in shaded columns for below items*

   *Note: The total for Items 8-9 should equal the Total number of subjects enrolled from Item #7.*

8. Number of subjects completed (no longer being followed):

9. Number of withdrawals, lost to follow-up, deaths:

10. Number of serious adverse events occurring at SLUHN since last review currently noted in consent form:

11. Number of serious adverse events occurring at SLUHN since last review **not** currently noted in consent form:

SECTION C: Progress Report (Interventional Studies)

1. Provide synopsis describing what has or has not occurred in the study, plus data related to subject responses to intervention, if applicable.

2. Please explain any withdrawals, subjects lost to follow-up, or deaths.

3. Describe any subject grievances or complaints.

4. Provide an itemization of amendments submitted since last review.

5. Provide a list of all investigator/co-investigator additions/removals submitted within the past year.

6. Please summarize UAPs since last IRB review.
7. Please summarize all reported SAEs since last IRB review.

8. Have you had any audits or monitoring visits (internal or external) since last review that have not been reported?  
   - Yes  
   - No  
   *If "YES" please attach report(s).*

9. Has a Data & Safety Monitoring Board (DSMB) or sponsor reviewed study-wide adverse events and interim findings?  
   - Yes  
   - No  
   - NA  
   *If "YES" please attach report(s).*

10. Have there been any protocol violations? If so, itemize the events and indicate any corrective measures taken.

11. Has the enrollment been less than projected?  
   - Yes  
   - No  

12. Have you changed any recruitment strategies since last review?  
   - Yes  
   - No  
   *If "YES" please describe:*

13. Are facilities and number of support staff the same as at the time of the original application?  
   - Yes  
   - No  
   *If "NO" please describe any changes in facilities and/or list all Key Personnel additions/removals below:*

   **Key Personnel Removals:**

   **Key Personnel Additions:**

14. If drug or device trial, has there been any change in FDA status?  
   - Yes  
   - No  
   *If "YES" please explain and attach copies of any correspondence with the FDA. Include copy of annual report to FDA.*

15. Please indicate whether the Risk/Benefit ratio for the study has changed from last IRB review by checking the appropriate box below.
   - No change in the risk/benefit ratio for subjects on this study, and no cause for subjects to reconsider their participation in the study.  
   - Change in the risk/benefit ratio for subjects on this study and/or cause for subjects to reconsider their participation in the study. Please explain:

SECTION D: Progress Report (Data/Chart/Specimen Collection)

1. Provide a synopsis of results so far and describe any data analysis that has taken place.
   *If no data have been collected or analyzed, please indicate why:*

2. Have any publications or presentations resulted from the research?  
   - Yes  
   - No  
   *If "YES" please attach copies.*

SECTION E: Final Study Impact and Future Plans

1. Please provide a bibliography of publications, abstracts and presentations to date.
2. If no publications to date, are publications planned or in preparation? □ YES □ NO
   
   If “YES” please describe:

3. Are future trials or grant applications related to this research planned? □ YES □ NO
   
   If “YES” please describe:

4. Have the data collected changed clinical practice? □ YES □ NO
   
   If “YES” please describe:

SECTION F: Signature and Attestation

I certify that the information contained above is correct, that the consent form currently reflects any and all modifications since the last approval by the Institutional Review Board, and that all study activities are complete, and this represents the Final Report.

Principal Investigator Signature

Date

Person Preparing Submission Signature

Date