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.

|  |
| --- |
| 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 sitesConsent for:       |       |       |
| [ ]  | Health Canada No Objection Letter for AmendmentIf not required please explain:       |       |       |
| [ ]  | Sponsor Letter(s) [[ ]  e-mail [ ]  memo [ ]  letter] |       |       |
| [ ]  | Participant Materials (please list):       |       |       |
| [ ]  | Other Documents:       |       |       |

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

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