



Maintaining IRB Approval

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Topics for today

- Creating the perfect modification
- Continuing reviews
- Termination
- Avoiding common errors with all three submissions

This is NOT an eIRB training but a discussion about submissions (modifications and continuing reviews) with Q/A along the way

Modification Request (MR)

The title of the modification should match what is being submitted

All questions in the MR answered

1. Total subjects enrolled since study began:

1.1. Number of those who were consented and who were not screen failures and therefore received treatment (includes placebo) or intervention:

1.1.1. If applicable, how many subjects are children?

1.2. Number of subjects currently receiving treatment or undergoing a research procedure or intervention (if applicable):

1.3. Number of subjects currently in follow-up (if applicable):

1.4. Optional Commentary – For complex study designs, please provide any helpful information to help the IRB better understand the current state of enrollment:

2. Is any part of this modification due to an unanticipated problem (UP)?

Yes No [Clear](#)

2.1. If yes, reference UP event #s:

3. Change/Add/Drop items:

3.1. Advertisement:

3.2. Consent Form:

3.3. Protocol:

Requesting to establish a [Repository](#) for the first time.

Already approved to store for future use and are submitting new information at this time. Indicate when approval of storage for future uses was first approved by the IRB:

[Clear](#)

Approved prior to the [Repository Policy Launch \(August 19, 2010\)](#)

After the [Repository Policy Launch \(August 19, 2010\)](#)

[Clear](#)

3.10. Other (specify in question 5):

3.5.1. If there is a DSMP related change, please upload a DSMP and indicate where the DSMP information is located (Check all that apply):

Within the Protocol

Specify Protocol page numbers where DSMP info is located (e.g. page 34, 76, ...)

Within another document

Specify name of document

Specify page numbers where DSMP info is located (e.g. page 34, 76, ...)

Uploaded as a complete & separate document titled 'DSMP'

4. Does this change affect subject participation?

Yes No [Clear](#)

5. Briefly describe and explain the reason for the modification. Please indicate any changes, revision, etc.

The risk profile of the drug has changed. Please see the uploaded memo for details and the revised consent form for changes to the risk section. The protocol amendment includes changes to the inclusion/exclusion criteria based on the increase risk of heart problems, see protocol summary of changes for details.

6. Does the proposed modification add or alter current exposure to radiation?

Yes No [Clear](#)

7. There has been a change in the funding source:

8. Adding/Changing the advertisement on the [Study Participation Opportunities](#) website:

9. Adding/Changing Researchmatch.org to recruit for this study:

3181 SW Sam Jackson Park Road , L106-RI
Portland, OR 97239
P: 503.494.7887
www.ohsu.edu/researchintegrity

MR Tips

- Q5 is the most important question in the form. If adding/removing staff list by name
 - The risk profile of the drug has changed. Please see the uploaded memo for details and the revised consent form for changes to the risk section. The protocol amendment includes changes to the inclusion/exclusion criteria based on the increase risk of heart problems, see protocol summary of changes for details.

MR Tips

- Make sure all forms affected by the change are revised
- Double check that you have uploaded all revised forms and your changes are tracked
- When uploading revised documents make sure the title is the same as the currently approved document
- It is helpful to include in the title if the document is “new” or “revised”

Continuing Review (CR)

- The expiration date of the study is *not* the due date of the continuing
- The CR is due to the IRB 6-10 weeks prior to the expiration date
- Closure information and numbers in treatment/follow-up must match
- CR is the best time to archive documents

CR Tips

- The following are what you will find in the CRQ pages:
 - Study Status
 - Enrollment
 - Documents Page

Closure questions

Continuing Review Form

PI: Melinda Roberts

Short Study Title: TEST

IRB Number: IRB00007831

Study State: Active

2. Enrollment for this study is Closed.

3. Do you want to re-open enrollment at this time?

Yes No [Clear](#)

If the study is permanently closed, answer the following questions:

3.1. Have all subjects completed study related visits and/or procedures?

Yes No [Clear](#)

3.2. If **Yes**, are subjects being followed? (Subjects are being followed if they are returning only for visits required for clinical care or being contacted for health status information.)

Yes

No

NA

[Clear](#)

3.3. Please indicate the month and year the last subject was enrolled:

Month:

Year:

Numbers

Study State: Active

* 5.5. Total subjects since study began:

This includes cases for studies involving chart reviews, surveys or biological samples and also comprises all who have been consented, including screen failures.

