

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

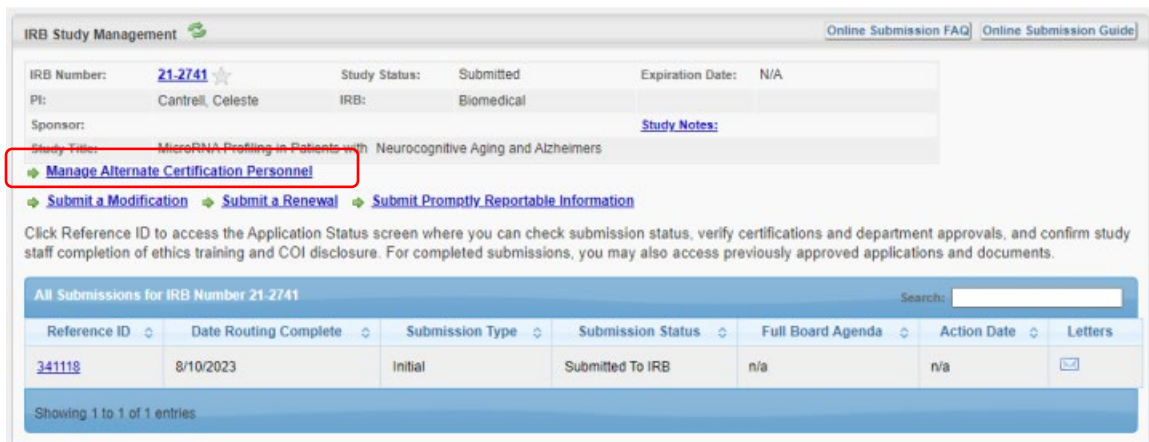
IRBIS System Update:

Summary of Changes	
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Alternate PI Certification

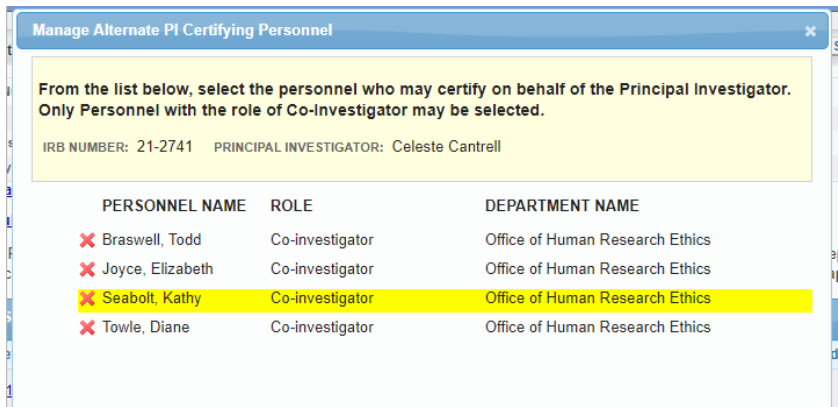
Principal Investigators can identify a Co-Investigator who is able to certify submissions on their behalf. This certification will only be available for Study Modifications, Personnel Modifications, Renewals, Administrative Reviews, and Promptly Reportable Information submission.

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.

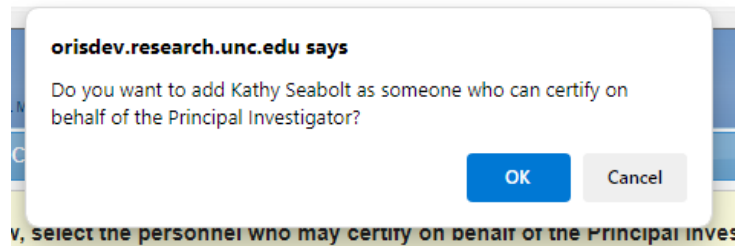


On the pop-up window will display a list of Co-Investigators. Note that only a Co-I can be designated as an alternate.

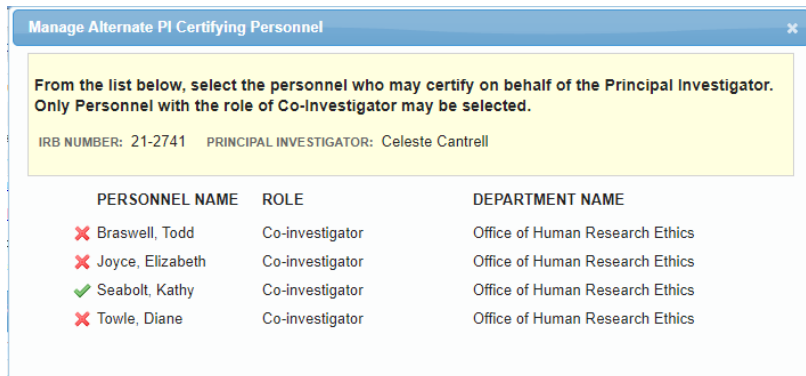
Select the person you wish to designate.



