

## - INSTRUCTIONS -

### The Request for Modification / Amendment to Approved Protocol Form

Section 1:.....	1
Section 2:.....	2
Section 3:.....	2
Section 4:.....	6
Section 5:.....	7
Section 6:.....	7
Section 7:.....	7
Section 8:.....	8
Section 9:.....	8
Section 10:.....	8

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Note: All the necessary forms are located in the forms section of our website and should be downloaded each time you need one.

The Request for Modification / Amendment to Approved Protocol form is intended to capture all of the required elements for a significant review of changes and amendments. When submitting amendments, you are not required to resubmit the entire protocol. Submit a completed Request for Modification / Amendment to Approved Protocol form to the Committee with all supporting documents that have been modified (i.e., protocol pages, questionnaires, recruitment flyers, consents, etc.).

Please Note: The GCRC and VCC also require review of changes to protocols under their purview. Please see our Combined Protocol Submission Chart for further guidance.

#### Section 1:

**CHRMS#:** (or **CHRBS#:**) Check the appropriate committee.

**Principal Investigator:** The name of the local Principal Investigator.

**Protocol Title:** The protocol title should be the same as the title stated on the original application and the Committee reminder letters.

## Section 2:

**Sponsor Study #:** Enter the study number that the sponsor (or cooperative group) uses for this protocol. For local studies without a sponsor type “n/a” in the text box.

**Sponsor’s Amendment Number:** Most sponsors number the amendments sequentially as they occur. Enter the number, if such exists, in the box provided. Locally initiated protocols may choose to use the same process for numbering amendments and should enter that number in the textbox.

**Date of Protocol Amendment:** All amendments should be dated regardless of whether they are locally initiated, multi-center, sponsored or not sponsored. Enter the date of the amendment in the box provided.

**Date of Consent Version:** Whenever a consent document is changed, it should receive a new version date. If this amendment required a change to the consent document, provide the new version date of the consent document in the space provided.

## Section 3:

**A. Did the IRB staff specifically request that you submit this amendment? Yes, No**

This is important for us to know as we will need to match up the amendment to previously submitted materials.

**B. Funding Modifications**

**Resubmission of a grant:** The Committee is mandated to review any grant that obtains funding. If you are resubmitting a grant for funding which is identical to an approved protocol already on file, you may submit an amendment to that protocol to include the resubmitted grant. Note: New competing or grant renewals require a new protocol, an amendment cannot be used in these cases.

**Provide the following if grant resubmission:**

**Infoed Proposal #:** This can be found within Infoed or obtained from your grants administrator.

**Grant Number:** This is located in Infoed or can be obtained from your grants administrator. Include version numbers of the grant.

**Indicate if the submission is identical to the previously approved protocol/grant.**

**If not, explain and request further changes to the protocol by completing the rest of the form.**

**Attach the corresponding grant including face page.**

**Supplemental Funding Has Been Requested:** The Committee is mandated to review any grant that obtains funding. If you have received supplemental funding to your original grant, you may submit an amendment to that protocol to include the supplement.

**Provide the following:**

**Infoed Proposal #:** This can be found within Infoed or obtained from your grants administrator.

**Grant Number:** This is located in Infoed or can be obtained from your grants administrator. Include version numbers of the grant.

**Explain how this supplement relates to the original grant.**

**Attach the corresponding supplement request.**

**C. All Other Modifications - check all that are applicable to this request.**

**Change in Study Title:** If the title of the study has changed for any reason, check this box.

**Addition or Deletion in Key Personnel:** If any change in key personnel (including a change in the principal investigator), check box.

Reminder: Key personnel are required to have completed the Protection of Human Subjects in Research on-line tutorial. Also if the person being removed is the assigned contact person for the study you must identify a new contact person at that time.

**Request for Review of Recruitment Materials:** Check box if requesting review of recruitment materials, e.g., posters, advertisements, radio spots, "Dear Colleague" letters, etc.

**Editorial Changes to Protocol:** If there have been changes to the protocol that are editorial in nature, please check this box.

Examples of editorial changes are:

Changes in addresses;

Changes in wording\*;

Clarifications without changes\*;

Changes to the Common Protocol Cover Form;

Changes in sponsor contact numbers, etc.

\*Please note that some clarifications and changes in wording may be more than simple edits if the sections affected are the eligibility and/or treatment sections. Typically this can occur in multi-center trials when the protocol is not written clearly. If either of these sections is affected, please also check “Scientific Changes in the Protocol” or “Eligibility Criteria Changes” and detail how it will change local procedures. (Example: The protocol did not state specifically that subjects with Alzheimer’s should be excluded. You enrolled several patients with very mild Alzheimer’s into the protocol. An amendment later comes out that specifically excludes subjects with any stage of Alzheimer’s. You should therefore detail how this change will affect your local procedures.)

**Change in Compensation:** Check box if there are any changes in compensation, increases or decreases, or remuneration timelines.

**Scientific Changes to Protocol:** If there are any scientific changes to the protocol, check this box. Any change that affects the science behind the research and/or the subject (i.e., changes to treatment, intervention, surveys, questionnaires, dosing, timeframes, statistics, etc.) is a scientific change. Eligibility changes, while scientific, are captured with the next question for ease of review.

**Eligibility Criteria Changes:** Check box if there is any change to the eligibility or ineligibility section of the protocol.

