IRB Policies and Forms Makeover

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IRB Process Improvement Goals

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

1. **Efficiency**: Improve turnaround time from submission to approval

2. **Consistency**: Ensure consistent, transparent, high-quality reviews that meet regulatory requirements

3. **Ease**: Reduce administrative burden for research community
Comprehensive, Standardized P&Ps

• **HRPP Toolkit** developed by IRB regulatory expert Jeff Cooper, MD

• Complete system of policies, procedures, review tools

• All regulatory criteria for approval consolidated in checklists and worksheets

• Investigator Guidance documents
Implementation

• November 2013: Adopted in office for expedited initial reviews
• Jan – Mar 2014: Piloted checklists and worksheets with board members
• Apr – May 2014: Trained all boards and implemented Toolkit for FB reviews
• NOW: Making Toolkit available to research community
How does this support our goals?

✅ Efficiency:
- Less back-and-forth
- Anticipate IRB requirements

✅ Consistency:
- Transparency in criteria for approval
- IRB and researchers referring to same documents

✅ Ease:
- Better organization
- Improved investigator tools
New Policies and Forms Website

• IRB Website Resources Working Group
• Single page w/ drop-down categories
• Two sections:
  ▪ Investigator Resources – what you need to prepare a submission and conduct your study
  ▪ HRPP – the documents the IRB uses to review your study
Important Notes

• No substantive changes to policy
• Nothing you need to do differently to comply with regulations or IRB requirements
• However, lots of new materials – DO take a look – you might learn something!
• Teeny tiny tweak to consent forms and liability language: “Sponsor” to “Funder”
Investigator Resources

• Investigator Manual – overview
• Investigator Guidance – outlines investigator responsibilities, replaces some former P&Ps
• All forms and templates – 3 categories
• Help Sheets and Quick Guides
  ▪ Help Sheet: Detailed guidance. Many former P&Ps became Help Sheets.
• Additional websites
HRPP

• Policies
• SOPs
• Forms (only one, used by IRB)
• Criteria for Approval (*HINT: refer to these in prepping your submission!!*)
  - **Checklists** – determinations that require documented protocol-specific justification
  - **Worksheets** – lists of regulatory requirements and considerations
Toolkit Tips

• “HRP-###” means Toolkit
• <Angled Brackets> see HRP-001 – Definitions
• [Square Brackets] see HRP-003 – Designations
• Help Sheets and Quick Guides reference relevant Toolkit documents
• PDF Checklists and Worksheets are snazzy! But tricky to open in some browsers.
What if I run across old documents?

- Ignore them!
- Removal of old documents is in progress but may take some time
- Most old pages have been redirected
- Google “OHSU IRB Forms” or “OHSU IRB Policies”
Where do I find...

• The subject injury policy? HRPP-Policies.
• The eIRB policy that talks about electronic signatures? HRPP-Policies.
• Guidance on research with kids? New Quick Guide.
• What else???
Watch for future updates

- HIPAA and Research page
- Board Information page
- About IRB Review
- Additional Help Sheets and Quick Guides
Questions? Feedback?

Help Desk – ext. 4-7887, opt. 1

Email – irb@ohsu.edu

IRB education resumes in the fall!