

IRBIS changes, effective 6:00 PM, April 9, 2019

IRBIS 5.11.00 Update:

Summary of IRBIS New Safety Information (NSI) Update

- [1\) Improved Navigation](#)
- [2\) NSI Stipulation Reminders](#)
- [3\) New NSI Stipulations Response Mechanism](#)
- [4\) Ability to Update the Initial NSI Report](#)
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1) Improved Navigation

The New Safety Information (NSI) submission process has been revised to improve navigation.

To submit an NSI, go to your IRB Study Management page and click: **Submit New Safety Information**

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

IRB Number: 14-0210	Study Status: Approved	Expiration Date: 01/26/2020
PI: Cowan, Laura	IRB: Biomedical	
Sponsor:		
Study Title: EPIC TEST RECORD #1		

[Current Study Documents](#)
included with the IRB Approval dated 01/23/2014

[Expiration Letters](#)

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

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 14-0210 Search:

Reference ID	Date Routing Complete	Submission Type	Submission Status	Full Board Agenda	Action Date	Letters
7467	n/a	New Safety Information	In Draft	n/a	n/a	n/a
177946	n/a	Renewal (w/ Modification)	In Draft	n/a	n/a	n/a
6772	8/30/2016	New Safety Information	Noted	n/a	8/30/2016	
133230	1/22/2014	Initial	Approved	n/a	1/23/2014	

Showing 1 to 4 of 4 entries

Next, you will respond to questions about the New Safety Information:

Item List

- NSI Submission
 - [Brief Description of NSI](#)
 - [Does This NSI Need to be Reported?](#)
 - [NSI Attachments](#)
- NSI Routing
 - [Submit NSI](#)
 - [PI Certification Needed](#)
- NSI Management
 - [View NSI](#)
 - [Follow Up](#)
 - [History](#)
 - [View PDF](#)

>> New Safety Information [Help](#)

IRB Number: 14-0210	Study Status: Approved	Expiration Date: 01/26/2020
PI: Cowan, Laura	IRB: Biomedical	
Sponsor:		
Study Title: EPIC TEST RECORD #1		

Reference Id: 7467	NSI Status: In Draft	Reportable: No
Date Submitted: Not Submitted	Date PI Certified: Not Certified	

>> Does This New Safety Information Need to be Reported?

A1. Did this event occur at a site for which a UNC-Chapel Hill IRB has direct oversight responsibility or involve a research participant at one of those sites?

Yes No

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Your responses determine what sections are required. To help researchers navigate the required sections, each section is now displayed on the left-hand item list menu. Completed sections will be indicated with a green check box, and sections requiring additional information are indicated with a yellow triangle:

Item List

NSI Submission

- ✓ Brief Description of NSI
- ✓ Does This NSI Need to be Reported?
- ⚠ Information About the Event
- ⚠ Was This a Serious Adverse Event?
- ⚠ Protocol/Concent Forms
- ⚠ Corrective Action
- ✓ NSI Attachments

NSI Routing

- ⚠ Submit NSI
- ⚠ PI Certification Needed

NSI Management

- ➡ View NSI
- ➡ Follow Up
- ➡ History
- ➡ View PDF
- Delete NSI

IRB
University of North Carolina - Chapel Hill
720 Martin Luther King, Jr. Blvd.
Bldg. 385, 2nd Floor
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113

>> New Safety Information [Help](#)

IRB Number: **14-0210** Study Status: Approved Expiration Date: 01/26/2020
PI: **Cowan, Laura** IRB: Biomedical
Sponsor:
Study Title: EPIC TEST RECORD #1

Reference Id: **7467** NSI Status: In Draft Reportable: Yes
Date Submitted: Not Submitted Date PI Certified: Not Certified

>> Information About the Event

B1) Date of Event: [clear_date](#)
B2) Location of Event:
B3) Full Description of Event.

>> Was this a serious adverse event?

C1) Did the event result in death? Yes No
If yes, date of death: [clear_date](#) Date Unknown
C2) Was the event life-threatening (i.e., placed the subject at immediate risk of death from the event, as it occurred)?

Until the NSI is submitted, you are able to easily delete and NSI submission by clicking Delete NSI on the left-hand menu:

Item List

NSI Submission

- ✓ Brief Description of NSI
- ✓ Does This NSI Need to be Reported?
- ✓ Information About the Event
- ✓ Was This a Serious Adverse Event?
- ✓ Protocol/Concent Forms
- ✓ Corrective Action
- ✓ NSI Attachments

NSI Routing

- ⚠ PI Certification Needed

NSI Management

- ➡ View NSI
- ➡ Follow Up
- ➡ History
- ➡ View PDF
- Delete NSI

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>> New Safety Information [Help](#)

IRB Number: **14-0210** Study Status: Approved Expiration Date: 01/26/2020
PI: **Cowan, Laura** IRB: Biomedical
Sponsor:
Study Title: EPIC TEST RECORD #1

Reference Id: **7467** NSI Status: Being Routed Reportable: Yes
Date Submitted: 06/01/2018 Date PI Certified: Not Certified

>> New Safety Information Submission

>> Brief Description of New Safety Information

This is a test.

>> Does This New Safety Information Need to be Reported?

