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

www.research.ucf.edu/Compliance/irb.html

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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?

- <u>Active Expedited and Convened Board Studies</u>
  - 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
- https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-november-13-2018/index.html

- 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

Toolkit Numbering Changes/New Forms

Was	Now
HRP-500 Research Activity Form	HRP-250 Request for NHSR Determination
HRP-509 Summary Explanation Exempt Research	HRP-254 Summary Explanation Exempt Research
HRP-509 Request for Exempt Determination	HRP-255 Request for Exempt Determination
Translation Verification Letter	HRP-256 Translation Verification
HRP-510 Debriefing Statement	HRP-509 Debriefing Statement
Individual Investigator Agreement	HRP-252 Individual Investigator Agreement
NA	HRP-251 Faculty Advisor Review
NA	HRP-253 External Members

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!

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