

## IRBIS changes, effective 6:00 PM, May 5, 2021

### IRBIS System Update:

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## Personnel Modification Submission Type

The Personnel Modification submission type will allow for changes to study personnel outside of the regular submission pipeline. Study teams have the ability to submit changes to personnel while there is a study modification or renewal that has already been submitted.

If a Personnel Modification is submitted as a part of a study modification or annual renewal, it will be processed separately from the other submission. This change alleviates the wait that occurs when personnel changes are submitted in conjunction with other study changes that require additional time for review.

The screenshot shows a web interface titled "Create a Modification". At the top, there are four navigation links: "Submit a Modification", "Submit a Renewal", "Submit New Safety Information", and "Submit a Closure". Below these links is a blue header bar with the text "Create a Modification". Underneath the header, there is a sub-header: "Use the choices below to begin the process of creating your Modification." The main content area contains three light blue boxes, each representing a modification type. Each box has a title, a description, and a "Choose" button with a help icon. The first box is "Study Only Modification" with the description "Modify the Study Only". The second box is "Personnel Only Modification" with the description "Modify the Project Personnel Only". The third box is "Full Study Modification" with the description "Modify Personnel and Study". Below these three boxes is a grey bar with the text: "Use this option to modify the personnel only. If modifying the PI or external, use Full Study Modification."

**Study Only Modification:** only allows changes to the study. No changes to personnel.

**Personnel Only Modification:** only allows changes to the personnel table. No changes to PI or Faculty Advisor roles are allowed in this modification.

- ❖ Add internal personnel. This includes UNC-CH, UNC Healthcare, and UNCH Network Entities.
- ❖ Revise profile information for any current personnel, internal or external.
- ❖ Remove any current personnel, internal or external

**Full Study Modification:** allows changes to all sections of the application. Use this option to add external personnel or make changes to the PI or Faculty Advisor.

**Timeline for implementation:**

Studies that do not have a submission started (in draft, routing, or under review) as of 5/5/2021 will have this modification type available beginning Thursday 5/6/2021.

If you have an active submission (in draft, in routing, submitted, etc), this modification type will be available after the current submission is finalized. There is no need to contact us to activate the Personnel Modification for you as it will be an automatic change.

OHRE provided a session for campus on May 4, 2021. The session recording and slides are available on the website: <http://research.unc.edu/offices/human-research-ethics/>

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## Update to Principal Investigator Change Process

When a change to the PI for a study is necessary, we have required the submission of a signed “PI Change Form” that was to be signed by both the current/departing PI and the incoming PI. This process is now revised, and both PIs will certify the submission in IRBIS that is requesting the change.

You will notice some differences when adding a new individual as PI or when changing a current study team member from another role to PI. An alert will display to select an option for the current PI. You can either change them to a different role or remove them from the personnel list.

Add Matamoros, Mike for IRB Number 21-0034 - Reference Id 316968

Last Name \* Matamoros  
First Name \* Mike  
Address CB:  
Phone \* (919) 966-3113  
UNC Email \* matamoro@email.unc.edu  
Department Name \* Office of Human Research Ethics  
External Institution \* University of North Carolina at Chapel Hill (UNC-CH)

**ATTENTION:** The department named above for the PI or Faculty Advisor will receive this submission for approval. If the department above DOES NOT represent the primary academic (faculty and students) or administrative (staff) department of the individual named, choose the correct department. Students should not list their employing department (e.g., Work Study) unless that department is directly supervising this research.

Role \*

- Principal Investigator
- Co-investigator
- Faculty Advisor
- Study Coordinator
- Research Assistant
- Regulatory Associate
- Other

If other, please describe

Should this person be included on IRB correspondence? (PI, Faculty Advisor, Co-Investigators, External Site PI roles and all roles for Independent Investigators will always receive)

Yes  No

**ALERT: PI REVISION REQUIRED**  
You must revise the current PI (Hannah, Marcus) to have a different role.  
Please select a NEW ROLE for the current PI or select the REMOVE option.

- Co-investigator
- Faculty Advisor
- Study Coordinator
- Research Assistant
- Regulatory Associate
- Other
- Remove Hannah, Marcus from Project Personnel

...please wait for PI Change... Cancel

Save and Stay Save and Continue

Upon submission, you will receive a reminder that the outgoing PI and their department will receive a notification to certify the change.

**Routing Notice** ✕

**Application:** Marcus study - backing out of multi-site on boarded study  
**Principal Investigator:** Mike Matamoros (Outgoing PI: Marcus Hannah)

At this point you are ready to proceed to submission. Please review for completeness and accuracy using either the Quick View or the PDF icons in the upper right corner. You should not submit until you (and your co-investigators, faculty advisor and other personnel, where applicable) are done editing. After you click submit, the application will be sent to the PI for certification (final approval). The application will be locked for editing once the PI has certified.

**DO NOT SUBMIT** until you (and your faculty advisor, co-investigators and other personnel, where applicable) are done editing. The application will be locked for editing once you submit. This may be especially important for STUDENTS if your Faculty Advisor has not reviewed your submission yet.

**⚠ ALERT: PI REVISION**

The PI is changing for this submission. Notification will also be sent to the outgoing PI (Marcus Hannah) and the outgoing Principal Investigator's Administering Department for certification.

Submit to PI for Certification
Cancel

**Outgoing Principal Investigator**  
Office of Research Information Systems may certify on their behalf.

Investigator(s) who must certify this Submission	Role	Decision
Investigator <a href="#">Mike Matamoros</a>	Principal Investigator	Not Yet Reviewed <span style="float: right;">✉</span>
<a href="#">Marcus Hannah</a>	Outgoing Principal Investigator <span style="color: green;">Office of Research Information Systems</span> may certify on their behalf.	Not Yet Reviewed <span style="float: right;">✉</span>
Department(s) that must approve this Submission	Approving Person(s)	Approving Decision
Department 1 Office of Human Research Ethics	<a href="#">Laura Cowan</a> <a href="#">Cassandra Myers</a>	Not Yet Reviewed <span style="float: right;">✉ <a href="#">Resend Notification</a></span>