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

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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

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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

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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

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What slows down IRB review?

Back and Forth

- Incomplete or inconsistent information from researchers
- Proposals do not meet regulatory criteria
- Inconsistency in review outcomes/requirements

Internal Processes

- Efficient workflow
- Board agendas full or reviewers unavailable
- Inconsistent review standards across 4 boards
- Non-IRB institutional ‘gate-keeping’
- Analyst and Chair bandwidth

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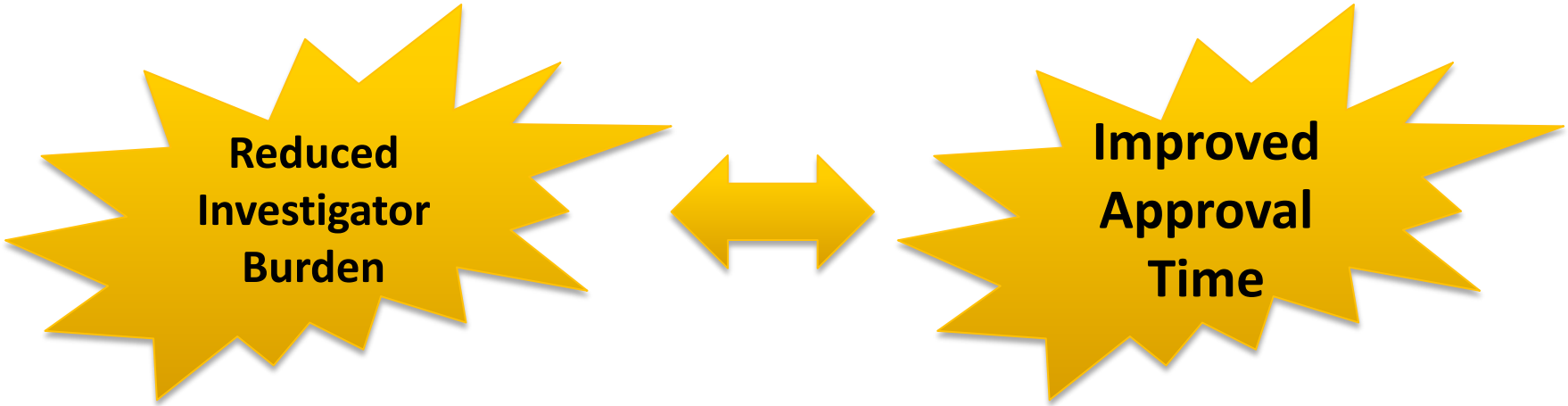
Sources of administrative burden for investigators

- 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.)



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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

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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

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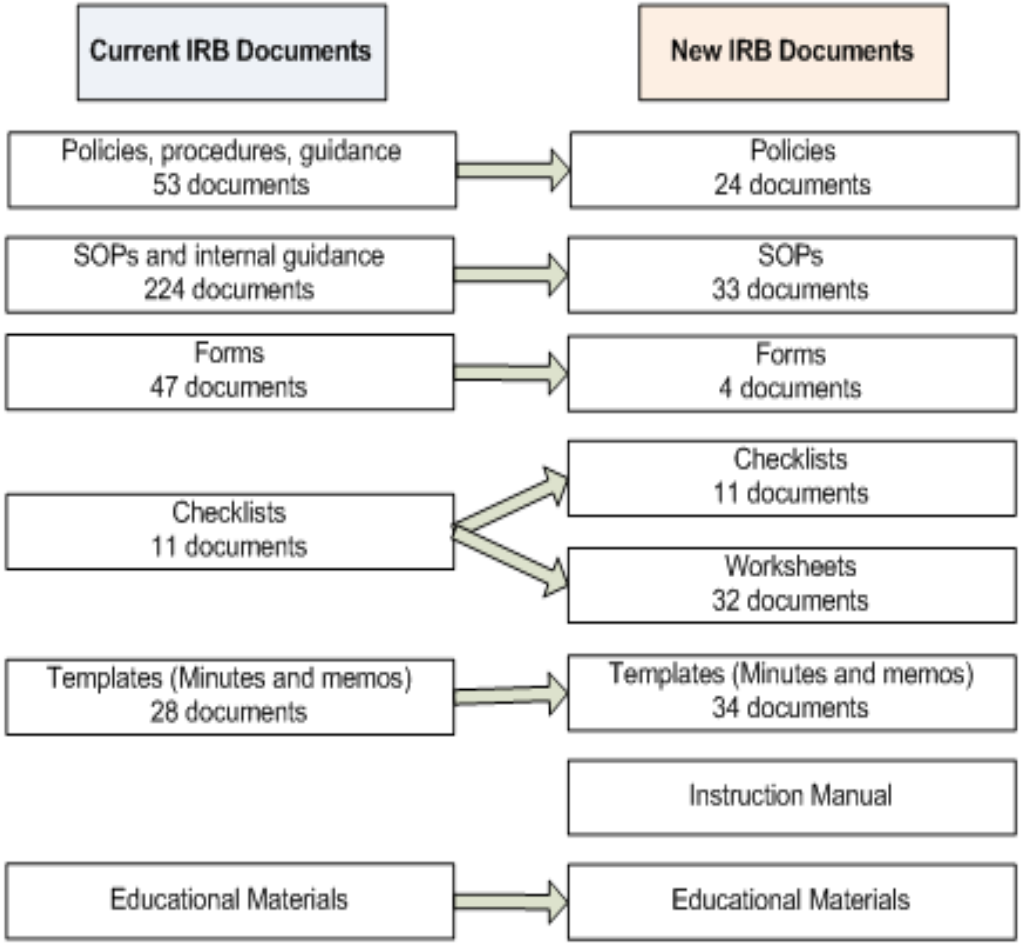
Toolkit implementation



