IRBIS changes, effective 5:30PM, November 7, 2023

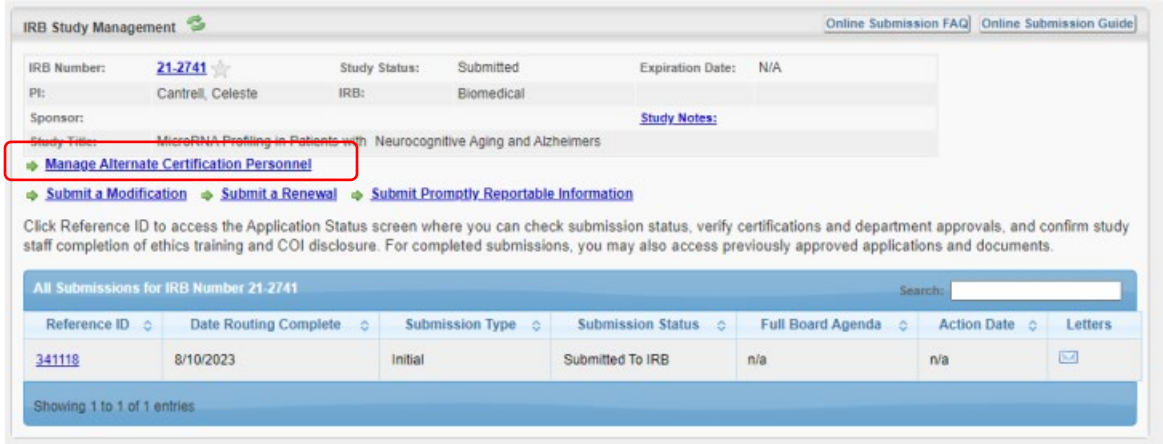
IRBIS System Update:

Summary of Changes

Alternate PI Certification

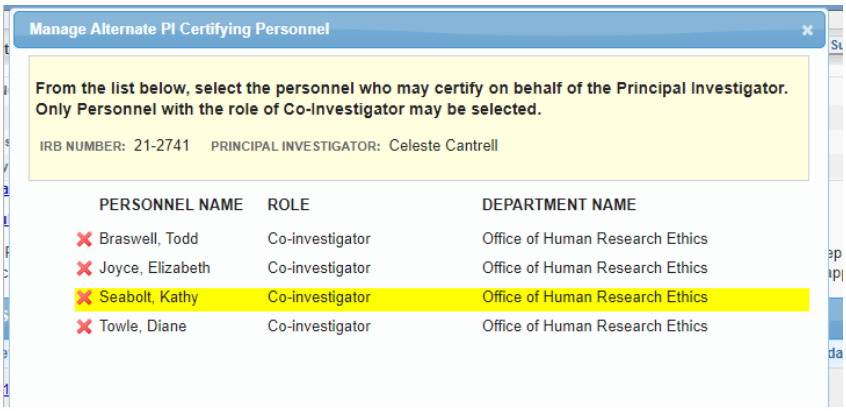
Principal Investigators can identify a Co-Investigator who is able to certify submissions on their behalf. This certification will only be available for Study Modifications, Personnel Modifications, Renewals, Administrative Reviews, and Promptly Reportable Information submission.

Once the initial submission is certified by the PI and has completed all routing steps, the management of this option can be accessed on the IRB Study Management screen. This designation of an alternate is only available to the Principal Investigator.

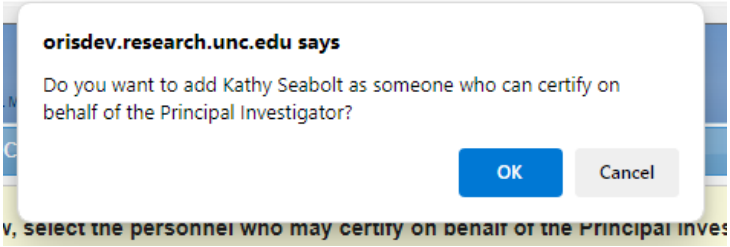


On the pop-up window will display a list of Co-Investigators. Note that only a Co-I can be designated as an alternate.