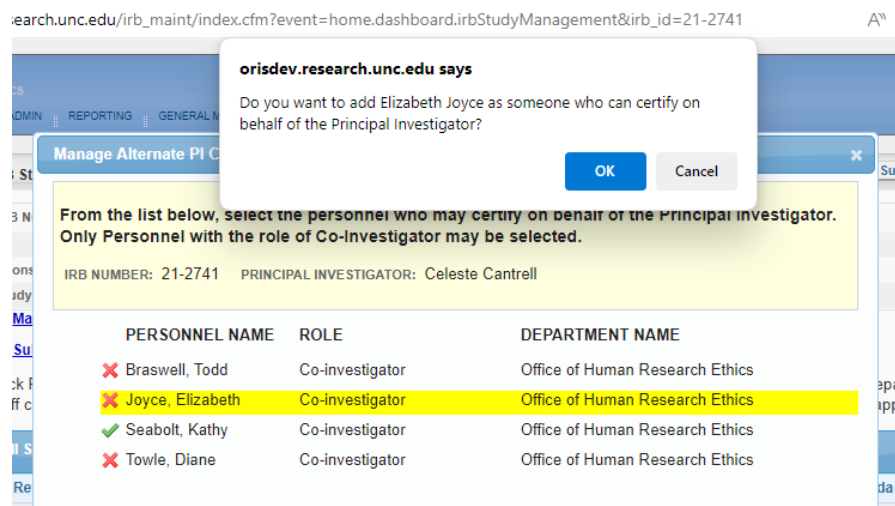
Confirm in the pop-up:



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.

Manage Alternate PI Certifying Personnel

From the list below, select the personnel who may certify on behalf of the Principal Investigator. Only Personnel with the role of Co-Investigator may be selected.

IRB NUMBER: 21-2741 PRINCIPAL INVESTIGATOR: Celeste Cantrell

PERSONNEL NAME	ROLE	DEPARTMENT NAME
<input type="checkbox"/> Braswell, Todd	Co-investigator	Office of Human Research Ethics
<input checked="" type="checkbox"/> Joyce, Elizabeth	Co-investigator	Office of Human Research Ethics
<input type="checkbox"/> Seabolt, Kathy	Co-investigator	Office of Human Research Ethics
<input type="checkbox"/> Towle, Diane	Co-investigator	Office of Human Research Ethics

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.

>> A.6. Risks and measures to minimize risks Reference ID: 352085

1. All research poses a potential risk for a breach of confidentiality. Please describe your plan for minimizing this risk. *

Source [Icons] [Undo] [Redo] [Refresh]

B *I* U abc x_2 x^2 $\frac{1}{3}$ [List] [Table] [Image] [Link] [Text]

[Tips and Techniques on using the HTML Editor](#)

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.

9d. Do you have plans to re-consent subjects as a result of this modification? *

Yes No

Please provide justification below: *

Are you planning to re-consent previously enrolled subjects as a result of this modification? *

Yes No

Please provide justification below: *

Are you planning to re-consent currently enrolled subjects as a result of this modification? *

Yes No

Please provide justification below: *

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.

IRB Study Management [Online Submission FAQ](#) [Online Submission Guide](#)

IRB Number:	22-2652 ☆	Study Status:	Approved	Expiration Date:	11/01/2024
PI:	Casey, Kent	IRB:	Biomedical		
Sponsor:	Study Notes:				
Study Title:	Development of Dad Talk				

[Current Study Personnel](#)
Included with the IRB submission finalized on 11/02/2023

[Current Study Documents](#)
Included with the IRB Approval dated 11/02/2023

[Expiration Letters](#)

Current Study Documents for IRB Number 22-2652

with IRB Number 22-2652

Current Application

File Name
renewal_as_finalized_383350_Approved.pdf <small>Uploaded by: Marcus Hannah On: 11/02/2023 At: 10:16:58 AM</small>

Current Consent Forms

File Name	Document Type
IRBAdultConsentFormTemplateversion231523_OHRE_11-02-2023.pdf <small>Approved by UNC-IRB on 11/02/2023 At: 09:30:58 AM</small>	Adult Consent Form
YSP EI Provider Consent Form 11-02-2023.pdf <small>Approved by UNC-IRB on 11/02/2023 At: 09:30:56 AM</small>	Adult Consent Form
events_testing_tickets_11-01-2023.pdf <small>Approved by UNC-IRB on 11/01/2023 At: 11:52:14 AM</small>	Assent Form Ages 7-14
HIPAA v1 2022DEC02 11-01-2023.pdf <small>Approved by UNC-IRB on 11/01/2023 At: 10:35:53 AM</small>	HIPAA Authorization
IRBAdultConsentFormTemplateversion231523_OHRE_11-02-2023.pdf <small>Approved by UNC-IRB on 11/02/2023 At: 10:17:03 AM</small>	Parental Permission Form

22-2652

Adult Consent Form
 Approved by UNC-IRB on **11-01-2023**

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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.

>> Application Status Reference ID: 383350 [My OnCore](#) [Online Submission FAQ](#) [Online Submission Guide](#)

Current Application: [Quick View \(HTML\)](#) [PDF](#) [View Revisions](#)

Submission Status:	Completed	Created By:	Marcus Hannah
Principal Investigator:	Casey, Kent	Being Routed By:	Marcus Hannah On 11/02/2023
Submission Type:	Renewal	Submission IRB:	Biomedical
Study Title:	Development of Dad Talk		

[Routing](#) [Routing Comments](#) [Status History](#) [Submitted Documents](#) [Addenda](#) [Personnel](#) [sIRB](#)

Attachments uploaded by the Investigator. Consent Forms attached to the submission.

Investigator(s) who must certify this Submission

>> 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