IRB 8.2 Modification and Continuing Review SmartForm

Contents

[Modification / Continuing Review 2](#_Toc497255107)

[Continuing Review / Study Closure Information 3](#_Toc497255108)

[Modification Information 5](#_Toc497255109)

|  |  |
| --- | --- |
| Modification / Continuing Review | Green = Help Text |
| 1. \* **What is the purpose of this submission?**Continuing Review

ModificationModification and Continuing Review   **Modification Scope:**There are no items to displayTo change the PI, choose ‘Other parts of the study/site’ scope**Active Modification for This Study Modification Type**Modification Name Study team member information**Active Continuing Review For This Study** Continuing Review Name | **Purpose of This Submission*** Continuing Review requests study closure or an extension of the approval period for your study.

Tip: If you select certain research milestones (as noted on a subsequent form), the IRB will close your study.* Modification requests approval of changes to your study.
* Modification and Continuing Review requests both approval of changes and extension of approval.

After you select the submission purpose and continue to the next form, you cannot change the submission purpose. |

|  |  |
| --- | --- |
| Continuing Review / Study Closure Information |  |
| 1. \* **Specify enrollment totals:**

|  |   |  Subjects Enrolled | Total | Since Last Approval |  |
| --- | --- | --- | --- | --- | --- |

At this investigator’s sites: Study-wide:  | **Enrollment Totals****At this investigator's sites:** All sites at which the sIRB PI is responsible for the research, including all research locations identified for the study. This does not include participating sites.**Study-wide:** All sites everywhere that are conducting this protocol, including participating sites. |
| 1. **Research milestones:** (Select only those that apply, if any)

[ ] Study is permanently closed to enrollment OR was never open for enrollment[ ] All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)[ ] Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)[ ] Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)[ ] Remaining study activities are limited to data analysis[ ] Study remains active only for long-term follow-up of subjects**Important!** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.\***I acknowledge that this study will be closed:** [ ] **Important!** This study cannot be closed until all active modifications have been approved or discarded.MOD ID MOD Name MOD State | **Research Milestones**Read each option carefully, because some of the options contain two different statements. If either statement is true, check the box.Usually the second statement in each option is intended for studies that do not involve interventions or enrollment of subjects, such as chart review and secondary data analysis studies. |
| 1. \* **Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?**

Yes  No        [Clear](http://hcapps6.huronclick.com/UHIRB/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?postback=1&form=0&qualifiedAttributeName=customAttributes.externalSites&valueField=_IRBSubmission.customAttributes.externalSites_setItemAdd&typeName=_ExternalSite&entityview=com.webridge.entity.Entity%5BOID%5B0652F9BD4FBAFF47A37FE59BF2A6380C%5D%5D&displayField=_IRBSubmission.customAttributes.externalSites_setItemAddDisplay&_webrChangeTrackingParentTransID=f46f540967b24c8c864163c3efd961bd&showOkAndAddAnother=true&rootEntity=com.webridge.entity.Entity%5BOID%5B667648EB6E036E4C9E38C9EB3B45370E%5D%5D&WizardPageOID=com.webridge.entity.Entity%5BOID%5B57EF03344D669341897CC4CA7C13B7D4%5D%5D&aldOID=com.webridge.entity.Entity%5BOID%5B6D52AB3FE31D4C4FB11A671DECD8BE85%5D%5D) | **Financial Interest Related to This Research**Definition of financial interest:Who holds the interest? The individual involved in the research, or the immediate family of the researcher. Immediate family means the spouse, domestic partner, children, or dependents.Interest in what? The study sponsor, a competitor of the sponsor, or a product or service being tested.What is an interest? Any of the following:◾Ownership interest of any value including (but not limited to) stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.◾Compensation of any amount including (but not limited to) honoraria, consultant fees, royalties, or other income.◾Proprietary interest of any value including (but not limited to) patents, trademarks, copyrights, and licensing agreements.◾Board or executive relationship, regardless of compensation.◾Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher-education institution or affiliated research institute, academic teaching hospital, or medical center.Important! If an individual has a financial interest, provide a copy of the Conflict of Interest Committee's determination regarding the interest. Attach a copy at the bottom of this page. |
| 1. **Check the items that are true since the last IRB approval for all sites involved in the study:** (initial review or last continuing review)

[ ] No subjects experienced unexpected harm[ ]  Anticipated adverse events have NOT taken place with greater frequency or severity than expected[ ]  NO subjects withdrew from the study[ ]  NO unanticipated problems involving risks to subjects or others[ ]  NO complaints about the study[ ]  NO publications in the literature relevant to risks or potential benefits[ ]  NO interim findings[ ]  NO multi-center trial reports[ ]  NO data safety monitoring reports[ ]  NO regulatory actions that could affect safety and risk assessments[ ]  NO other relevant information regarding this study, especially information about risks[ ]  In the opinion of the PI, the risks and potential benefits are unchanged[ ]  All modifications to the protocol have been submitted to the IRB[ ]  All problems that require prompt reporting to the IRB have been submitted |  |  |
| 1. **Attach supporting documents:** These must address every item left unchecked in Question 4 above, including safety monitoring information. See Help link at the top of this page for more guidance, including links to templates for reporting SAE’s etc.

|  |   | Name |  |
| --- | --- | --- | --- |
|  |  | There are no items to display |

 | **Attach Files for Continuing Review**Include the following information:◾Explanation of each item left unchecked above◾Brief summary of research progress◾Sponsor's progress report or annual report, if available |
| Title: File:  |  |

|  |  |
| --- | --- |
| Modification Information |  |
| 1. **Study enrollment status:**[ ] No subjects have been enrolled to date

[ ] Subjects are currently enrolled[ ] Study is permanently closed to enrollment[ ] All subjects have completed all study-related interventions[ ] Collection of private identifiable information is complete |  |
| 1. **Notification of subjects:** (check all that apply)

[ ] Current subjects will be notified of these changes[ ] Former subjects will be notified of these changesAttach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents Page. |  |
| 1. \* **Summarize the modifications**

 | **Summarize the Modifications**Write only a brief overview of the study modifications here. On subsequent forms, you can update the protocol document and change all applicable details of the existing study in the appropriate places. |