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

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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

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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***

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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

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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

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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"

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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.
  - Quick Guide: 1-2 pages, “At Your Fingertips” info.
- Additional websites

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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

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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.

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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”

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Where do I find…

- **The subject injury policy?** HRPP-Policies.
- **The eIRB policy that talks about electronic signatures?** HRPP-Policies.
- **Guidance on consent with non-English speakers?** New Quick Guide and Investigator Guidance on Consent.
- **Guidance on reportable events?** New Quick Guide and UP/PD Investigator Guidances.
- **Guidance on research with kids?** New Quick Guide.
- ***What else???***

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Watch for future updates

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

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Questions? Feedback?

Help Desk – ext. 4-7887, opt. 1

Email – irb@ohsu.edu

IRB education resumes in the fall!

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