

IRBIS changes, effective 6:00 PM, July 31, 2018

IRBIS 5.09.14 Update:

Changes to emails Investigators receive re: outdated stipulations have been made. Previously, there were slight differences in the text for the 30 and 60 day messages. These are now the same. As a next step, ORIS will be working on adding additional reminders for every 30 days until stipulations are resolved. This is expected in August 2018.

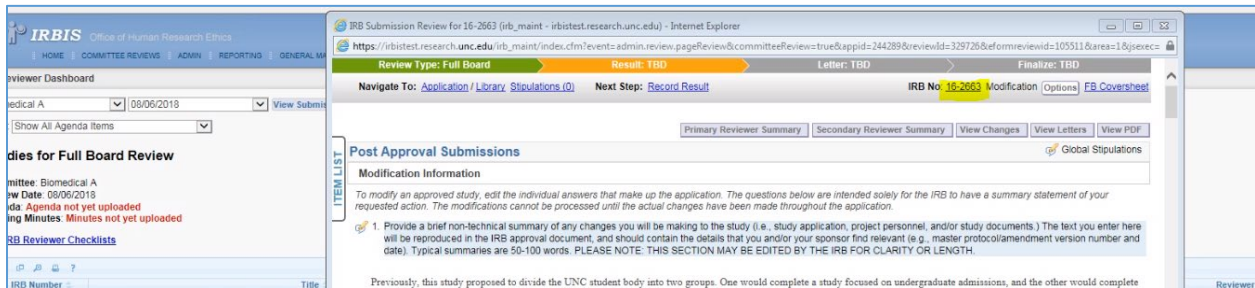
Current:

IRB records indicate that you have not responded to stipulations relating to study #18-0881. Please respond immediately. Submissions that are not resolved within 90 days from the date listed above will be withdrawn from consideration, unless the IRB has agreed to extend this time. Please contact the IRB Help Desk at 919-966-3685 for help

Revised:

IRB records indicate that you have not responded to stipulations relating to study #18-0881. Please respond as soon as the issues have been resolved by clicking the link below, responding to each stipulation, and then clicking Proceed to Resubmit.

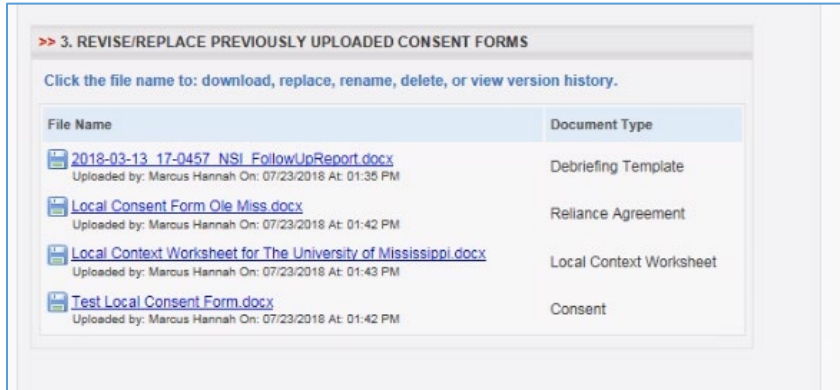
The IRB direct link from the Committee Reviews screen to the Admin full history of the study has been added for all IRBIS Admin roles. Previously, this was only available to Committee Members:



Letter templates have been updated to include both the Principal Investigator and the Faculty advisor in the TO field of the email. Previously, the Faculty Advisor was in the CC field of the email. This will impact all submissions Accepted by the IRB as of August 1, 2018. Submissions accepted prior to August 1 will have the FA remain in the CC field.

The IRB Full Board agenda document has been updated to remove studies with the study status of withdrawn and rely on an external IRB from the list of studies approved by expedited review.

New attachment types of Reliance Agreement, Local Context Worksheet, and Local Consent Form. This is for use on project where UNC is ceding review and relying on an external IRB.



>> 3. REVISE/REPLACE PREVIOUSLY UPLOADED CONSENT FORMS

Click the file name to: download, replace, rename, delete, or view version history.

