IRB Chair’s Forum:
Towards a Better IRB:
Efforts to Support Research at OHSU
12/11/2013
IRB Process Improvement project

• SoM Research Road Map Task Forces identified slow study start-up as a barrier to advancing research at OHSU
• IRB review is key component of study start-up
• OHSU currently undertaking numerous formal process improvement efforts
**IRB Process Improvement Goals**

To improve study start-up process, the IRB set the following goals:

1. **Efficiency**: Improve turnaround time from submission to approval
2. **Consistency**: Ensure consistent, transparent and high-quality reviews that meet regulatory requirements
3. **Ease**: Reduce administrative burden for research community
Major Initiatives

• Comprehensive, standardized P&Ps
• IRB Office and Board workflow and efficiency improvements
• Redesigned approach for collecting study information from investigators
• Reduced Investigator requirements
Criteria for IRB Approval

✓ Risks minimized
✓ Risks reasonable in relation to benefits
✓ Selection of subjects equitable
✓ Informed consent will be obtained, documented
✓ Adequate data safety monitoring
✓ Protection of privacy and confidentiality
✓ Additional safeguards for protection of vulnerable populations
### What slows down IRB review?

<table>
<thead>
<tr>
<th>Back and Forth</th>
<th>Internal Processes</th>
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<tr>
<td>• Incomplete or inconsistent information from researchers</td>
<td>• Efficient workflow</td>
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<td>• Proposals do not meet regulatory criteria</td>
<td>• Board agendas full or reviewers unavailable</td>
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<td>• Inconsistency in review outcomes/requirements</td>
<td>• Inconsistent review standards across 4 boards</td>
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<td>• Non-IRB institutional ‘gate-keeping’</td>
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<td>• Analyst and Chair bandwidth</td>
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Sources of administrative burden for investigators

- Volume and complexity of materials required for submission
- Back-and-forth during review to address missing and contradictory information
- Inconsistency in review outcomes
- Maintaining approval (reporting, continuing reviews, etc.)

Reduced Investigator Burden

Improved Approval Time
Comprehensive, standardized P&Ps

- Toolkit developed by IRB regulatory expert Jeff Cooper, MD
- Complete system of policies, procedures, review tools
  - All regulatory criteria for approval consolidated into a system of checklists and worksheets
  - Supports compliance with regulations
  - Efficient, consistent, transparent review process
- Includes Investigator Guidance documents, protocol templates
- Implemented at a number of other institutions

Ensures reviews are thorough and consistent
How does this affect investigators?

- Most IRB policies replaced by Toolkit documents
- Goals of the Toolkit:
  - Increase consistency of reviews - anticipate IRB requirements
  - Reduce back-and-forth
  - Eventually - faster review, reduced investigator burden
- Investigator tools:
  - “Investigator Guidance” documents outline PI responsibilities
  - Protocol templates: Better guidance on information required for IRB approval
  - Review Checklists and Worksheets will be made available – transparency in review criteria
Toolkit implementation

• Reducing number of IRB documents by 72%

• New review process implemented for Expedited reviews November 1

• Use for Full Board reviews in progress, to be completed early 2014

• Watch for changes to IRB policy and forms websites (currently in development)
**Improve Office and Board Efficiency**

- Expand use of right level of IRB staff for appropriate review and approval functions
- Fully utilize Expedited review for modifications, for situations allowed by regulation
- Reduced administrative document preparation for full board meetings
- Modified IRB roster to eliminate review delays due to loss of quorum
Redesigned collection of study information
Lay Language Summary Eliminated

• Too detailed for a protocol summary
  – Resulted in duplication of information
  – Inconsistency between documents
  – Requests for Revisions

• Not detailed enough to be a protocol template
  – Resulted in requests for additional information

• Purpose not clear
  – Often mistakenly thought to be for subjects

Replaced with templates better targeted to each purpose
New Templates Available Now

• Brief Project Description
  ▪ Open-ended, non-technical overview
  ▪ Assist IRB members and staff to get overview of study
  ▪ Required for all studies

• Minimal Risk Protocol Template
  ▪ For investigator-initiated low risk studies (non-FDA)
  ▪ Outline of all information needed to meet IRB requirements
  ▪ Detailed Instructions
  ▪ For simple studies (chart review): 1-2 pages

Required for studies submitted on or after December 1
Reduced Investigator Requirements

• Effective 12/1: Extend Exempt study determination from 1 year to 3 years

• Eliminate IRB review of certain documents
  – CLIA certificates
  – Clinical Research Billing Schedule
  – Nursing summary to go soon...

• In process – streamline PI eligibility exceptions for affiliate faculty and non-faculty employees
Reduced Investigator Requirements: IRQ Simplification

- **Problem:**
  - IRQ is long, redundant, results in contradictory information
  - Info not required for IRB review

- **Solution:**
  - Remove items not required
  - Capture required information more effectively
  - Move info to eCRIS, protocol, Local Context Supplement

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**Remove:**
- 250 IRB fields \(\downarrow 47\%
- 126 IRB questions \(\downarrow 54\%
- 9 pages of IRQ \(\downarrow 25\%

- Introducing **Local Context Supplement** document
  - Supplement for multi-site studies
  - Local plan for recruitment, privacy

- IT development January 2014, go-live shortly thereafter

Temporal measure until new eIRB system rolls out...
IRB 7

• New eIRB system
  – Designed specifically to support use of Toolkit
  – Technological sustainability – easier to maintain and update
  – Conceptual shift - Streamlined submission materials for investigators

• Currently working on details of development and implementation

• Start design/development process early 2014
Overview and Timeline

- Finalize Toolkit Documents
- Implement Expedited Review Process
- Implement Full Board Review Process
- IRQ Cut
- Updated IRB Roster
- Lay Summary Eliminated
- Exempt 3-year Approval
- IRB 7 Development (ongoing)

Timeline:
- 2013: Aug Sep Oct Nov Dec
- 2014: Jan Feb Mar Apr May Jun
Improving Turnaround Time: Measuring progress

21% improvement in IRB TAT...

Despite 26% ↑ in Full Board and 17% ↑ in Expedited studies
What can I do to help my study get approved faster?

- Know the requirements for approval
- Ensure all information is provided
- Double check that all documentation is consistent
- Use templates, forms, guidance from our website for most recent versions
- Respond promptly and completely to IRB requests
- Attend IRB education sessions and brown bags
- Contact us when you have questions!
Keeping up with what’s coming next...

• Brown bag sessions over next 6 months focus on changes in submission requirements
• Updates will be communicated via:
  – IRB website   – IRB Notes
  – eIRB listserv – Research News
• Look for new guidance, forms, templates and policies, on our website
• Get involved - help us make the process better!
Thank you:

Andrea Johnson  Dave Holmgren
Kelly Kidner  Wendy Rosling
Kaija Maggard  Melinda Allie
Triana Nagel  Trish Lindstrom
Jen Ruocco

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