Protocol Amendment Form

Please complete form, print for signature by Principal Investigator, and mail to HREBA – CC. Incomplete forms will be returned.

Use this form to report changes to the approved research such as updated protocol, consent form, or participant materials.

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| General Study Information | | | |
| Ethics #: | Lead Principal Investigator: | | |
| Study Title: | | | |
| Protocol #: | | Sponsor: | |
| Date of Original Approval: | | Is this is multisite study? Yes No | |
| Study Originally Approved by: Delegated Review Full Board Review | | | |
| Amendment | | | |
| Relation to Reportable Event | | | |
| Is this amendment related to a previously submitted Reportable Event? Yes No | | | |
| Brief Description of Event: i.e. local SAE: hemmorhage | | | Date Event Submitted: |
| General Information | | | |
| Please check all the apply:  Administrative changes (i.e. correcting format, typos, etc.)  Changes to the protocol (non-administrative e.g. changes to study design, drug dosage, etc.)  Changes to the informed consent form(s)  Changes/new participant materials (non-administrative) | | | |
| Summary of Amendment: | | | |

| Attached Documents: Please provide the updated versions of all applicable documents | | | |
| --- | --- | --- | --- |
|  | **Document** | **Version** | **Date** |
|  | Protocol |  |  |
|  | Protocol Summary of Changes |  |  |
|  | Main Consent Form : Track Changes and Clean Version  \*If Multisite Study, include Main ICFs for all participating sites |  |  |
|  | Other Consent Form(s) – Track Changes and Clean Version  \*If Multisite Study, include ICFs for all participating sites  Consent for: |  |  |
|  | Health Canada No Objection Letter for Amendment  If not required please explain: |  |  |
|  | Sponsor Letter(s) [ e-mail  memo  letter] |  |  |
|  | Participant Materials (please list): |  |  |
|  | Other Documents: |  |  |

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| Sign-off | | | |
| Person Completing Form | | | |
| Name: | E-mail: | | Date: |
| Principal Investigator Lead Site | | | |
| Signature: | | Name (printed): | |
| E-mail: | |
| Date: | |

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| --- | --- | --- |
| CHAIR/DESIGNATE USE ONLY | | |
| ⬜ Approved  ⬜ Not Approved  ⬜ Full Board Review Required | Comments/Concerns: | |
| Signature: | | Date of Review: |