**Increase in Accrual Target to: #** If there has been an increase in the projected accrual target, or if the accrual target has already been exceeded, please check this box. To the right of the question is a textbox. Enter the new accrual target number and provide an explanation as to why the originally approved accrual target was exceeded and/or justification for the increase in accrual.

**Change in Sponsor:** If there is a change in funding or additional sponsorship check there may be implications beyond just the change in sponsor. Contact the office prior to submitting the amendment.

**Change in Procedures (describe below):** Check if the amendment proposes any change to the previously approved procedures which are listed in section 13 of your originally submitted Protocol Cover Form.

**Change in Consent Form (may also affect currently approved HIPAA authorization):** If there are any changes in the consent form, even editorial changes, please check this box and attach a clean copy as well as a highlighted copy of changes to the consent form. Make sure that this change does not affect your currently approved HIPAA authorization form.

**Change Requiring Re-Consent (HIPAA authorization may also be necessary):** This would apply to those studies that completed enrollment prior to April 14, 2003 and did not require the subjects sign a HIPAA authorization. If a signed addendum to the consent or full re-consent is necessary as the study progresses to inform previously enrolled subjects of new information, then the HIPAA authorization is also required at this time. Attach a clean copy as well as a highlighted copy of the changes to the addendum. If a HIPAA form has not been previously approved for the study, one must be developed and submitted along with a HIPAA Authorization Cover Form for review, approval and stamp.

**Change in HIPAA Authorization (may occur if consent is revised):** If there are any changes to the authorization form, check this box. Attach a clean copy and a highlighted copy of the changes to the authorization form. Authorization form revision would be required if the sponsor changes study procedures or the PI changes.

**Study Suspension:** Check box if the study is being temporarily suspended, regardless of the reason and provide the reason for suspension.

**Closure to Accrual – Interventions still occurring locally:** Once a protocol has closed to accrual, the Committee needs to be notified. Please check this box and include a short description of why the protocol is being closed to accrual (i.e., “met accrual goal of \_\_\_” or “study not projected to meet accrual goal of \_\_\_,” etc.) in the comment field.

**Close Protocol – No further research activity:** A research protocol for which all subject interventions are complete, all follow-up has ceased and the data analysis is complete can be permanently closed. Please check this box and complete the final study summary in the box provided at the end of the form. NOTE: Some sponsors require that the protocol remain active until all participating sites have closed and the database for the study has been locked. Confirm with the sponsor regarding this possibility prior to closing the protocol with the IRB.

**Change in Collaborating Sites:** If there is any change to the collaborating sites, check this box and describe changes. If UVM/FAHC is the lead site, agreements should be in place with collaborating sites before research activities begin at those sites.

**Data Safety and Monitoring Report:** Data Safety and Monitoring Reports need to be submitted to the Committee. These reports may be generated internally (e.g., UVM, GCRC, VCC, OCTR, or pharmacy drug visits) or externally (e.g., sponsors, CROs). Any serious adverse events or findings requiring amendments to the protocol will be reported through SAEs or protocol amendments, respectively. If the protocol has a Data and Safety Monitoring Board or Plan, please check this box and attach the reports to the Request for Modification / Amendment to Approved Protocol form. They should be reported as they are received.

**Retention Materials:** Check this box if you are requesting review of retention materials, e.g. subject specific letters, group newsletters, etc.

**Other (please describe in additional comments below):** Check box if the changes do not meet any of the above criteria, describe accordingly, and provide supporting documentation. Do not use this form to report safety information such as revised drug brochures, study progress reports, or safety alerts. Refer to our forms page for the appropriate submission forms for these materials.

**D. Provide a description and justification for the requested items.** Tell us what the amendment is in more detail and why the amendment is being requested.

**E. Supporting documentation for this amendment is attached. Check this box to confirm.** We require some type of documentation for the amendment request.

## **Section 4:**

**Does the proposed change affect the risk to subjects, either increase or decrease?**

If, in the opinion of the PI (or claimed by the sponsor), any risk is increased or decreased because of this proposed amendment, check “Yes” and provide details in the box provided.

## **Section 5:**

**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, in the opinion of the PI, the proposed amendment requires changes to the consent form, check “Yes,” provide a brief description of the changes required to the consent form and attach a revised highlighted as well as a clean version of the consent form.

If you checked “No” here and “Yes” section IV, it is important to document the reasons for not revising the consent. Use the box provided for response.

Remember to attach a highlighted and a clean copy of the consent form when applicable.

## **Section 6:**

Are there subjects currently enrolled? Yes or No  
If there are subjects enrolled you must explain how the new information will be conveyed to subjects. The IRB prefers that subjects be informed via either an information sheet or a consent addendum addressing only the new information.

Sponsors may wish to have the subjects resign a full consent form, however the IRB discourages this practice. This can be confusing for the subject especially if there are several new findings over the course of a study.

## **Section 7:**

### **Final Summary of Activities:**

Use this box to document the final summary of activities for amendments that close the study permanently. The summary should include final number of subjects studied, summary of events, withdrawals, etc., and outcome of research.

## **Section 8:**

### **Additional Comments:**

Use this area to provide any explanations or special requests.

## **Section 9:**

### **Other Reporting**

If this is a GCRC or a VCC study, you must submit a copy of the form to their respective committees as well.

## **Section 10:**

### **Principal Investigator Signature:**

The principal investigator must review, sign and date the form.