- **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)

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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

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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

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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

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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

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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

Remove:

250 IRB fields	**↓47%**
126 IRB questions	**↓54%**
9 pages of IRQ	**↓25%**

- Introducing **Local Context Supplement** document
  - Supplement for multi-site studies
  - Local plan for recruitment, privacy
- IT development January 2014, go-live shortly thereafter

Temporary measure until new eIRB system rolls out…

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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

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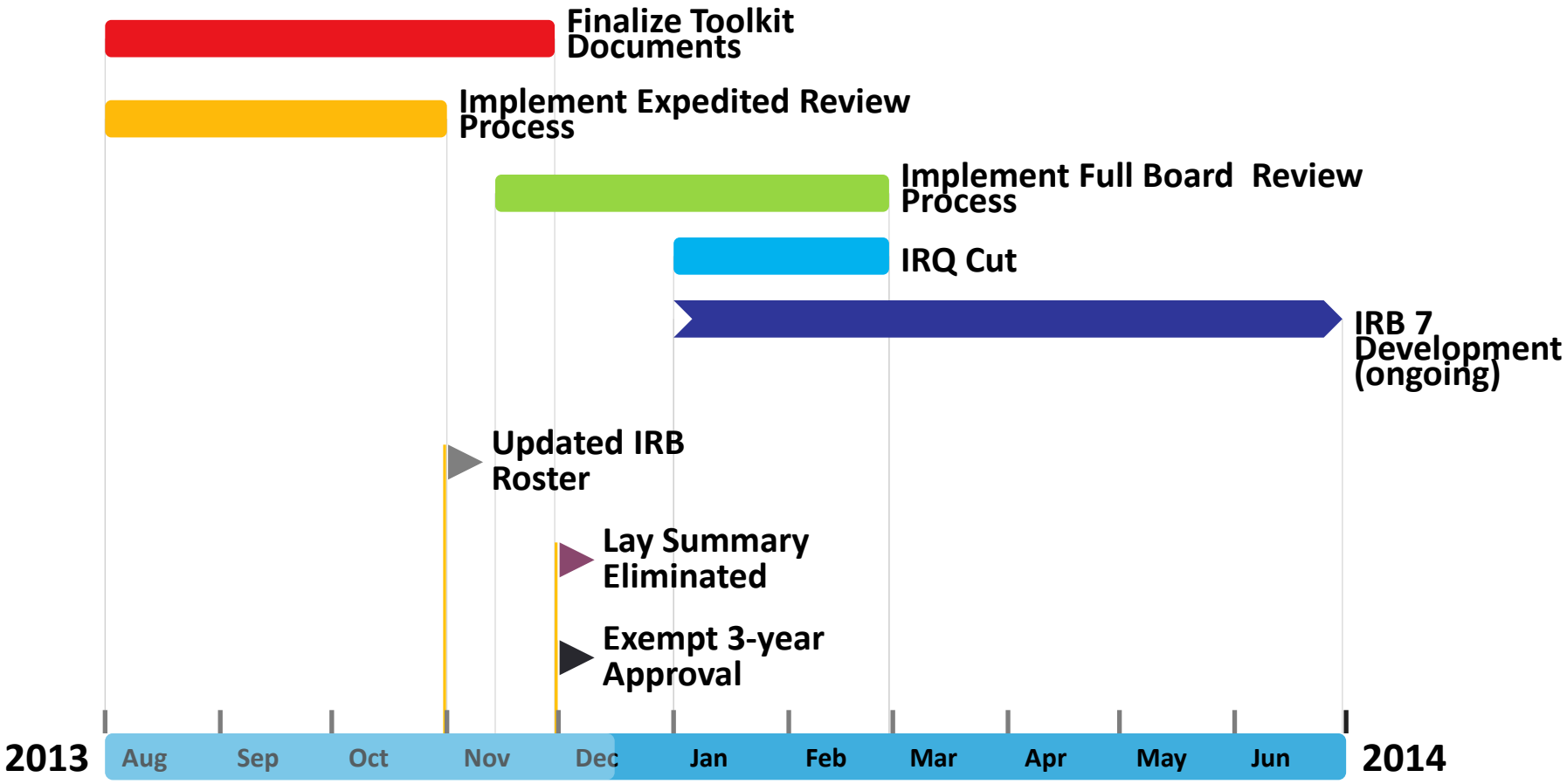
Overview and Timeline