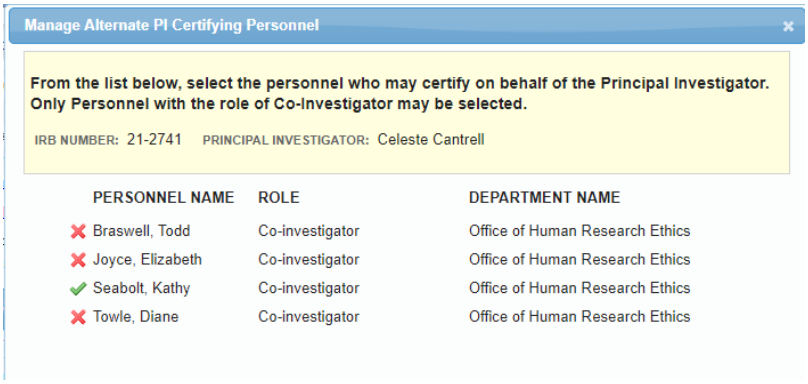
Select the person you wish to designate.



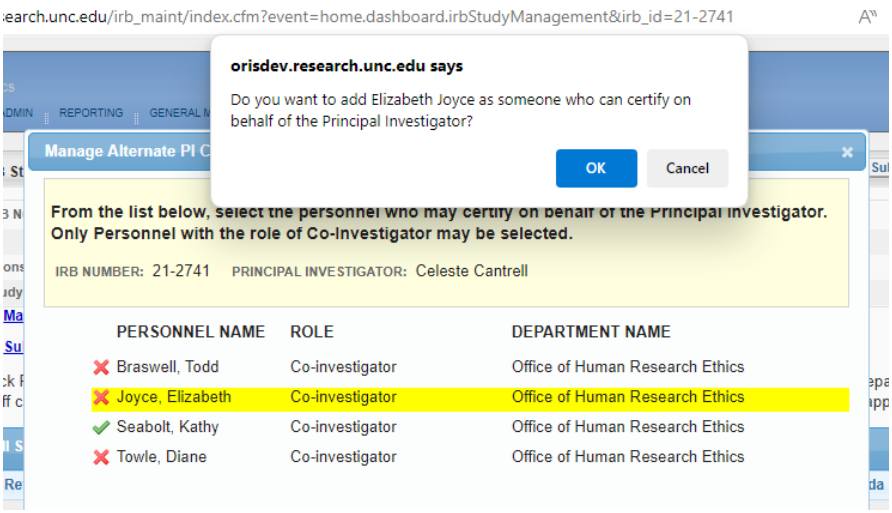
Confirm in the pop-up:



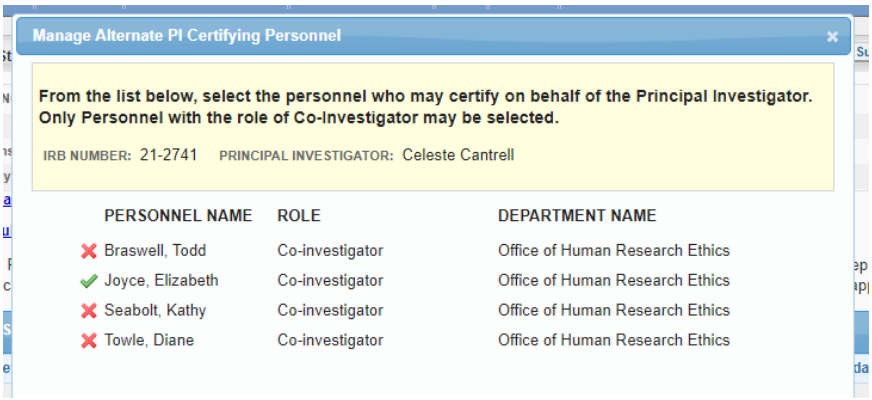
The list will update to indicate the alternate.



