

IRBIS changes, effective 6:00 PM, December 16, 2021

IRBIS System Update:

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Rely-on letters and COI Management Plans

When a COI disclosure result is anything aside from 'No conflict', a message will be automatically populated to the Rely On External IRB letter that states the investigator that has a conflict of interest.

| University of North Carolina at Chapel Hill (UNC-CH) | | | | | | | | | | | | | |
|--|------------|-------------|------------------------|----------------------------|--------------------|-------------------|--------------------|-----------|----------------|------------------------|--------------------|--------------------|-------------------|
| | Full Name | Credentials | Role | Department | CITI HSP Training | CITI GCP Training | COI Training | COI WebID | COI Number | Initial COI Disclosure | Potential Conflict | COI Review Process | COI Review Result |
| | [Redacted] | MD | Principal Investigator | Medicine-Hematology | ✓ | ✓ | ✓ | 1065178 | [Redacted] | ✓ | Yes | Completed | COI Management |
| Job Dept: 411490: Medicine-Hematology | | | | Title: Professor | Pos. Type: Regular | | Emp. Type: Faculty | | Status: Active | | FTE: 1 | | |
| | [Redacted] | ANP | Co-investigator | Medicine-Hematology | ✓ | ✓ | ✓ | 1065177 | [Redacted] | ✓ | | Completed | No Conflict |
| Job Dept: 411490: Medicine-Hematology | | | | Title: Research Instructor | Pos. Type: Regular | | Emp. Type: Faculty | | Status: Active | | FTE: 1 | | |

UNC Personnel:

The following research personnel have met UNC's institutional requirements regarding their qualifications, ethics trainings and conflicts of interest disclosures:

- [Redacted]
- [Redacted]

A member of the UNC research team has disclosed a conflict of interest which requires management. This conflict information should be provided to the reviewing IRB.

PI Change during Initial submission

When PI change is required during the review of an Initial submission, the Administering Department and the PI's home department will be required to re-approve in order to satisfy regulatory requirements that investigators have the required training and resources to conduct the research. The departments will receive notification email that indicates the PI has changed since their previous review.

This re-approval has previous occurred when the department was changed, but there was not a process in place when the department remained the same. This change addresses that oversight.

Alerts on expired studies

When studies have expired while awaiting PI responses on a previously submitted modification, the IRB cannot approve the modification for an expired study as we cannot certify the study continues to meet the regulatory requirements.

The modification submission should be returned to OHRE for withdrawal so that a Renewal application can be submitted. Study teams may include the modification with the Renewal. When navigating to view the stipulations, there will be an alert to return the submission to OHRE for withdrawal.



Similarly, neither study nor personnel modifications can be submitted if a study has expired. The study team should submit a Renewal application which may include the needed changes.



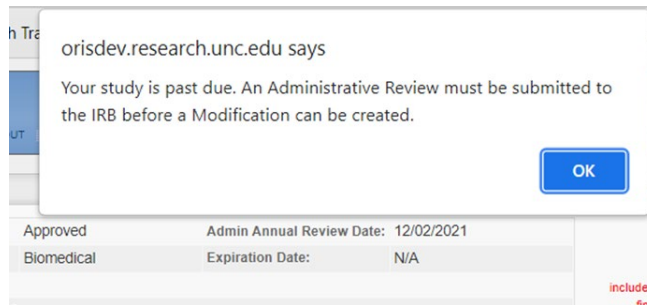
Modifications within 45 days of expirations

For studies that are within 45 days of their expiration, no study modifications can be submitted. The study team should submit a Renewal application with the needed changes. The alert in the section above will display should the study team attempt to draft a modification.

Personnel modifications can be submitted during this window for internal personnel aside from the PI or Faculty Advisor. No changes to external personnel, PI, or Faculty Advisor without a Renewal application.

AR Past Due alert on Modification creation

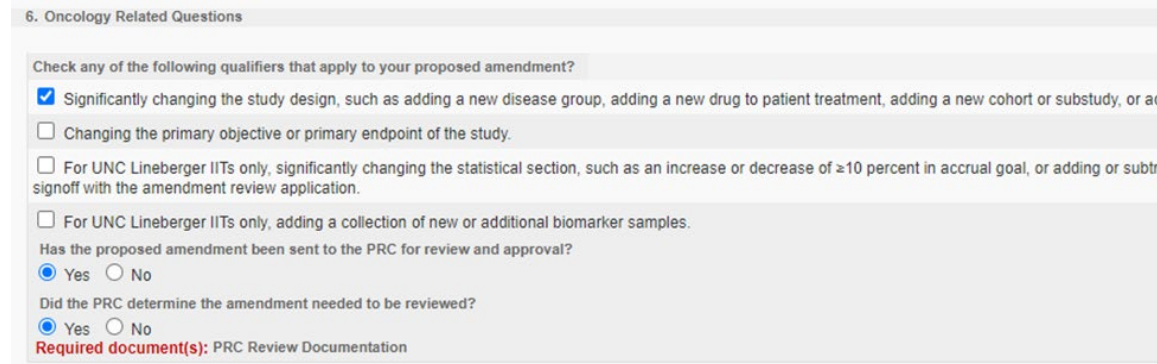
For studies where an Administrative Review application has not been submitted and the AR date has passed, an alert will display upon attempting to create a modification.



Once the Administrative Review has been certified and is submitted to the IRB, the study team will be able to draft a modification.

PRC Section changes

Additional questions will be included in the modification section to capture information for Oncology studies. This is intended to capture whether there is a requirement for the modification to be reviewed by PRC. If so, PRC Review Documentation will be a required document.



Personnel Modification for NHR and JIT determinations

Not Human Subjects Research (NHR) and Just-in-Time (JIT) determinations are a one-time determination. Changes to personnel do not need to be submitted to the IRB. NHR studies are not under IRB oversight and JIT determinations are to satisfy a federal funding agency requirement.

If the PI changes and you require a separate determination, please submit a new NHR or JIT application. Please submit documentation with the new JIT that the federal funding agency has requested a new determination.

In the event the study team attempts to draft a personnel modification, an alert will display to include the information above.