OIRB Investigator Training:
IRB ePortfolio

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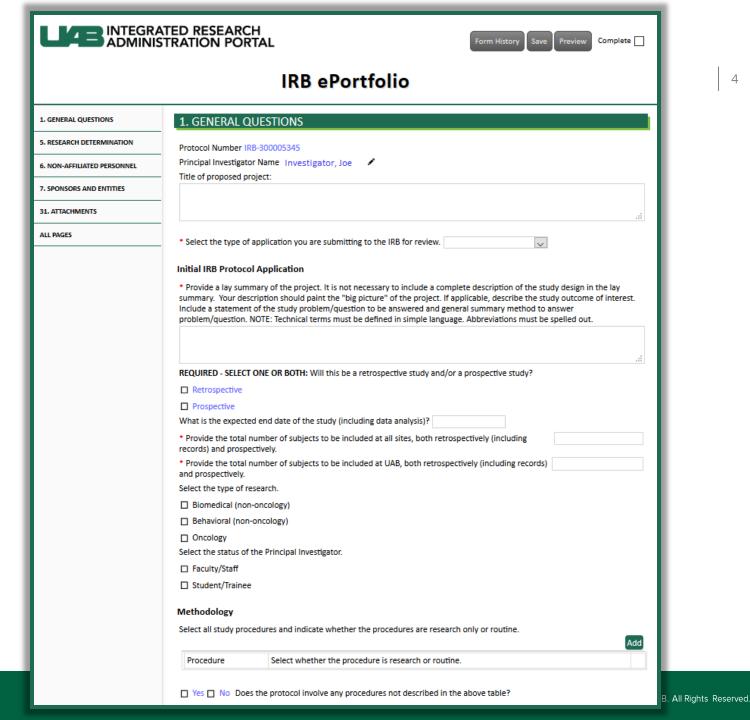
Introduction: Expectations for Training

- This is a high-level introduction.

- Questions

    - Use the Zoom chat feature to submit questions.

    - Submitted questions will be compiled as FAQs and posted on the OIRB website

- Resource documents will be available on the Office of the IRB website during the week of launch.

Introduction: Objectives

- Provide a working understanding of the ePortfolio and the features that will improve IRB processes

- Discuss the concept of identifiability when answering branch logic questions within the ePortfolio

- Walkthrough how to access the ePortfolio on August 28, 2020

- Things to Know after the ePortfolio is launched

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IRB ePortfolio

- Electronic submission form

- Uses branching logic

- Single-Threaded

- Ability to save as PDF

- Dynamic and Flexible

IRB ePortfolio

The ePortfolio will serve as the replacement for 12 documents, including:	
Application for Designation of Not Human Subjects Research	Waiver of Informed Consent Documentation
Gene Therapy Full Submission Checklist	Device Review Sheet
Expedited Review Submission Checklist	Drug Review Sheet
IRB Exemption Review Application	Special Population Review Form – Children
Waiver of Authorization	Special Population Review Form – Pregnant Women, Fetuses, Neonates
Waiver of Consent	Special Population Review Form – Prisoners
NOTE: The HSP will only be used for Expanded Access and HUD submissions	

IRB ePortfolio

Branching Logic

- The ePortfolio uses branching logic to display only questions that are relevant to the application.

- Example – If you complete the form for a retrospective only study, the form will not show questions only relevant to prospective studies.

IRB ePortfolio

What is Single-Threaded?

- This means the ePortfolio will be a "living document."
- When you complete the ePortfolio during your initial application, those responses will carry over for each subsequent amendment and continuing review submission.
- When an amendment is submitted, you'll be asked to update the relevant sections of the ePortfolio.
- No more 5 year HSP updates!

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A Discussion of Identifiability

- This is one of the first key branching logic questions.

- Misinformation about when data/specimens are identifiable could send you down the wrong branch.

- One of the most common errors.

- Could cause delays.

De-identified vs. Coded vs. Anonymized

CODED (Common Rule)

Creating a dataset of previously identifiable data where

- Identifying information is removed so that the identity of the participant can't be readily ascertained, and identifying data has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and

- a key to decipher the code exists (kept separately), enabling linkage of the identifying information to the private information or specimens.

CODED (HIPAA)

Creating a dataset of previously identifiable data where that code has been used and

- the code is not derived from or related to the information about the individual;

- the code could not be translated to identify the individual; and

- the covered entity does not use or disclose the code for other purposes or disclose the mechanism for re-identification.