Should you wish to amend the selection, simply select a new person and confirm.



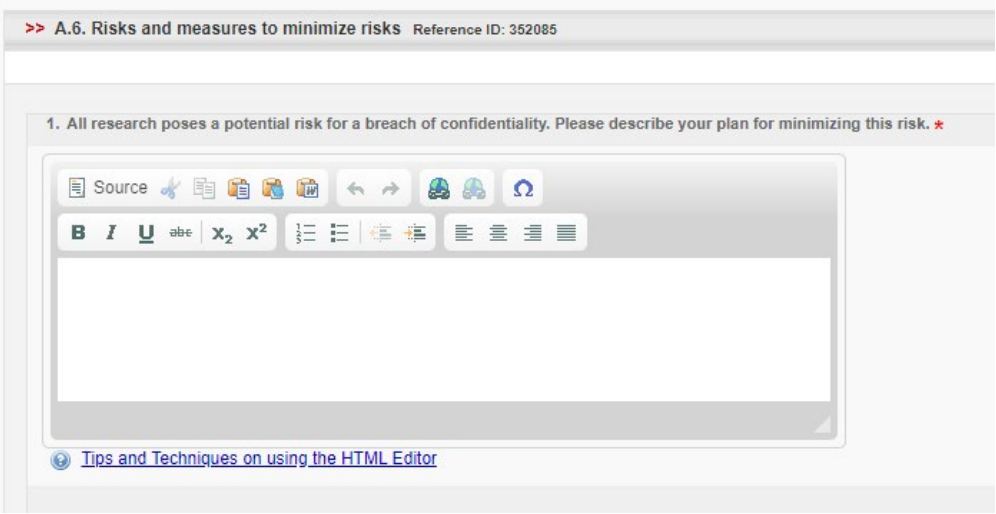
The alternate will update.



New Question in Risk Section

One of the most-stipped questions in the application is for the study team to address what will be done to mitigate the potential risk for a break of confidentiality. In order to reduce the burden on both the IRB Analysts and the study team, a new required question directly addressing that risk has been added to the Risk section of the application.

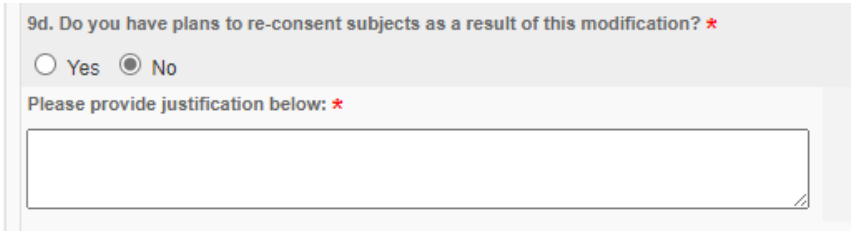
If you have already included this information in this section, please copy and paste the response into the new text box or reference the location of the response.

