

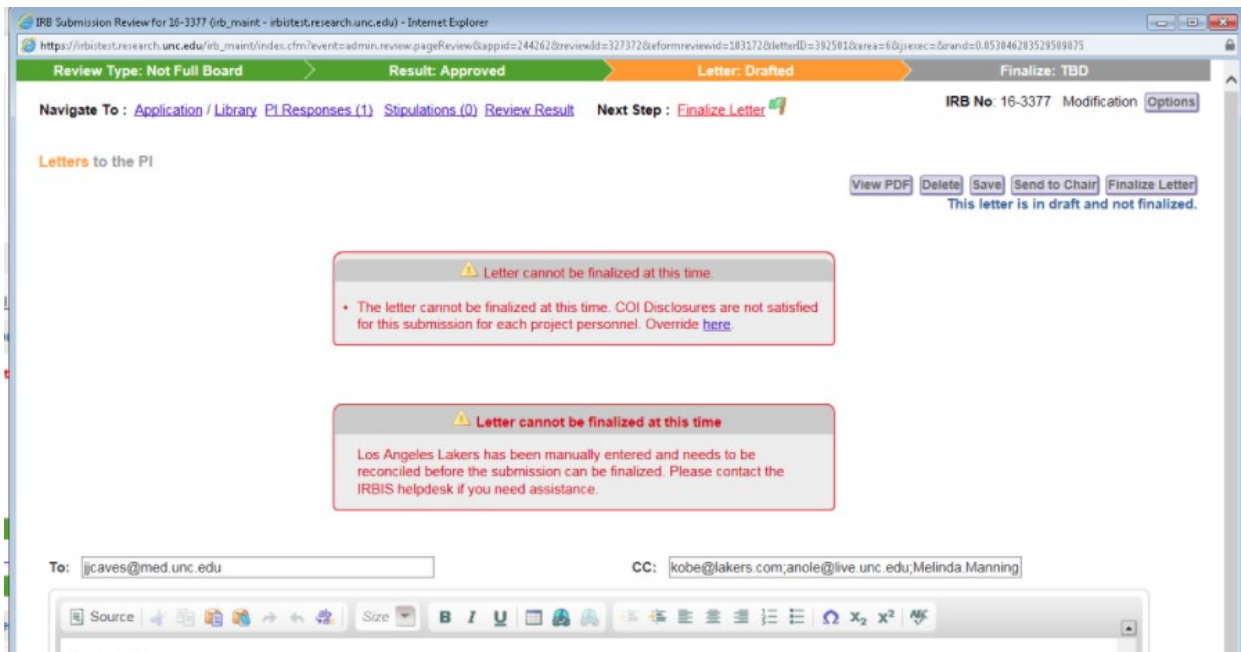
IRBIS changes, effective 6:00 PM, March 22, 2018

IRBIS 5.09.07 Update:

For external institutions that have been manually entered (rather than using the look-up), the data must be reconciled before the submission can be finalized.

Previously only the COI hardstop was being displayed, as COIs cannot be created until the external institution has been verified. This is done by ORIS staff.

If you process a submission and are ready to finalize a letter, a hard stop will be displayed if the external institution has not yet been reconciled by that time. This new warning will better alert you to the actual cause of the issue.



Part B.1.1 (Methods of Recruiting) and B.3.4 (Research Locations) are being added to the IRB applications for studies that Rely on an External IRB. This is useful for UNC institutional purposes.






UNC COIs will now be automatically generated for all Independent Investigators.

The submission flags have been revised as follows:






If multiple flags are indicated, they are displayed according to a hierarchy (highest to lowest priority):

- Full Board
- Other
- Athletic
- Agreement

Current:

	No Flag
	Agreement
	Athletic
	FB Pre-review
	Other

Revised:

	No Flag
	Agreement
	Athletic
	FB Pre-review
	Other

The Certificate of Confidentiality question has been updated in section A.10. Confidentiality of the data:

Prior:

Do you plan to obtain a federal Certificate of Confidentiality for this study?

Revised:

Do you plan to obtain a federal Certificate of Confidentiality for this study? Please note that all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable, information is [automatically issued a Certificate of Confidentiality \(CoC\)](#). You should also select “Yes” if your study is NIH funded and has been issued a CoC under this updated NIH policy.

In addition, the Data Security requirements have been updated:

- Previously this was one of many questions used to determine the data security level. If yes, this automatically triggered a data security level III, as it was previously a risk.
- This has been revised to no longer be included in the data security level determination.

The COC consent form tag has also been updated:

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

[This short version of the language may be used for research enrolling subjects in the international setting. Please delete the version that will not be used.]

What is a Certificate of Confidentiality?

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

Three new Certificate of Confidentiality macros have been added:

1- COC consent update long version

The NIH expects that subjects enrolled moving forward be informed that the project has been issued a Certificate of Confidentiality. Please update the consent forms to include the CoC language below. A sponsor or reviewing IRB may provide alternative language, in which case you may use the alternative language provided to you.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

2- COC consent update short version

The NIH expects that subjects enrolled moving forward be informed that the project has been issued a Certificate of Confidentiality. Please update the consent forms to include the CoC language below. This language may be used for research enrolling subjects in the international setting and some minimal risk research.