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De-identified vs. Coded vs. Anonymized

DE-IDENTIFIED (Common Rule)

Removing the code or deleting the key file from an existing coded dataset.

DE-IDENTIFIED (HIPAA)

Creating a dataset of previously identifiable data where

- an *experienced expert* determines that the risk that certain information could be used to identify an individual is "very small" and documents and justifies the determination,

<div align="center">

OR

</div>

- the *data do not include any of the 18 identifiers* (of the individual or his/her relatives, household members, or employers) which alone or in combination with other information can identify the subject. Note that even if these identifiers are removed, they are considered identifiable if the covered entity knows that the identity of the person may still be determined.

- NOTE: HIPAA allows for coding (see previous slide)

De-identified vs. Coded vs. Anonymized

ANONYMIZED (Common Rule):

- Anonymous data is **_collected_** in a manner where the identity of the subject cannot be determined by *anyone at any time*; not even the researcher. There are no links between the data and the individual person.

ANONYMIZED (HIPAA)

- Same, but **_collected_** without any of the 18 HIPAA identifiers (more specific)

IRB ePortfolio

Why are we doing this?

- IRAP was designed to be used with eForms.

- It's time to make IRAP work for **US**.

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IRB ePortfolio

How will it help?

- The ePortfolio will eliminate most redundant data entry for IRB staff
  - More resources will be available for reviewing.

- Standardizes most questions.

- It will create a less confusing submission process.
  - This begins to address one of the most common complaints we receive: A form that is suited to the research conducted at UAB.

IRB ePortfolio

- **How to access/use the form**
  - On August 28, the ePortfolio will be live in IRAP
  - Log in to IRAP and create a new project
  - Select "Add" (This is where you would normally upload documents.)
  - Under "Add Initial Application Components," select the IRB EPORTFOLIO, and click "Add"
  - On the Documents/Forms list in your IRAP record, you will see IRB EPORTFOLIO
  - Open the IRB EPORTFOLIO and begin your submission
  - In the first section of the ePortfolio, be sure to select "Initial Application"
  - When finished, save the form, and check "Complete"

- **Note:** To ensure you do not lose any progress, please save the form often.

IRB ePortfolio

- Amendments and Continuing Reviews for protocols **initiated** on the ePortfolio
  - Because the ePortfolio is single-threaded, Amendments and Continuing Reviews will be required in the same form.
  - When you are ready to submit an Amendment or Continuing Review,
    - Create the submission in IRAP as you currently do
    - Click "Add" (This is where you would normally upload documents.)
    - Under "Add Revision/Amendment [Continuing Review] Components" select the IRB EPORTFOLIO, and click "Add"
    - On the Documents/Forms list in your IRAP record, you will see IRB EPORTFOLIO
    - Open the IRB EPORTFOLIO and begin your submission
    - In the first section of the ePortfolio, be sure to select either "Amendment" or "Continuing Review"

IRB ePortfolio

- Amendments and Continuing Reviews for protocols **not initiated** on the ePortfolio
  - Separate Amendment and Continuing Review eForms have been created for existing protocols.
  - These eForms will not be required for use until November 30 but will be available on August 28.
  - Copies of these eForms will be housed in the "Add" link in the Documents/Forms section of the Revision/Amendment and Continuing Review submissions.

Single IRB – Site Additions

- A separate Single IRB Site Addition Amendment eForm has been developed.

- This eForm will allow multiple submissions at the same time and functions independently of the ePortfolio.

- This submission type and eForm will go live on August 28.

What else is Changing?

- Only one open Continuing Review or Revision/Amendment submission at a time.

- Changes to the protocol will no longer be available as part of Continuing Review.

What else is Changing?

Naming Conventions:

- The use of the naming conventions list will not be required for any document uploaded within the ePortfolio.
  - Consent forms, recruitment materials, external approvals, and other ancillary documents will be uploaded within the ePortfolio.

- Documents uploaded for Continuing Reviews and Revision/Amendments for protocols not *initially* submitted via the ePortfolio (existing protocols and those approved before 9/30) must follow the required naming conventions.

What else is Changing?

Submission Distribution System

- Currently, the OIRB uses a "push" system to assign submissions to reviewers on a rotating schedule.

- When a protocol comes in, it is immediately assigned to one of our review staff.

What else is Changing?

Submission Distribution System – Why?

- The push system has proven to be inefficient.

- When a reviewer has a complex review that takes days to complete, other assignments do not stop coming in.

- This sometimes leads to an overwhelming backlog of reviews for one staff member.