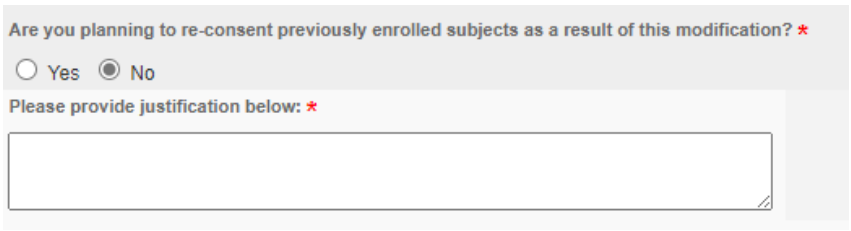


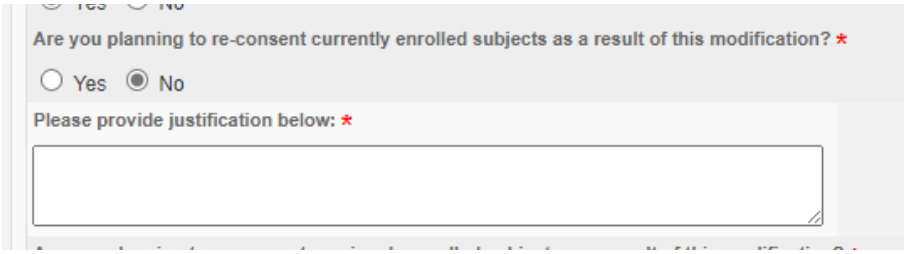
Reconsent Justification for Modification Submissions

When a modification to a study is submitted and subjects will not be reconsented, a justification will be required that describes why the changes to the study do not warrant reconsent. This change will provide the information needed by the IRB reviewers and prevent delays in approving modifications and renewals with mods.

There are three different questions that may require justification: overall reconsent, reconsent of current subjects, and reconsent of previously enrolled subjects.





