###### The University of Vermont Committees on Human Research

### Request for Modification/Amendment to Approved Protocol

|  |
| --- |
| Study modifications may not be instituted until you have received written approval from the Committee. All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the [InfoEd Resource Materials](http://www.uvm.edu/~irb/?Page=infoed.html) page for more information. |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1.** | **CHRMS** |  | **CHRBSS** |  | **#:** |  | **Principal Investigator (PI):** |  |
|  |  |  |
|  | **Protocol/Project Title:** |  |
|  | **Contact Name:** |  | **Contact Email:** |  |
|  |  |  |
|  |  | **Sponsor’s** |  |  |  |
| 2. | Date of Protocol Amendment:  |  | **Study #** |  |  **Sponsor’s Amendment #** |  |
|  | Date of Consent Version (if applicable) |  |  |  |  |
|  |  |  |  |  |
|  |
|  |  |  |  |  |  |
| **3.** | Request for Revisions |
|  | A. Did IRB staff specifically request that you submit this amendment? |  | Yes |  | No |
|  | B. Is this protocol a Cancer Center protocol (involve the study of cancer)?  |  | Yes |  | No |
|  | i. If yes, provide the date the amendment was approved by the Protocol Review and Monitoring Committee of the Cancer Center. |  |
|  |
|  |  |  |
|  | C. Is this protocol a Clinical Research Center protocol? |  | Yes |  | No |
|  | *If yes, make sure that you have submitted this amendment to that Committee as well.* |
|  | D. Check all that are applicable, explain in E. below, and attach supporting documentation. |
|  |  |  |  |
|  | Scientific Changes to Protocol  |  | Change in Study Title |
|  |  |  |  |
|  | Eligibility/Ineligibility Criteria Changes |  | Changes to Consent/Assent Form (submit revised consent form and consent addendum or information sheet if applicable)  |
|  |  |
|  | Change in Protocol Procedures |  | Changes to Information Sheet or other previously approved materials given to subjects for information purposes |
|  |  |
|  | Change Requiring Re-consent  |  | Closure to Accrual (e.g. interventions and/ or follow-up still occurring locally) |
|  |  |
|  | Study Suspension |  | Change in Sponsor (contact the office if you have a new or additional sponsor) |
|  |  |
|  | Addition of surveys/questionnaires, etc. |  | Change in Collaborating Sites (may need agreement, see manual guidance.) |
|  |  |
|  | Change to surveys/questionnaires, etc. |  | Request for Review of Recruitment Materials |
|  |  |
|  | Change in Compensation |  | Request to Share Data/Specimens with another institution (a data use or material use transfer agreement maybe required)  |
|  |  |
|  | Increase in Accrual Target to: |  | Other – Describe below in E. |
|  |  |  |  |

|  |
| --- |
| **E. Provide a description and justification for the requested change(s) listed in Section D. above.**  |
|  |
|  |  |
|  | F. Grant Funding Changes |
|  | The IRB has the following regulatory mandate:*“Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(f) require that each application or proposal for HHS-supported human subject research be reviewed and approved by the Institutional Review Board.”* |
|  | To meet this mandate, the IRB has to be made aware of when originally pending (including JIT) grants have subsequently been awarded or when supplements have been awarded. This gives us the opportunity to review the subsequent version of the grant in respect to the currently approved protocol. It is at this point that you need to revise your consent, if applicable, to include the new sponsor.  |
|  | Check the Appropriate Funding Change Below |
|  |  | Resubmission of Grant that was not previously funded *(Note: If this is a new competing grant* |
|  | *or a renewal, an amendment is not appropriate, a new protocol is required.)* |
|  |  |  Original Grant has now been funded  |
|  |  | Supplemental Grant funding has been received |

|  |  |
| --- | --- |
|  | If any of the options above are checked, provide the specific grant information below.  |
|  | InfoEd Proposal # |  |
|  | Grant # *(full number including the version # related to the submission)* |  |
|  | Is this new grant identical to the originally approved grant/protocol?  |  | Yes |  | No |
|  | If yes, skip to #9 below. If no, explain the changes below and formally request an amendment to the protocol by completing this form. *(Note: Now is when you would need to revise your consent, if applicable, to include the new sponsor.)* |
|  |  |
|  | Confirm that the new corresponding grant is attached to this submission. |  | Confirmed |

|  |  |  |
| --- | --- | --- |
|  |  | Grant Funding has ended  |
|  |  |  |
|  |  | If so, and you are still using a consent form, you must remove the reference to the old sponsor and put in the new one. List the new sponsor below and the InfoEd number, if applicable.  |
|  |  |  |
|  |
| **G. Supporting sponsor documentation for this amendment is attached.** |  | Confirm by checking here. |
|  |
| **4.** | **Is this change being submitted as a result of safety information already submitted to the IRB?**  |
|  |  | **Yes** |  | **No** |  |
|  |  |
|  | **If yes, provide the date of the safety information and a brief description of the safety information: *(example: IDB submitted on 1/1/2001 with increased risk of seizures)*** |
|  |  |
| **5.** | **Does the proposed change affect the risk to subjects, either increase or decrease?**  |
|  |  | **Yes** |  | No |
|  |  |  |  |  |
|  | **If yes, please explain:** |
|  | **NOTE: Any change in research procedures that has active federal sponsorship that could result in an increased risk to human subjects will require prior NIH approval before implementation. Find guidance here** [**http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html**](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html) |
|  |  |
| **6.** | **After review of the proposed change, in the opinion of the Investigator, does the currently approved consent form require revision in order to adequately convey the potential risks of study participation?** *If yes, remember to attach a highlighted and a clean copy of a fully revised consent form for new subjects.*  |
|  |  | **Yes** |  | No |
|  |  |  |  |  |
|  | **If yes, please explain:** |
|  |  |
| **7.** | Are there subjects currently enrolled? |  | Yes |  | No |
|  | If yes, describe the process for re-consent and indicate how many participants you anticipate re-consenting. You need to develop and attach a consent addendum for review. |
|  |  |
|  | What is your approximate timeframe for informing current subjects? *Failure to inform subjects in a timely manner may be considered noncompliance depending upon the new information.* |
|  |  |
|  |  |
|  **8.** | Additional Comments:  |
|  |  |
| **\*\*IMPORTANT: You must revise your protocol using tracked changed, and submit the revised full protocol. Thank you.\*\*** |
|  **9.** | Principal Investigator Signature |  | **Date** |  |