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

IRBIS System Update:

Summary of Changes

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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.

- **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**

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