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

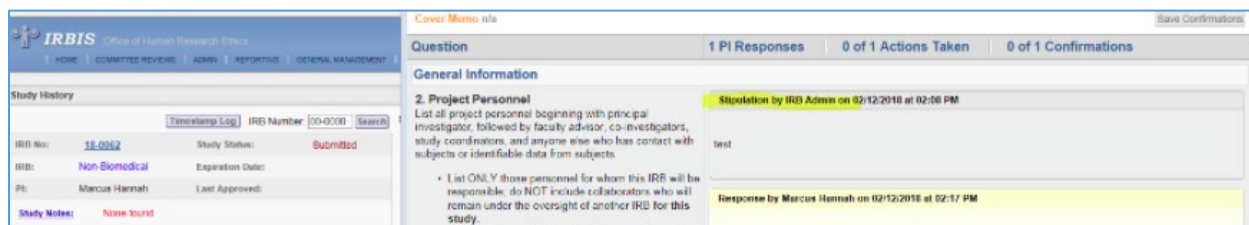
3- COC application update

The NIH has updated their policy regarding Certificates of Confidentiality (COCs). According to the updated policy, this project is considered to have been issued a COC because it is funded in whole or part by the NIH and the funded period included dates on or after 12/13/2016. Additional information about the new policy may be found here: <https://humansubjects.nih.gov/coc/index>

The PI must review the new policy and understand how the COC may impact their project from the perspective of confidentiality of the information collected.

Please change this response to 'yes', otherwise indicate why a COC would not apply to this research project.

In scenarios where you are reviewing the PI responses of a resent stipulation, IRB Admin was showing instead of the Analyst name. This has been corrected.



Department Approval certification reminders will now be sent. They will be created following the same schedule as the existing PI certification reminders. One certification request when routed to them, one seven days following the initial, and then daily.

Reminders of Impending Expiration of IRB Approval have been updated to send to research personnel listed on the most recent approved submission. Previously the expiration reminders were being sent to research personnel listed on the most recent renewal.

The Full Board COI Macro has been updated:

COI disclosure(s) for **[investigator(s)]** has/have not been submitted **AND/OR**
COI review(s) for **[investigator(s)]** is/are pending.

- The status of COI disclosures can be viewed on the "Personnel" tab on the "Application Status" screen.
- Do not resubmit to the IRB until all COI disclosures are submitted **AND** the review process is **complete**.
- If there are questions about COI disclosures, contact the COI Office at (919) 843-9953 or coi@unc.edu.

ONCE COI REVIEW IS COMPLETE, please confirm that the determination fits one of the following conditions and state which is met:

- (1) The COI Office determined there were no conflicts of interest for any member of the research team.
- (2) The COI Office made a COI determination of "Acknowledged" as the interest was disclosed and no additional action was required.
- (3) The COI Office made a COI determination of "Transparency", for which the conflict will be disclosed in publications and presentations, and the following template language will be used in relevant consent documents:

This research is funded by the INSERT NAME. (the Sponsor). This means that the research team is being paid by the sponsors for doing the study. In addition, Dr. XXX the ROLE of this study, receives money from SPONSOR NAME for work that is not part of this study. These activities may include consulting, service on advisory boards, giving speeches, or writing reports.

A committee at the University of North Carolina at Chapel Hill has reviewed these financial arrangements. If you would like more information, please ask the researchers or the study coordinators listed on the first page of this form.

- (4) The COI Office made a COI determination of "Administrative Considerations", for which the conflict will be disclosed in publications and presentations, and the template language above will be used in relevant consent

documents.

If COI review results in Administrative Consideration plans beyond those spelled out in option 4 or FCOI management plans, the plan will need to be reviewed at the next available meeting.

The Consent Form Injury Language has been updated:

What will happen if you are injured by this research?

This section cannot be modified without the approval of the Office of Industry Contracting. Doing so may result in approval delay. Contact OIC at 919-962-3630 if you have questions.

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care.

The Sponsor of the study, [INSERT SPONSOR NAME], has agreed to pay all reasonable medical expenses for the treatment of reactions, illnesses or injuries related to the use of the study drug/device, defects in the manufacture of the study drug/device, or as a direct result of properly performed study tests and/or procedures, except to the extent such expenses are due to the negligence of the study staff or due to your current disease or condition unless it is made worse because you are taking part in this study.

The Sponsor has not set aside funds to pay for lost wages or any other losses or expenses. Any costs for medical expenses not paid by the Sponsor will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If required by Sponsor, ONLY the following Medicare Reporting language is acceptable:

To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number. This is because the Sponsor has to check to see if you have health care insurance through Medicare, and if so, report to Medicare the payment the Sponsor makes toward your medical expenses. We will not collect your social security number for this purpose unless you are injured and a claim is submitted to the Sponsor to pay medical expenses.

If you think you have been injured from taking part in this study, call Dr. (PI Name) at (24 hour phone number). He/she will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

For UNC-Chapel Hill Investigator-initiated studies, insert only the following:

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical

expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

The following have been added as attachment types in OHRE Attachments:

- NSI: Documentation
- NSI: PI Correspondence
- NSI: OHRP/FDA Notification
- NSI: OHRP Response