Logistics of Review
Wendy Doggett and Trish Lindstrom
Topics for today

1. Full Board vs. Expedited Review
2. Full Board Process
3. Expedited Process
4. Tips for Quicker Approvals
5. New Business – eIRB updates coming this Friday, 10/28/2011
General Guideline for Full Board vs. Expedited (Administrative) Review*

Greater than Minimal Risk studies need full board review.

- Unapproved drugs or devices
- Approved products used for unapproved purposes or in unapproved ways
- Approved products if randomized rather than clinically assigned (usually)
- Withholding medications (usually)
- Placebo (usually)
- Invasive procedures
- Radiation
- Lots of blood or lots of draws
- Grave consequences if breach of confidentiality

Minimal Risk studies may be reviewed administratively.

- Approved products used according to label
- Noninvasive clinical procedures
- Program evaluation/curricula evaluation
- Surveys/interviews/focus groups
- Basic science
- Chart review
- Repositories
- Non-human subjects (NHS) research
  - Decedents only
  - Truly anonymous data/samples
  - Case Studies (3 or fewer)
  - Not “generalizable” – true QA/QI

*The IRB Chair may determine that any study must be reviewed by the full board.

Initial Study Review
Full Board Review Process

Analyst sends complete study materials to Board Reviewers

Preboard Review

Postboard Review
Preboard Reviewers

- Knight Cancer Institute
- OCTRI
- Radiation Safety Committee (RSC)
- Conflict of Interest in Research Committee (CoIR)
- Clinical Research Billing Office (CRBO)
- Chair’s Pending Docket
- Analyst
Analyst Pre-Review

Common Requests

• Additional Documents
• IRQ Pages (FDA)
• Clarification of Genetics and Banking
Before Submission Checklist

- IRQ
  - Complete
  - Matches Protocol, Lay Summary, Consent Form, recruitment materials
- Drug/Device Information
- DSMP
- Billing Schedule
- All Study Measures
- OHSU Template Followed
- Recruitment Materials that meet Ad Requirements
Before Submission – is it clear?

• Does the study include genetic testing to meet the aims of the protocol?
  – Is this optional?

• Does the study include storage for future uses?
  – Is this optional?
  – Will this include genetic testing?
Data and Safety Monitoring Plan

• There are 8 questions on the OHSU Template.
• All 8 questions must be answered for all full board studies.
• Upload the charter, if you have one.
• When in doubt, complete the OHSU template.
Write this in lay language.
<table>
<thead>
<tr>
<th>Title</th>
<th>History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Billing Schedule</td>
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<td>CLIA - Eurofins (exp 05-8-2012)</td>
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<tr>
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<td>Cover Memo to IRB at Initial</td>
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<tr>
<td>DSMP (OHSU)</td>
<td>History</td>
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<tr>
<td>Investigational Brochure dated June 2011</td>
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<tr>
<td>Lay Summary</td>
<td>History</td>
</tr>
<tr>
<td>Protocol V 1.1 dated 22 Aug 2011.pdf</td>
<td>History</td>
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<tr>
<td>Q - AAO-HNS</td>
<td>History</td>
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<td>Q - SF-36</td>
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<td>Q - THI</td>
<td>History</td>
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<tr>
<td>Q - Vertigo Cards</td>
<td>History</td>
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<tr>
<td>Recruitment - Facebook Ad</td>
<td>History</td>
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<tr>
<td>Recruitment - Google</td>
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<tr>
<td>Recruitment - IVR Script</td>
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<tr>
<td>Recruitment - ResearchMatch</td>
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<tr>
<td>Recruitment - TV Ad Script</td>
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<tr>
<td>Recruitment Brochure</td>
<td>History</td>
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<td>Recruitment Flyer</td>
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<tr>
<td>Recruitment Postcard</td>
<td>History</td>
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<tr>
<td>Recruitment Website</td>
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<td>Signed PPQ.pdf</td>
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<tr>
<td>Signed Prep to Research 08-30-11.pdf</td>
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</table>
1. Experts present a review of the study.
   A. “Big Picture” questions such as ethical considerations
   B. Review of study’s IRQ and all documents
2. Members of the board, including community members, discuss it.
3. The board votes and makes regulatory determinations.
4. The analysts take minutes.
Postboard Review

Analyst gathers notes from all board reviewers and members, revises study documents, and writes a summary for the chair’s review.

Once the chair approves the memo, the PI receives a Review Summary.
Review Summaries are sent to the P.I. about three business days after the board review.

Human subject research may not begin until final approval has been issued.
Sample Review Summary

INSTRUCTIONS

• Follow the instructions. Do not delete study documents. Track changes.

IRB CLARIFICATIONS

• Genetics
• Banking
• Purpose statements do not match. Protocol, Lay Summary, and Consent.

CONSENT AND AUTHORIZATION

• Organize visit descriptions chronologically. Eliminate redundant descriptions.
• The severity and rate of risks are not clear. List risks in order of gravity and indicate their likelihood.
• Risks are not easy to understand. Describe risks in lay language, from the subject’s perspective.
• Standard of care risks unrelated to study participation have been moved to an appendix after Signatures.

