

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

## IRBIS System Update:

Summary of Changes	
IRBIS changes, effective 6:00 PM, December 16, 2021 .....	1
Rely-on letters and COI Management Plans .....	1
PRC Section changes .....	1
PI Change during Initial submission .....	1
Alerts on expired studies .....	2
Modifications within 45 days of expiration .....	2
AR Past Due alert on Modification creation .....	3
Personnel Modification for NHR and JIT determinations .....	3

## 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

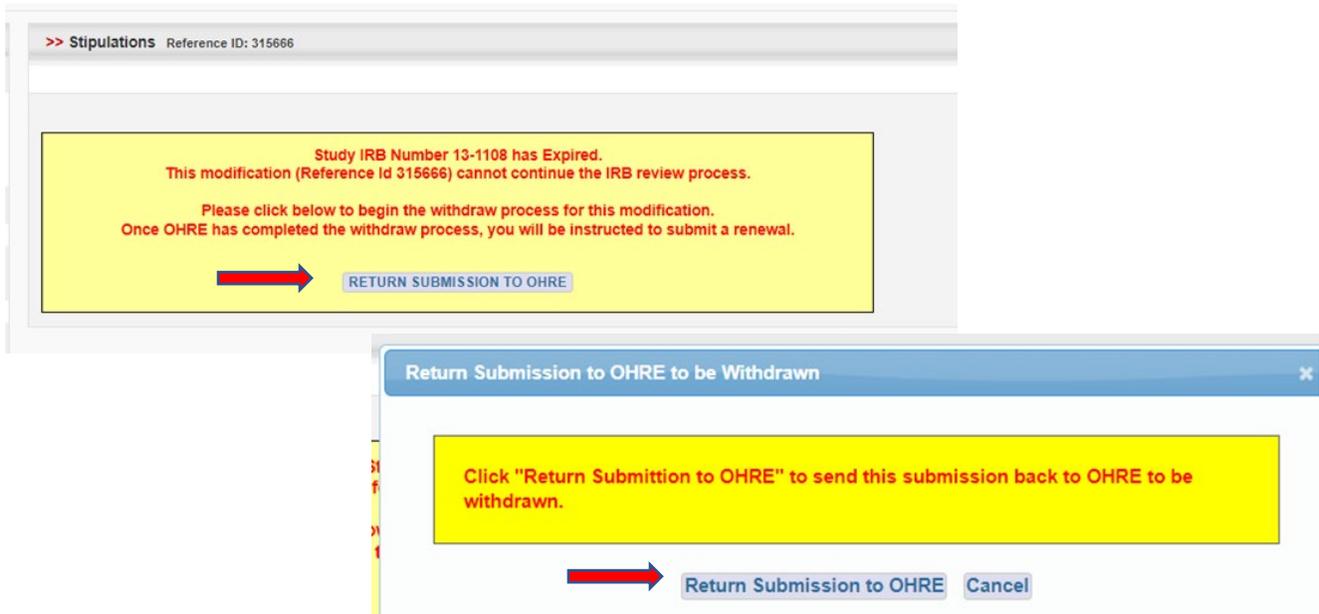
When PI change is required during the review of an Initial submission, the Administering Department and the PI's home department will be required to re-approve in order to satisfy regulatory requirements that investigators have the required training and resources to conduct the research. The departments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

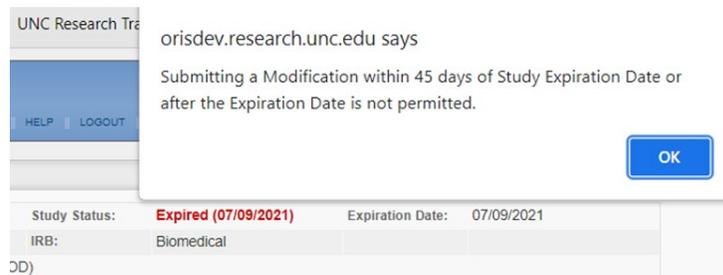
## Alerts on expired studies

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.

6. Oncology Related Questions

Check any of the following qualifiers that apply to your proposed amendment?

- Significantly changing the study design, such as adding a new disease group, adding a new drug to patient treatment, adding a new cohort or substudy, or adding a new primary endpoint or primary objective of the study.
- Changing the primary objective or primary endpoint of the study.
- For UNC Lineberger IITs only, significantly changing the statistical section, such as an increase or decrease of  $\geq 10$  percent in accrual goal, or adding or subtracting a cohort with the amendment review application.
- For UNC Lineberger IITs only, adding a collection of new or additional biomarker samples.

Has the proposed amendment been sent to the PRC for review and approval?

Yes  No

Did the PRC determine the amendment needed to be reviewed?

Yes  No

Required document(s): PRC Review Documentation

---

## 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.