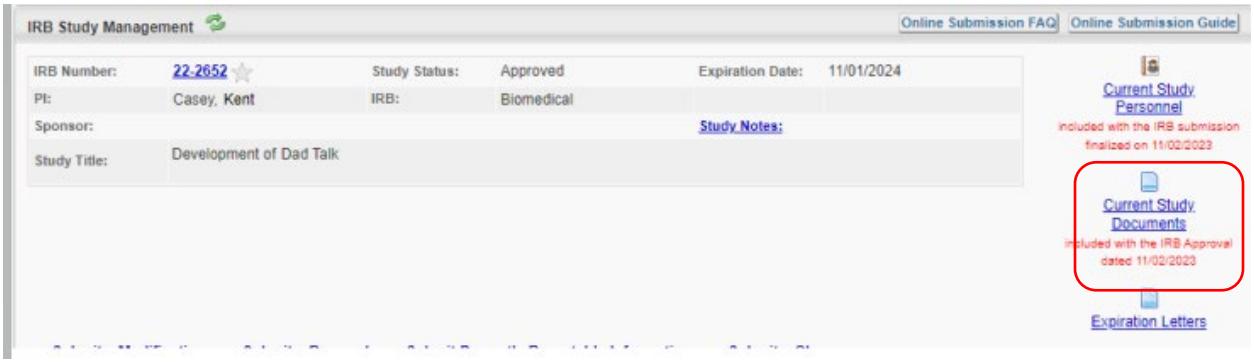


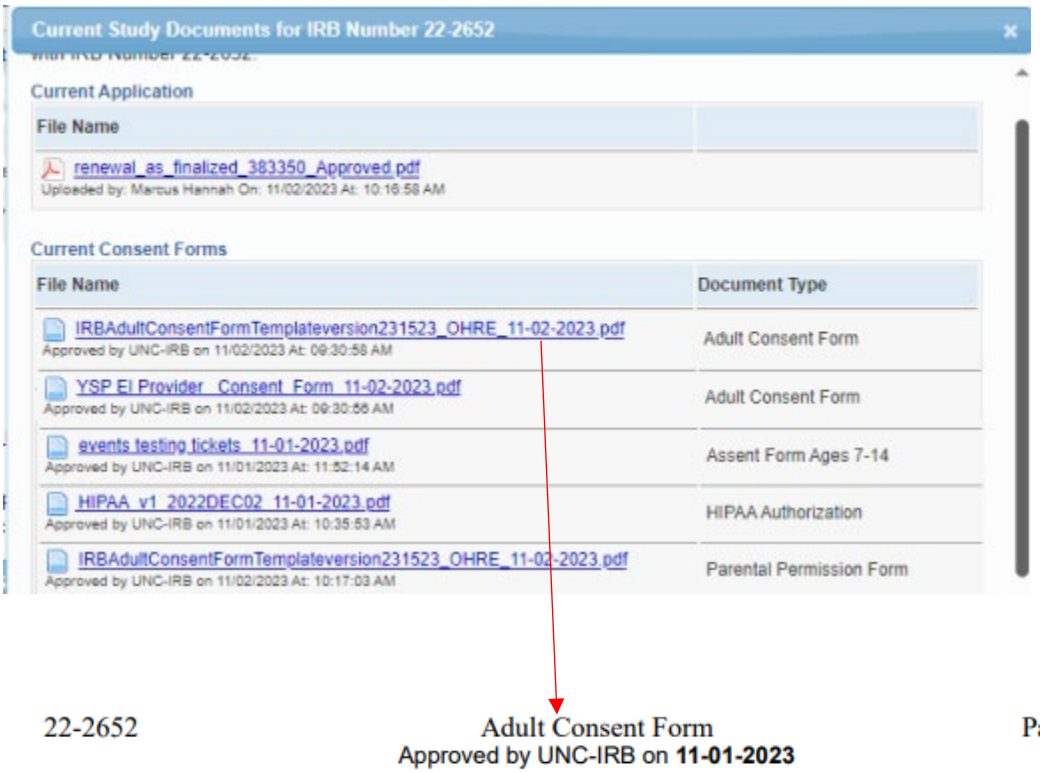
If you are reconsenting subjects and respond 'Yes', no justification is required.

Consent Forms Stamped with Approval Date

In response to inquiries from Sponsors regarding documentation of consent form approval, we will implement a stamped approval date on all Adult Consent Forms, Parental Permission Forms, Assent Forms, and HIPAA Authorization Forms.

When a consent form is stamped, it will be converted to a pdf document which can be accessed in the Current Study Documents section on the IRB Study Management screen.