What else is Changing?

Submission Distribution System - Benefit to you?

- We will transition to a "pull" system in which reviewers will assign themselves submissions.

- They will be reviewed in a more first-come/first-served fashion (more timely).

What else is Changing?

Submission Distribution System - How it affects you

- Use of the submission distribution system will mean that you can no longer determine in IRAP who the coordinator of your protocol is until it has been pulled by an OIRB staff member for review.

- For queries about your submission status, please email irb@uab.edu.

- We can still handle RUSH/JIT and staff-specific assignments.

Pull System - What does this mean?

- **Convened Continuing Reviews**
  - Will no longer have a deadline to be assigned to a meeting.
  - Will be processed in order of expiration date, undergo pre-review, and assigned to the next available IRB meeting.

- To ensure a timely review, **please submit Continuing Reviews 6 weeks in advance of your expiration date.**

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What else is Changing?

- Administrative Pre-Review Letter
  - The administrative preview letter is changing, and we have template available in the packet
- Why it is changing?
  - ePortfolio doesn't allow for numbered questions.
- How does it help?
  - The letter will identify the specific question needing clarification.
  - Will allow for a clear indication on where the investigator should provide the response
- How should Investigators respond?
  - After your response is complete, upload the document in the "Attachments" page in the ePortfolio.

Query No.	Page No.	Questions/Responses
1	1	Provide the total number of subjects to be included at all sites, both retrospectively (including records) and prospectively. Provide the total number of subjects to be included at UAB, both retrospectively (including records) and prospectively.
	8	What is the total *expected* number of records that will have data extracted from them at UAB?
	8	Is this a multi-site study?
a		*These three responses are not concordant (some say 300 and some say 400 and this is not a multi-site study. Revise for concordance.*
Response: I have now revised the 3rd question to 300 to be in concordance with the rest of the document.		
2	28	Request for HIPAA waiver for some or all of the subjects (e.g., for retrospective review of PHI, and/or to review PHI for recruitment purposes and obtain HIPAA authorization during enrollment)
	28	Explain.
a		*Both of these responses indicate that you will interact with and obtain written consent and HIPAA authorization from participants; however, no consent was provided.*
Response: We will not be obtaining a HIPAA authorization. We have changed this to requesting a Waiver of HIPAA authorization for all participants.		
b		*The "Explain" question indicates both retrospective participants and prospective participants will be included; however, on Page 1, you only indicated retrospective participants will be involved. Resolve for concordance.*
Response: No prospective participants will be involved. We have revised the explanation.		

Other Things to Know:

- Submitting the initial application for relying on an external IRB does NOT change after go live.

- The OIRB has created a survey for users to provide comments and feedback to help with prioritizing improvements to the ePortfolio.
  - Quarterly updates, etc.
  - Example: Entering dates in the ePortfolio using the drop-down calendar

- Remember to "Save" your progress in the ePortfolio often

- All questions should be directed to the Office of the IRB email address: irb@uab.edu .

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Other Things to Know:

- August 28, 2020: Go Live!
  - ePortfolio is live and available for submission of new protocols
  - Amendments and continuing reviews submissions will be integrated as eForms for protocols initiated using the ePortfolio.
  - Standalone Amendments and continuing review eForms will be available for protocols that were not initiated using the ePortfolio.

- September 30, 2020: HSP Cutoff Date
  - Current Microsoft Word HSP will be accepted until this date
  - ePortfolio is required for submission of new protocols on this date

- November 30, 2020: PRAF/IPR Cutoff Date
  - Current Microsoft Word PRAF and IPR forms will be accepted until this date for protocols not initiated on the ePortfolio

Recap

- The ePortfolio will replace 13 Word documents and forms.

- Naming Conventions are not required for documents submitted in the ePortfolio.

- The ePortfolio is a Single Threaded form. A living document!
  - Complete one process (continuing reviews or amendments, etc.) before beginning another.
  - If you don't, one form may override the other.

- Cutoff Dates:
  - HSP will no longer be accepted after September 30, 2020.
  - PRAF/IPR will no longer be accepted after November 30, 2020.

- The ePortfolio will issue quarterly system updates. The OIRB relies on the research community for feedback and suggestions.

Questions

What's Next?

- Training resources will be available on the IRB Training website starting the during of launch.

- Training will continue to be offered after the launch of the ePortfolio.
  - Dates and times will be announced using the IRB List Serv.

All other questions or concerns about individual protocols should be sent via email to irb@uab.edu.

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Thank you!