Maintaining IRB Approval

Melinda Allie
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: 5

1.1. Number of those who were consented and who were not screen failures and therefore received treatment (includes placebo) or intervention: 5

1.1.1. If applicable, how many subjects are children? 0

1.2. Number of subjects currently receiving treatment or undergoing a research procedure or intervention (if applicable): 5

1.3. Number of subjects currently in follow-up (if applicable): 0

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

2.1. If yes, reference UP event #: [blank]

3. Change/Add/Drop Items:

3.1. Advertisement: [ ]

3.2. Consent Form: [ ]

3.3. Protocol: [ ]

4. Does this change affect subject participation?
   - Yes
   - No
   - Clear

5. Briefly describe and explain the reason for the modification. Please indicate any changes, revisions, 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 in 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: [ ]
**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. Adding Melinda Allie.
**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 review.
- 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.
- Ethnic/Race charts must match.
- CR is the best time to archive documents.
Closure questions

Continuing Review Form

Pt: Melinda Roberts
Short Study Title: TEST
IRB Number: IRB00007831
Study State: Active

2. Enrollment for this study is permanently 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: August  
Year: 2011
Numbers

* 5.5. Total subjects enrolled since study began: 10

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

5.5.1. Number of those who were consented and who were not screen failures and therefore received treatment (includes placebo) or intervention:
10

5.5.1.1. If applicable, how many subjects are children?
0

5.5.2. Number of subjects currently receiving treatment or undergoing a research procedure or intervention (if applicable):
2

5.5.3. Number of subjects currently in follow-up (if applicable):
8

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): 0

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

# Ethnic/Race chart

The total of the Ethnic Category table and the Racial Category table must be equal. This total should be a cumulative summary of all subjects consented. The table below should only indicate information regarding enrollment in the research study and should not include information about any \textit{excluded} or \textit{unenrolled} that may be approved with this submission.

Please verify your tables below and make sure the numbers are correct. Once you are done, hit the "Continue" button to complete your Continuing Review form.

<table>
<thead>
<tr>
<th>Ethnic Category</th>
<th>Male</th>
<th>Unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Not Hispanic or Latina</td>
<td>5</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5</td>
<td>0</td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Racial Category</th>
<th>Male</th>
<th>Unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian or Alaskan Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>5</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>More than one race</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5</td>
<td>5</td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>

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<td>HealthyMeals Cafe Signs - Third floor.ppt</td>
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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
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 trial sand 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
**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
Mark your calendars!

Next Brown Bag Session is Thursday October 27th

Logistics of Review

Presented by Wendy Doggett and Trish Lindstrom

Visit our website for more information:
www.ohsu.edu/researchintegrity