5.5.2. Number of subjects currently participating in the study (i.e., receiving treatment or undergoing research procedures, visits, or interventions as applicable, and are not in follow-up or discontinued from the study):

5.5.3. Number of subjects currently in follow-up (if applicable):

5.5.4. Optional Commentary - For complex study designs, please provide any helpful information to help the IRB better understand the current state of enrollment.

Number of subjects (or cases) approved for the study (this is the number approved at initial review plus any increase in enrollment requested after initial review): **120**

6. If more subjects have been consented than were approved, please explain:

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: Continuing Review Form Ethnic/Race Categories Totals ▾

Continue >>

Done

Local intranet | Protected Mode: Off

100%

F. 303.434.7007

www.ohsu.edu/researchintegrity

Documents

<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Baseline Survey.pdf			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Consent and Authorization Form Media.doc			0.03
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Consent and Authorization Form.doc			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Email and Text Message.docx			0.01
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	FFQ_gsel.pdf			0.01
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Health and Fitness Guide.pdf			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Healthy Meals Cafe Signs - 9th floor.pptx			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Healthy Meals Cafe Signs - Mac Hall .pptx			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Healthy Meals Cafe Signs - Third floor cafe.pptx			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Healthy Meals Content.xlsx			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Healthy Meals Salad Bar Sign.pdf			0.01
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Lay Summary.doc			0.01
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Medical history form.docx			0.01
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Pedometer.pdf			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	PPQ Goldberg Wellness.pdf			0.01
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Protocol.doc			0.01
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Recruitment.pdf			0.01
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Results Sheet.docx			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Serving Size_gsel.pdf			0.01
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Summary of Revisions to Team Leader and Team Workbook Curriculum.docx			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Survey Follow-up Assessment.pdf			0.01
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Team Leader Manual Curriculum.pdf			0.01
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Team Workbook Curriculum.pdf			0.01
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Testing Directions.doc			0.01
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Testing Instructions.docx			0.01
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	T-Shirt.pptx			0.01
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Website Link and Additional Content.pptx			0.01

CR Tips

- When NOT to submit changes with your continuing
 - If you cannot wait 6-10 weeks for approval
 - If you have study staff changes
- Note: If the study needs revision that cannot wait until continuing review is completed, i.e., changes in risks to subjects, submit a modification.

CR Tips

- If you are submitting changes with your CR Q13 is like Q5 in the MR form
 - Discuss any new information (summary of any recent literature, amendments, or modifications to the research since the last IRB review, reports of multi-center trials and any other relevant information). Include any information that might affect the risk/benefit ratio or the willingness of current study subjects to participate in the research.

Important CR Reminders

- Even though the IRB provides several reminders, it is still the Principal Investigator's responsibility to ensure studies do not lapse and meet the regulatory requirements of annual review.
- Analysts will make every effort to get the study to the Board prior to the study expiration date; however, we rely on you to help with the process by getting your CR submitted 6 – 10 weeks prior to expiration. There may be additional clarifications prior to review.

Principal Investigator Leaving?

- Make sure all eIRB studies are either transferred to another PI or terminated **BEFORE** leaving OHSU
- Submit a modification to change the PI and include a memo from the researcher stating her/his willingness to be the PI
- You cannot change the PI in the eIRB, your IRB analyst will do this when reviewing the modification

Termination Request Definitions

- Closed to enrollment: the study is no longer enrolling new subjects
- Termination: all research is complete and the study is either in data lock or has been accepted for publication

Termination Request

- Before you start a termination request make sure that
 - The study has been accepted for publication or the data have been locked and the sponsor is requesting termination
 - You do not have any outstanding projects for the study (modification, protocol deviations, unanticipated problems, or continuing reviews) in process in the eIRB

Termination Tips

- Enrollment numbers must match the last submission, mod or continuing
- You must provide a summary or clarify why one is not available
- Documents do not get approved with terminations. If the sponsor wants something approved, submit a modification
- Expired Conflict of Interest in Research is not enforced with terminations

Next Brown Bag

IRB Policies & Forms Makeover

Tuesday* 7/22 11:30AM – 12:30PM

UHS 8B60

The IRB Policies and Forms web pages are getting a makeover in early July! Come to the special Brown Bag in July to get a tour of the new website structure!

*Please note this Brown Bag is on Tuesday instead of the normal day



Mark your calendars!

Next Brown Bag Session is
Tuesday July 22nd
IRB Policies & Forms Makeover

Visit our website for more
information:

www.ohsu.edu/researchintegrity