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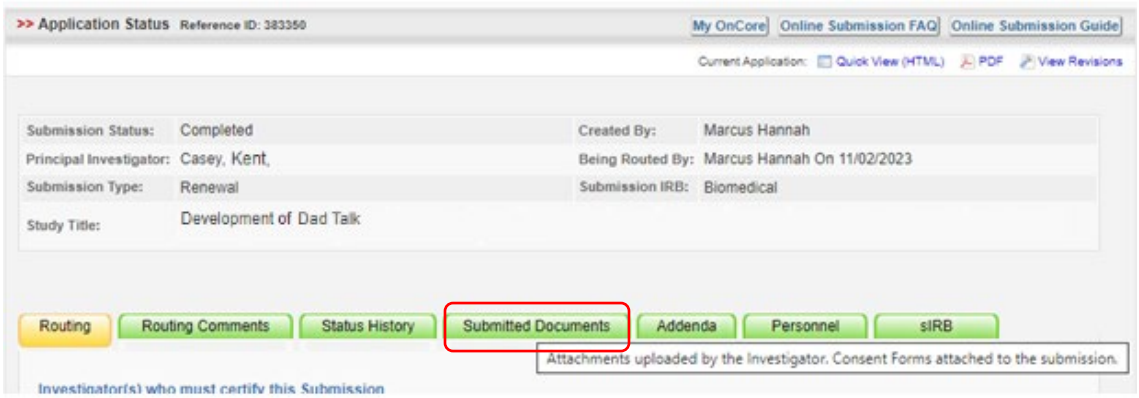
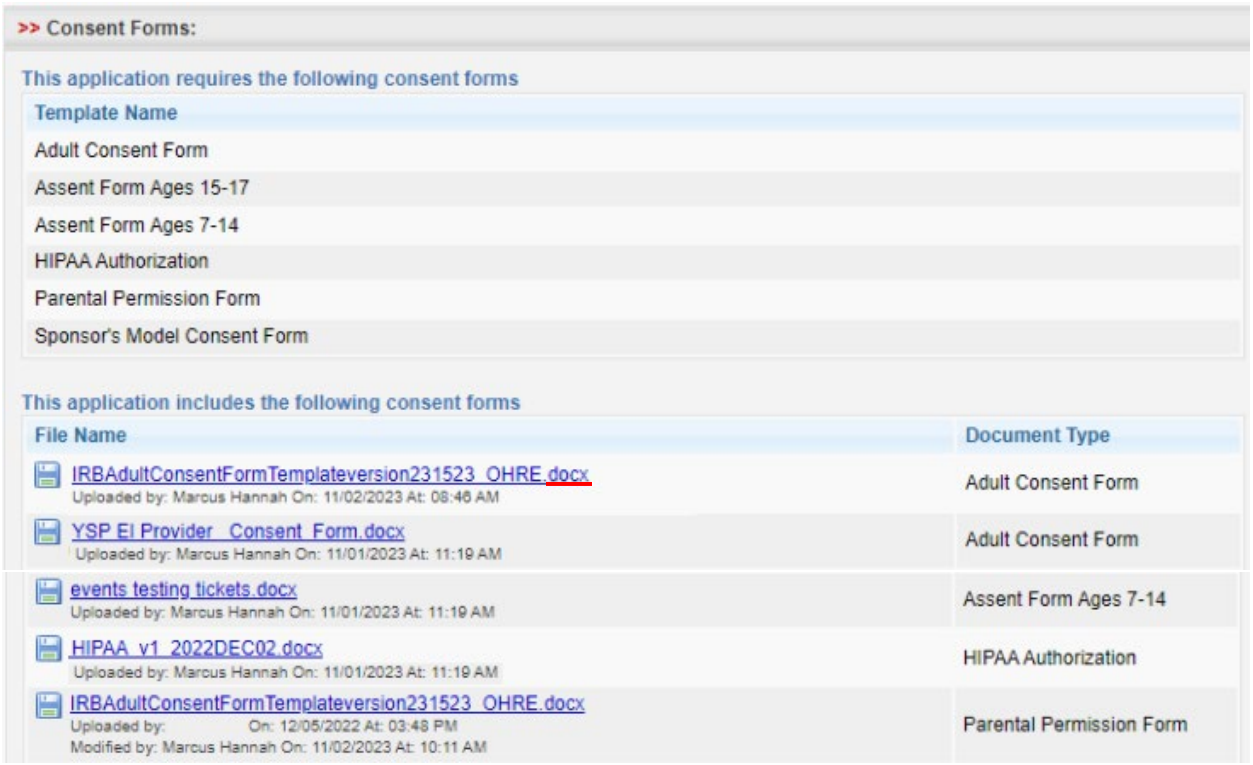
Approved by UNC-IRB on **11-01-2023**

In the event you need to update the consent forms, you can access Word document versions under the 'Submitted Documents' tab on the Application Status page.





>> Consent Forms:

This application requires the following consent forms

Template Name
Adult Consent Form
Assent Form Ages 15-17
Assent Form Ages 7-14
HIPAA Authorization
Parental Permission Form
Sponsor's Model Consent Form

This application includes the following consent forms

File Name	Document Type
IRBAdultConsentFormTemplateversion231523_OHRE.docx Uploaded by: Marcus Hannah On: 11/02/2023 At: 08:46 AM	Adult Consent Form
YSP EI Provider_Consent_Form.docx Uploaded by: Marcus Hannah On: 11/01/2023 At: 11:19 AM	Adult Consent Form
events testing tickets.docx Uploaded by: Marcus Hannah On: 11/01/2023 At: 11:19 AM	Assent Form Ages 7-14
HIPAA_v1_2022DEC02.docx Uploaded by: Marcus Hannah On: 11/01/2023 At: 11:19 AM	HIPAA Authorization
IRBAdultConsentFormTemplateversion231523_OHRE.docx Uploaded by: On: 12/05/2022 At: 03:48 PM Modified by: Marcus Hannah On: 11/02/2023 At: 10:11 AM	Parental Permission Form