



801 Ostrum St.
Bethlehem, PA 18015
Institutional Review Board
Rebecca Jeanmonod, MD, Chair
William Peters, DO, Vice Chairman
Phone: 610-776-4832 or 610-776-4856

IRB Amendment Form

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

<p>IRB Review Classification Certification of Compliance with Regulatory Requirements:</p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <p>Pick One:</p> <p><input type="checkbox"/> Full Board Review</p> <p><input type="checkbox"/> Expedited Review <i>(please select reason below)</i></p> <p style="margin-left: 20px;"><input type="checkbox"/> Minimal Risk Study</p> <p style="margin-left: 20px;"><input type="checkbox"/> Minor or Administrative Changes (e.g. advertising, informational materials, grammar/syntax corrections to protocol and/or consent form)</p> </td> <td style="width: 50%; vertical-align: top;"> <p>All Must be Checked:</p> <p><input type="checkbox"/> FCOI is current for all listed personnel</p> <p><input type="checkbox"/> No FCOI exists for any listed personnel</p> <p><input type="checkbox"/> CITI training is current for all listed personnel</p> </td> </tr> </table>	<p>Pick One:</p> <p><input type="checkbox"/> Full Board Review</p> <p><input type="checkbox"/> Expedited Review <i>(please select reason below)</i></p> <p style="margin-left: 20px;"><input type="checkbox"/> Minimal Risk Study</p> <p style="margin-left: 20px;"><input type="checkbox"/> Minor or Administrative Changes (e.g. advertising, informational materials, grammar/syntax corrections to protocol and/or consent form)</p>	<p>All Must be Checked:</p> <p><input type="checkbox"/> FCOI is current for all listed personnel</p> <p><input type="checkbox"/> No FCOI exists for any listed personnel</p> <p><input type="checkbox"/> CITI training is current for all listed personnel</p>	<p>IRB #: _____</p>				
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<p>Attachments: Check and include all that apply:</p> <table style="width: 100%;"> <tr> <td><input type="checkbox"/> New Revised Protocol</td> <td><input type="checkbox"/> Updated IB/Device Brochure/Package Insert</td> </tr> <tr> <td><input type="checkbox"/> Protocol Amendment Summary of Changes</td> <td><input type="checkbox"/> Revised Consent(s) with changes in TRACKED changes</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other: _____</td> </tr> </table> <p>***Is a Continuing Periodic Review being submitted simultaneously with this amendment? <input type="checkbox"/> YES <input type="checkbox"/> NO</p>		<input type="checkbox"/> New Revised Protocol	<input type="checkbox"/> Updated IB/Device Brochure/Package Insert	<input type="checkbox"/> Protocol Amendment Summary of Changes	<input type="checkbox"/> Revised Consent(s) with changes in TRACKED changes	<input type="checkbox"/> Other: _____	
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PROTOCOL TITLE:

DEPARTMENT:

SECTION A: Summary of Amendment Changes and Study Status

1. Summarize key points of the amendment.
2. Address the main changes affecting the subjects, the protocol, and the consent form(s) and provide rationale for the main changes (e.g. dose-limiting toxicities, suspension of enrollment for interim analysis, etc.).
3. Summarize ANY change involving risk.
4. Number of SLUHN subjects enrolled to date:
5. Number of SLUHN subjects currently receiving study treatment:
6. Status of subjects on follow-up not receiving intervention:
7. In your opinion, does this amendment add increased risk to the study? YES NO
Please explain:
8. Are changes in Investigators being made with this amendment? YES NO
If "YES" please describe any changes in investigator additions/removals below:

Investigator Additions:

Investigator Removal:

For amendments relating to new risk information, please attach all relevant information that would allow the Board to assess the risk data (SAE reports, IND Safety Reports, correspondence from sponsor, DSMB reports, data from previous studies, publications, etc.).

SECTION B: 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.
- 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.
- 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 C: Re-Consent Determination For Revised Consents ONLY (please check appropriate box below)

To maintain our primary objective of human subject protection, the following subjects will be re-consented in order to provide information which may relate to the subjects' willingness to continue participation:

- All subjects who received study intervention
- All active subjects (not subjects 30 days* post last treatment, in follow-up, withdrawn or off study)
- All active subjects including subjects 30 days* post last treatment (not subjects withdrawn or off study)
- Subjects will not be re-consented
- Subjects will not be re-consented, but will be informed of the change(s)
- IRB to make determination

SECTION D: Signature and Attestation

I certify that, in my opinion, this amendment:

- Is consistent with the re-consent determination indicated above.
- Increases the risk of the study.
- Does not increase the risk of the study.

Principal Investigator Signature

Date

Person Preparing Submission Signature

Date