IRB Modification Request Worksheet

Key:

Italics: explanatory text

Yellow highlight: information everyone needs to complete

Gray highlight: instructions about when additional questions need to be completed

Teal highlight: information you may need to complete depending on previous answers

General Project Information

Submitter: [the system will enter this]

Protocol Number: [the system will enter this]

Protocol Title: [the system will enter this]

Faculty Assurance: [the system will enter this]

> *NOTE: If blank, there is no Faculty Assurance currently assigned to this project.*

Currently Approved Level of Review: [the system will enter this]

Modification Details

Please confirm that all research activity is being conducted under the currently approved protocol. (Modifications will not be implemented until IRB has approved this modification request.):
[check the box for "I Confirm"]

Is this a study-wide modification? (i.e., does this modification affect all sites?) [yes/no]

> If you selected "no":
>
> Please indicate which sites are affected by the modification in the text box below and provide the names, email addresses, and phone numbers for the Site Investigator and Study Contact that the IRB can contact with questions related to the substance of the modification:
> [enter sites and contacts]

Current Protocol Enrollment Status [pick one of the following]

> Study has not begun (no participants consented)
> Open to participant enrollment
> Closed to participant enrollment

Modification Purpose(s): [pick all that apply]

> *NOTE: Change in PI requires reason for the change, proposed PI's professional experience to be appropriate for the study, and alteration of all study documents to include the new PI's information.*

Add Personnel
Remove Personnel
Change PI
Submit revisions to/addition of data collection and storage study protocols
Submit revisions to/additions to recruitment protocols and/or materials
Submit revisions to/additions to study participant population
Addition of non-English speaking participants
Addition of documents for non-English speaking participants
Submit revisions to/additions to inducement or compensation protocol or material
Submit revisions to/additions to study locations
Submit revisions to/addition of study documents
Provide regulatory documentation that does not alter study activity (e.g., administrative updats or updates to improve statement clarity or to correct typographical errors)
Other

If you selected "add personnel":

Person to Add: [start typing name and select from drop-down]

Role on Project: [select from: "Co-investigator, Consultant, Research Team Member"]

Please describe any changes to non-Whitworth project personnel: [enter description; if non, please enter N/A]

If you selected "remove personnel":

Whitworth Personnel to Remove: [select from supplied list]

Please describe any changes to non-Whitworth project personnel: [enter description; if non, please enter N/A]

If you selected "change PI":

Enter the new Primary Investigator: [start typing name and select from drop-down]

Please explain the reason for the PI change: [enter explanation]

Please explain the proposed new PI's professional experience as appropriate for the study: [enter explanation]

Please attach any supporting documentation regarding the new PI's experience, if applicable: [upload attachment]

Please describe the modification, including literature-based support and reasoning for modifications: [enter description]

What are the anticipated effects or implications, if any, of this modification? [enter description]

Does the current modification request change the content of the consent form or process for obtaining consent? [yes/no]

If you selected “yes”:

Reconsent Plan for Enrolled Participants: [select from the following]

N/A – no participants enrolled
Our site plans to reconsent all participants (active, follow-up, and completed participants)
Our site plans to reconsent only a select number of participants
Our site does not plan to obtain reconsent

If you selected “our site does not plan to obtain reconsent”:

Explain why you do not plan to obtain reconsent. (E.g., changes to consent form are spelling/typographical only.) [enter explanation]

Has an inducement been modified or added? [yes/no]

If you selected “yes”:

Please specify how the inducement has been modified or added. [enter specification]

Have benefits of participation changed or additional benefits been identified? [yes/no]

If you selected “yes”:

Please explain additional or modified benefits: [enter explanation]

Do any elements of this amendment/modification pose any new or elevated risk to participants? [yes/no]

If you selected “yes”:

If risks or potential for risks have changed, please describe how additional or elevated risks will be mitigated. Please include a justification for the additional risks: [enter description and justification]

Attach Revised Documents (if applicable): [upload any documents that supersede currently approved documents and any documents specific to the proposed modification]

Attestation

By submitting this application, I attest that the application is complete and accurate to the best of my knowledge: [check the box “I Attest”]

Submission

Submission: [click the button “Submit”]