IRB Continuing Periodic Review Form

Submit this Periodic Review form (signed) with all required documents to the IRB Office

<table>
<thead>
<tr>
<th>IRB Review Classification Certification of Compliance with Regulatory Requirements:</th>
<th></th>
<th>IRB #:</th>
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<tbody>
<tr>
<td>Pick One:</td>
<td>All Must be Checked:</td>
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<tr>
<td>□ Full Board Review</td>
<td>□ FCOI is current for all listed personnel</td>
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<tr>
<td>□ Expedited Review <em>(please select reason below)</em></td>
<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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<td>□ 45 CFR 46.110, List of Categories (8a)</td>
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<td>Where (i) the research is permanently closed to the</td>
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<td>enrollment of new subjects; (ii) all subjects have completed</td>
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<td>all research-related interventions; and (iii) the research</td>
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<td>remains active only for long-term follow-up of subjects</td>
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<td>□ 45 CFR 46.110, List of Categories (8b)</td>
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<td>Where no subjects have been enrolled and no additional risks</td>
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<td>have been identified</td>
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<td>□ 45 CFR 46.110, List of Categories (8c)</td>
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<td>Where the remaining research activities are limited to data</td>
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<td>analysis.</td>
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Attachments:
Check and include all that apply:

- □ Current Protocol
- □ Copy of Current Stamped Consent
- □ AE and UAP Spreadsheets since last review
- □ Audit/Monitoring Visit Reports (if applicable)
- □ Accrual Policy Justification (if applicable)
- □ Publications/Presentations
- □ Current IB/Device Brochure/Package Insert
- □ Current Consent for Re-Stamping (open to accrual studies only)
- □ Off-Site INDSR Spreadsheet since last review
- □ DSMB Reports
- □ FDA Correspondence/Annual Report
- □ Other: ______________________________

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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<th>Name</th>
<th>Address</th>
<th>City</th>
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### SECTION B: Enrollment Information

1. Period of most recent 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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<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 Continuing Review, “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 8-11 should equal the Total number of subjects enrolled from Item #7.*

8. Number of subjects currently receiving study intervention:

9. Number of subjects on follow-up not receiving intervention:

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

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

12. Number of serious adverse events occurring at SLUHN within the past year currently noted in consent form:

13. Number of serious adverse events occurring at SLUHN within the past year **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 within the past year.

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) within the past year that have not been previously 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 for the past year been less than projected?  
   - [ ] YES  
   - [ ] NO  

   If “YES” please attach Justification letter as to why the study should remain open per SLUHN Accrual Policy

12. Have you changed any recruitment strategies?  
   - [ ] 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:**

   Have all newly added Key Personnel completed all required Institutional and protocol trainings?  
   - [ ] YES  
   - [ ] NO

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: Current Study Status (please check appropriate status below)

- Study is active and subject recruitment/chart review/tissue collection is ongoing.
- Chart review/tissue collection is completed. Study is in data analysis.
- Enrollment is closed. However, subjects are currently receiving study treatment or are undergoing study procedures. *(A new stamped consent form will not be issued.)*
- Enrollment is closed. Subjects are not receiving study treatment and are not undergoing any study procedures. Study is in long term follow-up (to determine survivorship) or data analysis phases only. *(A new stamped consent form will not be issued.)*
- Study enrollment is suspended. *(Please provide reason and relevant sponsor correspondence.)*
- Study enrollment was suspended by the IRB because continuing review was not submitted prior to expiration date. PI certifies that no subjects were enrolled after the expiration date.

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 I will only conduct study-related activities with an active IRB approval.

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<thead>
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<th>Principal Investigator Signature</th>
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<th>Person Preparing Submission Signature</th>
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