OTHER

• Clinical Research Billing Office (CRBO) review is required prior to final IRB approval.
• The study requires a PPQ with all signatures prior to final approval.
Sample Review Summary Response

**IRB CLARIFICATIONS**

Genetics – We have clarified genetics and made the descriptions consistent in the IRQ and throughout all study documents. All OHSU boilerplate has been added to the consent form.

Banking – The study does not include banking. We have clarified this in the IRQ and in all study documents.

**CONSENT AND AUTHORIZATION**

Organize visit descriptions chronologically. Eliminate redundant descriptions. – Done.
The severity and rate of risks are not clear. List risks in order of gravity and indicate their likelihood. – Done.
Risks are not easy to understand. Describe risks in lay language, from the subject’s perspective. – Done.
Standard of care risks unrelated to study participation have been moved to an appendix after Signatures. – We have reinstated the standard of care risks because this is likely to be the best description of these risks ever given to the subjects.

**OTHER**

Clinical Research Billing Office (CRBO) review is required prior to final IRB approval. - Completed.
The study requires a PPQ with all signatures prior to final approval. – PPQ uploaded.

We have not included any new materials at resubmission.
APPROVAL!

- Documents uploaded in 3 days
- Ancillary approvals may be required
Expedited (Administrative) = Minimal Risk

~1 week  ~1 – 3 weeks  ~1 – 3 weeks
Sample Expedited Submission
Chart Review with Repository (Cat #5)

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<th>Title</th>
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<tr>
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<td>Repository Sharing Agreement</td>
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<td>Repository Tracking Sheet</td>
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These 3 fulfill Repository Policy Requirements.
Sample Expedited Submission
Survey Study (Cat #7)

<table>
<thead>
<tr>
<th>Unofficial Documents</th>
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<tbody>
<tr>
<td><strong>Title</strong></td>
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<tr>
<td>Advertisement - Flyer</td>
</tr>
<tr>
<td>Complete Grant</td>
</tr>
<tr>
<td>Consent and Authorization</td>
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<tr>
<td>Lay Summary</td>
</tr>
<tr>
<td>PPQ</td>
</tr>
<tr>
<td>Protocol</td>
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<tr>
<td>Survey for Patients</td>
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<tr>
<td>Survey for Providers</td>
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</tbody>
</table>
Sample Exempt Submission

Research on Effectiveness of Curricula (Exempt Cat #1)

<table>
<thead>
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<th>Title</th>
<th>History</th>
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<tbody>
<tr>
<td>Information Sheet</td>
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<tr>
<td>Lay Summary</td>
<td>History</td>
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<tr>
<td>Links to Curriculum and Tests</td>
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<tr>
<td>PPQ</td>
<td>History</td>
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<td>Protocol</td>
<td>History</td>
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<td>Recruitment Email</td>
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<td>Survey</td>
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</table>
Quicker Reviews

Full Board

1. Before Review
   A. Know the Protocol
      I. Genetics
      II. Banking
      III. Purpose
      IV. Population
   B. Complete IRQ
   C. Drug/Device Information
   D. DSMP
   E. Billing Schedule
   F. All Study Measures
   G. Use OHSU Template Forms
   H. Lay Summary in Lay Language
   I. Meet Ad Requirements

2. After Review
   A. Review Summary Instructions
   B. PPQ

Expedited

1. PPQ
2. Complete grant application
3. OHSU Template Forms
4. Ad Requirements

All Studies

1. Respond to IRB requests
2. PI must “resubmit to IRB”
NEW BUSINESS

eIRB upgrade scheduled for Friday, 10/28/2011

• The system will be unavailable between noon to 4:00 p.m.
• New IRQ questions about FDA-regulated devices
• New Modification project questions
eIRB Downtime Notice

In our continuing attempts to improve the eIRB user experience, the system will be down

Friday, October 28 from noon–4:00pm

We thank you for your patience and apologize for any inconvenience this downtime may cause.
New IRQ Device Questions

Easier Questions!

New Information to Assist Researchers!

Pop-Up Help Text. Awesome.
New Modification Request Form Questions

4. Does this change affect subject participation OR risks to subjects?
   - Yes  No  Clear

4.1. If yes, describe how the modification affects subject participation or risks to subjects.

5. Briefly describe the change(s) included in this modification. List the names of any personnel being added or deleted from the study.
The sponsor notified all sites on 22-Jul-2011 that the study would close to enrollment after meeting its accrual goal.
Personnel: removing Susan Granat. Adding Susanne McGlothlin, Bridget Boyle, Caron Campbell, and Tijana Jovanovic. Daniel Hansen will remain the primary study contact.

5.1. Explain the rationale for these changes, including if any changes are due to an unanticipated problem, a protocol deviation, DSMB recommendations, Investigator Brochure update, etc.

6. Does the proposed modification add or alter current exposure to radiation?
   - Yes  No  Clear

*New:
* Question 4
* Question 4.1
* Question 5.1

Checking "yes" will likely require consent form modifications.

If you select "Yes" please upload a new Radiation Safety form with the changes highlighted.
Mark your calendars!

Next Brown Bag Session is
Thursday December 1st

PI Eligibility and Research Collaborations

Presented by Andrea Johnson

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