Institutional Review Board
Transitioning to the New Toolkit and Huron Click IRB

www.research.ucf.edu/Compliance/irb.html
Agenda for Today

• Discuss software transition details
• Review changes to the **IRB Toolkit**
  • Toolkit = **IRB program documents** used by both the IRB and Researchers
    • Standard Operating Procedures and Investigator Manual
    • Templates (like the protocol and informed consent)
    • Worksheets
    • Checklists
    • Forms
• Brief Overview of **Common Rule** Changes
• Software Demonstration
Software Transition-What to Expect

- **Initial Study and Addendum Requests** submitted in iRIS 12/3-12/21 will not be reviewed in iRIS.
  - Initial studies will require use of the new Toolkit documents
- Submission responses will continue to be reviewed through 12/21.
- What happens to submission responses not received by the requested return date (usually 30 days, 12/17 here on)?
- What happens to currently expired or closed studies?
What Information Will Transfer from iRIS to Huron?

- **Active Expedited and Convened Board Studies**
  - Check your expiration date! Expired studies will not transfer.

- Shell information will be copied from iRIS to the new system.

- This information will need to be verified and updated upon the first study modification or continuing review in the new system.
  - more information on this during the software demo.

- Modifications should be made to the existing protocol and consent forms.
What Information Will Not Transfer from iRIS to Huron?

• **Exempt Determinations** and **Not Human Subjects Determinations**
  • Will not transfer
  • Your determination letter remains “active” as long as no changes are made to the study.
  • Changes to the study can be made using the new Toolkit template documents submitted through Huron IRB as a new study determination request.

• **Rely Upon Determinations**
  • Same as above, but use the documents approved by the external IRB.
Investigator Manual Updates
HRP-103

• Additional guidance on required training and who is eligible to serve as PI
• Major changes to software instructions
• Additional guidance on what group of forms/templates to use
• Additional guidance on modification and continuing review requests
• Additional single IRB (sIRB) information for multi-site studies
Informed Consent Form Changes
HRP-502 or 502b

• Major change-Key Information vs Detailed Information
  

• Additional language for studies involving the collection of identifiable information (data and biospecimens).

• What hasn’t changed? A lot of template language for you to select from and delete if not applicable.
Protocol Changes ( Expedited and Board Studies )

HRP-503

• Major reorganization
  • Moved multi-site information to the end!

• Added Revision History

• Added Study Summary

• What hasn’t changed? A lot of template language for you to select from and delete if not applicable
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<th>Now</th>
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<td>HRP-250 Request for NHSR Determination</td>
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<td>HRP-509 Summary Explanation Exempt</td>
<td>HRP-254 Summary Explanation Exempt Research</td>
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<td>HRP-509 Request for Exempt Determination</td>
<td>HRP-255 Request for Exempt Determination</td>
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<td>HRP-251 Faculty Advisor Review</td>
</tr>
<tr>
<td>NA</td>
<td>HRP-253 External Members</td>
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</table>
Routing Changes

• Currently, new submissions require PI, faculty advisor, and departmental sign-off prior to submission to IRB.

• Updates
  • [HRP-251 Faculty Advisor Review](#)
    • Faculty Advisors to complete the review form
    • Student PI to upload the form with the study submission
    • Submissions without the form will be returned without additional review
  • Faculty advisor and departmental sign-off added as an **Ancillary Reviewer**
    • Ancillary review may take place concurrently with IRB review
    • More on this later
External Team Members

• Currently, listed on the iRIS application in section 4.4
  • Includes both engaged collaborators and other contacts.

• HRP-253 External Members

• New look for the Individual Investigator Agreement, same content.
Common Rule Change  1/21/19

• Mostly IRB SOP’s and Worksheets

• Major Changes for Researchers
  • Changes to Exempt Categories
  • “Brief Benign Behavioral Interventions”
  • “Limited IRB Review”
  • New instructions for retrospective data review “Secondary Research”

• Will required further toolkit changes.
Upcoming Training

• Toolkit and Software Transitioning Sessions
  • 11.27.18 10:00 -12:00 UTWR 602
  • 11.29.18 9:30 -11:30 TA 304
  • 12.11.18 1:00- 3:00 TA 322
  • 12.19.18 9:30- 11:30 CB2 101
  • College of Medicine TBD

• IRB Consultation/IRB 101
  • 11.29.18, Consultations 12 -1, Presentation 1- 2, SU 224

• Common Rule Revision Workshop(s)
  • TBD January, 2019
Software Demonstration

- Basic Navigation
- Creating a Study
- Submission Response
- Modifications/Continuing Review
- Reportable New Information
Thank you!