File Name	Document Type
2018-03-13_17-0457_NSI_FollowUpReport.docx Uploaded by: Marcus Hannah On: 07/23/2018 At: 01:35 PM	Debriefing Template
Local Consent Form Ole Miss.docx Uploaded by: Marcus Hannah On: 07/23/2018 At: 01:42 PM	Reliance Agreement
Local Context Worksheet for The University of Mississippi.docx Uploaded by: Marcus Hannah On: 07/23/2018 At: 01:43 PM	Local Context Worksheet
Test Local Consent Form.docx Uploaded by: Marcus Hannah On: 07/23/2018 At: 01:42 PM	Consent

For studies currently expired, we displayed a warning noting that a renewal was recommended, but it was still possible to proceed with a modification. With this update, expired studies will block the creation of modification and force users to instead submit a renewal submission.



IRB Study Management [Online Submission FAQ](#) [Online Submission Guide](#)

IRB Number: [10-0295](#) Study Status: **Expired (01/28/2013)** Expiration Date: 01/28/2013

PI: Plevy, Scott IRB: Biomedical

Sponsor: National Institutes of Health (NIH), National Institute of Diabetes, Digestive and Kidney Diseases

Study Title: The Biomarkers of Inflammatory Bowel Disease Behavior and Treatment Options

[Current Study Documents](#)
[Expiration Letters](#)

[Submit a Modification](#) [Submit a Renewal](#) [Submit New Safety Information](#) [Submit a Closure](#)

This study is Expired, Suspended, Closed or Terminated.
To reopen the study at this time, click 'Continue with Renewal' below.

[Continue with Renewal](#)

Click Reference ID to access the Application Status screen where you can check submission status, verify certifications and department approvals, and confirm study staff completion of ethics training and COI disclosure. For completed submissions, you may also access previously approved applications and documents.

All Submissions for IRB Number 10-0295 Search:

Reference ID	Date Routing Complete	Submission Type	Submission Status	Full Board Agenda	Action Date	Letters
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Conflict of Interest Disclosures have been revised for projects designated Exempt.

Current:

- NHR: No COI created or required
- Exempt: Initial submission

Revised:

- NHR: No COI created or required
- Exempt, Initial submission, any modification where new staff are added

Changes have been made to the Debriefing Template. The document has been relabeled to Debriefing Template and made a required document. It links to an updated form: <https://research.unc.edu/files/2018/04/Debriefing-Form-Template.docx>

IRB Number: [18-0233](#) PI: [Marcus Hannah](#)
 Study Title: Marcus' task 24387 - Rely-on external IRB Related Documents and task 24392 - Debriefing Template

Item List click on section name to expand

>> D.3. Full or partial waiver of consent Reference ID: 195244

The default is for subjects to give informed consent. A waiver might be requested for research involving only existing data or human biological details at the outset (e.g., behavioral research involving deception). In limited circumstances, parental permission may be waived. This section is for information (PHI) subject to HIPAA regulation, such as patient records.

1. Are you requesting any of the following:

a waiver of informed consent in its entirety
 a waiver or alteration of some of the elements of informed consent
 a waiver of HIPAA authorization (If you are accessing patient records for this research, you must also request a waiver of HIPAA authorization)

2. If your request for a waiver applies to some but not all of your subject groups and/or consent forms, please describe and justify

[Tips and Techniques on using the HTML Editor](#)

3. Does this request for waiver support a study design that involves deception or withholding of information?
 Yes No
 Required document(s): [Debriefing Template](#)

RAMSeS listings of Prime sponsors have been cleaned; previously they would show the prime sponsor name multiple times:

Current:

Is UNC-CH the direct recipient of any Federal funding for this study? You should answer 'yes' only if you are the grantee. You should answer 'no' if you are the recipient of a sub-award or contractor under the grant.

No

Funding Source(s) and/or Sponsor(s)

Sponsor Name	UNC Ramsees Number	Sponsor Type	Prime Sponsor Name	Prime Sponsor Type	Sponsor/Grant Number	Detail
Cancer Research Institute					0967654321	view
Dartmouth College	17-4172	Federal	Cystic Fibrosis Foundation,Cystic Fibrosis Foundation,Cystic Fibrosis Foundation,Cystic Fibrosis Foundation,Cystic Fibrosis Foundation,Cystic Fibrosis Foundation			view
Duke University	08-0658	Foundation	National Heart Lung and Blood Institute	Federal		view

Revised:

Is UNC-CH the direct recipient of any Federal funding for this study? You should answer 'yes' only if you are the grantee. You should answer 'no' if you are the recipient of a sub-award or contractor under the grant.

No

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