IRB ePortfolio – Things to Know – Investigators

The Office of the Institutional Review Board (OIRB), in collaboration with the UAB Research Technology & Communication (RTC) office, is excited to launch the new IRB e-Portfolio on August 28, 2020. This dynamic and user-friendly application process has been streamlined to utilize branching logic with specific questions to better ascertain the regulatory information necessary to make IRB determinations.

1. The IRB ePortfolio was developed to eliminate all existing IRB submission forms and to combine the information from those forms into a single electronic form. The ePortfolio will replace:
   - Human Subjects Protocol (HSP)
   - Application for Designation of Not Human Subjects Research
   - IRB Exemption Review Application
   - Expedited Review Submission Checklist
   - Gene Therapy Full Submission Checklist
   - Waiver of Authorization
   - Waiver of Consent
   - Waiver of Informed Consent Documentation
   - Device Review Sheet
   - Drug Review Sheet
   - Special Population Review Form – Children
   - Special Population Review Form – Pregnant Women, Fetuses, Neonates
   - Special Population Review Form – Prisoners

   NOTE:
   - The Human Subjects Protocol will continue to be used for submission of Expanded Access and Humanitarian Use Device applications.
   - Requests to rely on an external IRB (e.g., WIRB, Advarra, or other academic institutions) should not be submitted using the ePortfolio. Please continue to use the "Institution Review Form" on the Office of the IRB Forms webpage.

2. The ePortfolio uses branching logic to guide you to the questions only relevant to your application.
   - It is anticipated to reduce Administrative Review questions.
   - While the ePortfolio requests all necessary information from you, the presentation of only relevant questions creates a less confusing submission process.
   - The number of open-ended questions has been greatly reduced. As many questions as possible were formulated to be dichotomous or multiple choice.
   - Some questions on the current suite of forms have been eliminated from the review process, and some new questions have been added.
   - The implementation of the ePortfolio marks a substantial change in the IRB review process for all applications.

3. The ePortfolio is a Single-Threaded form
   - The ePortfolio will be a "Living Document".
   - When an investigator completes the ePortfolio during their initial application, those responses will carry over for each subsequent amendment and continuing review submission.
   - When an amendment is submitted, investigators will be asked to update the relevant sections of the ePortfolio.
   - Changes to the protocol will no longer be available as a part or Continuing review.
   - It is important that investigators con only have one open Continuing Review or Amendment submission at a time for the SAME PROTOCOL. If more than one submission is open at one time, investigators run the risk of overriding one submission over the other. Submissions processed for different protocols may be initiated at the same time.

4. Please do not submit the ePortfolio for a study existing prior to August 28, 2020.

5. What the ePortfolio is **not**
   - The ePortfolio is not an application for relying on an external IRB. Please continue to use the form titled "Institution Review Form for Relying on an Outside IRB."
   - The ePortfolio is not an application for a Humanitarian Use Device submission. The Human Subjects Protocol will continue to be used for submission of Humanitarian Use Device applications.
   - The ePortfolio is not an application for an Expanded Access submission. The Human Subjects Protocol will continue to be used for submission of Humanitarian Use Device applications.

6. An easy URL has been created to take users directly to the IRB ePortfolio Training website: http://go.uab.edu/eportfolio.

7. Additional eForms will also be available on August 28, 2020:
   - **Amendment**
     - Protocol submissions, initiated using the ePortfolio, will have Revision/Amendment eForm integrated within the ePortfolio.
       - A "How to Create an Amendment within the ePortfolio" Tip Sheet can be found HERE.
     - Protocol submissions, that were not initiated using the ePortfolio, will need to use a Revision/Amendment eForm that will function independent of the ePortfolio.
       - A "How to Create an Amendment for Pre-ePortfolio Applications" Tip Sheet can be found HERE.
     - eForms can be accessed in the "Documents/Forms" section of the Revision/Amendments submissions.
     - The PRAF document may be used until November 30. After that date, the Revision/Amendment eForm will be required.

- **Continuing Review**
  - Protocol submissions, initiated using the ePortfolio, will have Continuing Review eForms integrated within the ePortfolio.
    - A "How to Create a Continuing Review within the ePortfolio" Tip Sheet can be found HERE.
  - Existing protocols, that were not initiated using the ePortfolio, will need to use the Continuing Review eForm that will function independent of the ePortfolio.
    - A "How to Create a Continuing Review for Pre-ePortfolio Applications" Tip Sheet can be found HERE.
  - eForms can be accessed in the "Documents/Forms" section of the Continuing Review submissions.
  - The Continuing Review eForm will be required after November 30.
- **Single IRB – Site Additions**
  - This eForm can be used for protocols initiated before or after the ePortfolio.
  - This eForm will allow multiple submissions at the same time and functions independently of the ePortfolio
    - A "How To Create a SIRB Site Addition Amendment" Tip Sheet can be found HERE.

8. Convened Continuing Reviews:
   - Will no longer have a deadline to be assigned to an IRB 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, **Investigators should submit Continuing Reviews 6 WEEKS in advance of their expiration date.**

9. Adding Documents
   - The ePortfolio eliminates several official forms, but the upload of other documents such as consents, participant communications, investigator brochures, etc. is still needed.
   - To allow for logical upload of these documents, many of these documents will be uploaded in the section where they are referenced. However, you will be able to upload other documents in the Attachments page.
   - Naming conventions have been eliminated. The eForm will guide you in naming your file uploads. Note that tracked copies are required for any changed documents.

10. Documentation of Review (Administrative Pre-Review Letter)
    - Specific question references (e.g., Item 13.a) will not be possible as the references would change depending on the branching logic.
    - Your correspondence from the IRB will change and will include a letter which will identify the specific question needing clarification. The letter will allow for a clear indication on where the investigator should provide the response.
    - This process will require you to review that entire page to find the cited question.

- The use of the response memorandum is critical and requires a more thorough response than "completed" in most cases.
- Investigators will submit their responses, via the "Attachments" page in the ePortfolio.

11. The ePortfolio will updated quarterly based on the needs and the feedback of the users. Users will be able to submit comments or feedback using this survey.

Transition Plan

1. On August 28, 2020, the IRB ePortfolio will go live.
2. For protocols initially reviewed prior to August 28, the OIRB will continue to accept submissions using the existing Microsoft Word based Project Revision/Amendment Form (PRAF) and Investigator's Progress Report (IPR) until September 30, 2020.
3. On November 30, 2020, eForms for both PRAFs and IPRs will be deployed for Amendment and Continuing Review submissions initially reviewed prior to August 28.
4. Continuing Reviews and Amendments for initial applications submitted after August 28 must use the Continuing Review and Amendment section of the ePortfolio.