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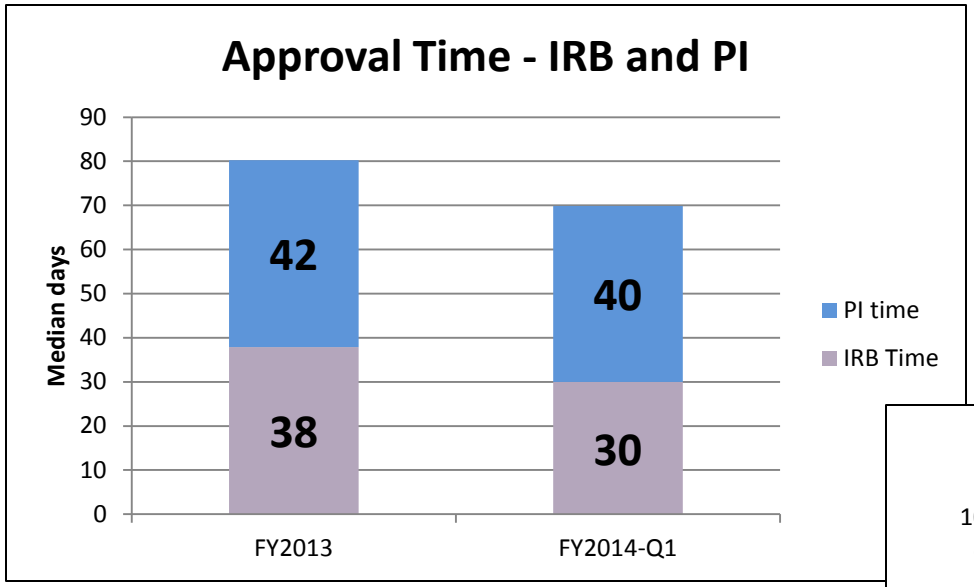
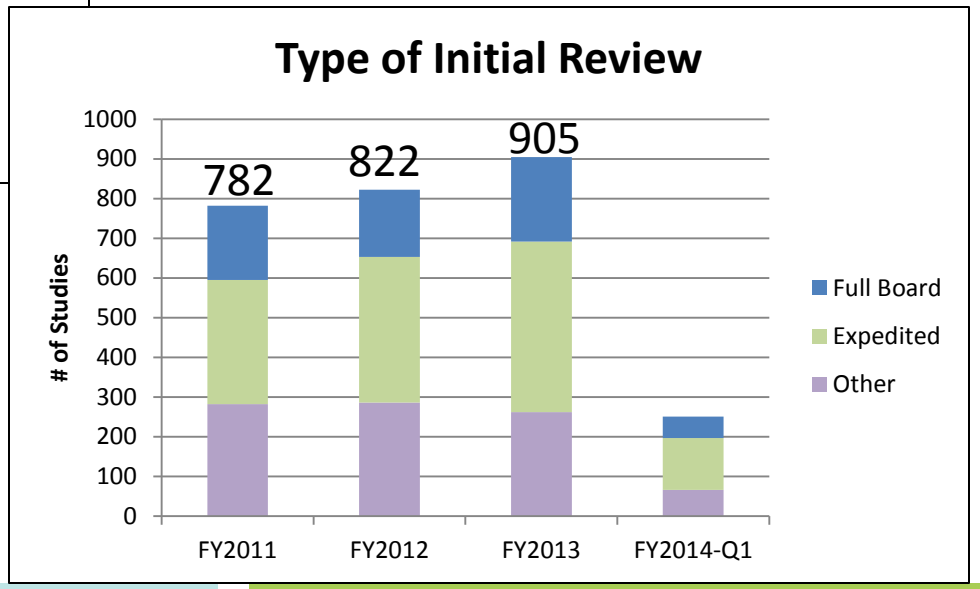
Improving Turnaround Time: Measuring progress



21% improvement in IRB TAT…

Despite 26% ↑ in Full Board and 17% ↑ in Expedited studies



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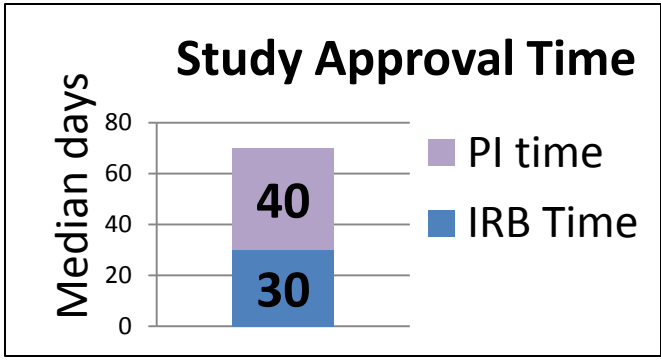
What can I do to help my study get approved faster?



- 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!

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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
  - eIRB listserv
  - IRB Notes
  - Research News
- Look for new guidance, forms, templates and policies, on our website
- Get involved - help us make the process better!

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Thank you:

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Visit our website for more info:
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