A1) Did this event occur at a site for which a UNC-Chapel Hill IRB has direct oversight responsibility or involve a research participant at one of those sites? **Yes**
A2) Was the event unexpected in nature, severity, or frequency? **Yes**
If yes, please explain:
Sample
A3) Do you think the event was related or possibly related to this research? **Yes**
If yes, please explain:
Sample

2) NSI Stipulation Reminders

The IRB will now send you reminders if your responses to NSI stipulations are past the due date indicated in the initial stipulation letter. When the NSI Stipulation letter is sent, reminders will be sent at the following intervals:

- Due date + 3 calendar days
- Due date + 7 calendar days
- Due date + 11 calendar days (final notice)

On day 11, if you have not submitted your response, you will receive a final reminder that states that the IRB will not review any new IRB submissions until the NSI responses are received. Note: This policy does not pertain to NSI submissions.

3) New NSI Stipulations Response Mechanism

The NSI stipulation letter will now contain a link to stipulations rather than listing each stipulation. Click the NSI stipulations link to access your stipulations on the NSI stipulations screen. You no longer need to initiate a follow-up report to respond to stipulations. Respond to each stipulation using the text box provided below.

The screenshot shows the IRBIS web application interface. The top navigation bar includes links for HOME, COMMITTEE REVIEWS, ADMIN, REPORTS, GENERAL MANAGEMENT, HELP, DEVELOPER, and LOGOUT. The left sidebar contains a navigation menu with sections for NSI Submission, NSI Routing, and NSI Management. The main content area is titled '>> New Safety Information' and displays details for IRB Number 19-0077, PI Hannah Marcus, and Sponsor Cancer Research Institute. Below this, there are instructions for responding to stipulations and a text box for providing a detailed description of the event.

4) Ability to Update the Initial NSI Report

If the IRB requests that you update the NSI report, it is now possible to revise it. You should use the left-hand menu to navigate to the different sections of the application that have been requested to be revised.

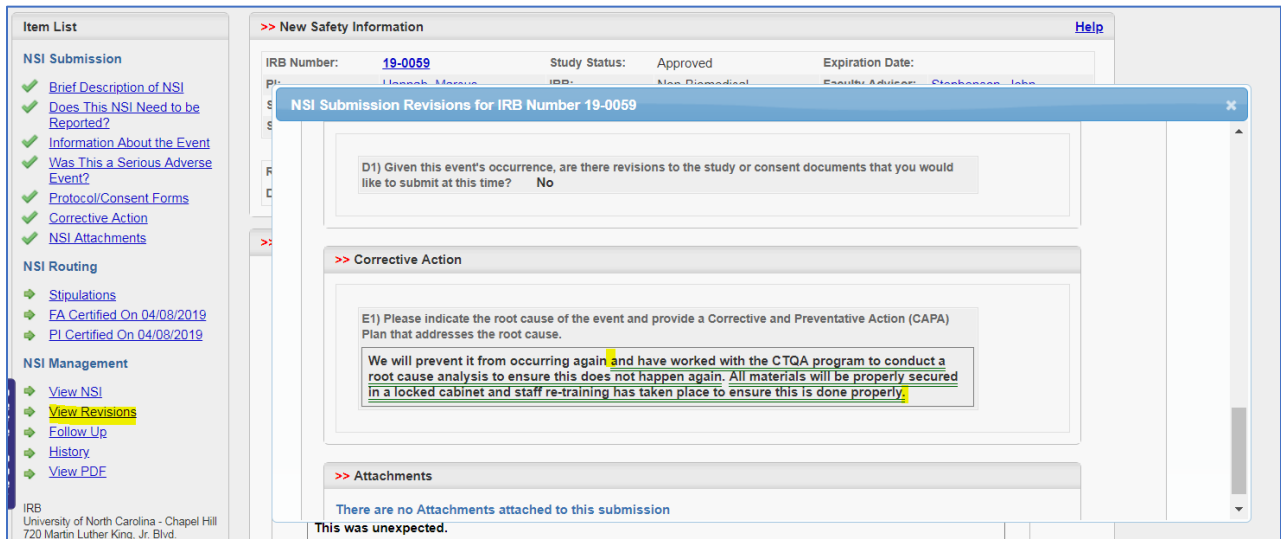
Edit the existing answers to provide additional detail or corrections. Please note that some revisions will trigger new question requirements or sections.

The screenshot displays the IRBIS interface for a 'New Safety Information' submission. On the left, a navigation menu lists various actions under 'NSI Submission', 'NSI Routing', and 'NSI Management'. The 'Resubmit' option is highlighted in yellow. The main content area shows submission details for IRB Number 19-0059, including PI Hannah Marcus and Study Title 'Marcus special symbols test'. Below this, the 'Information About the Event' section contains fields for 'Date of Event' (03/29/2019), 'Location of Event' (Office of Human Research Ethics), and 'Full Description of Event' (Expected date a sample collection). A 'Was this a serious adverse event?' section is partially visible at the bottom.

When all changes and responses are complete, please click the yellow Resubmit button, on the left-hand menu. PI certification of NSI responses is still required. Upon resubmission, the NSI will be route to the PI for certification. The PI will continue to receive an email prompting the certification.

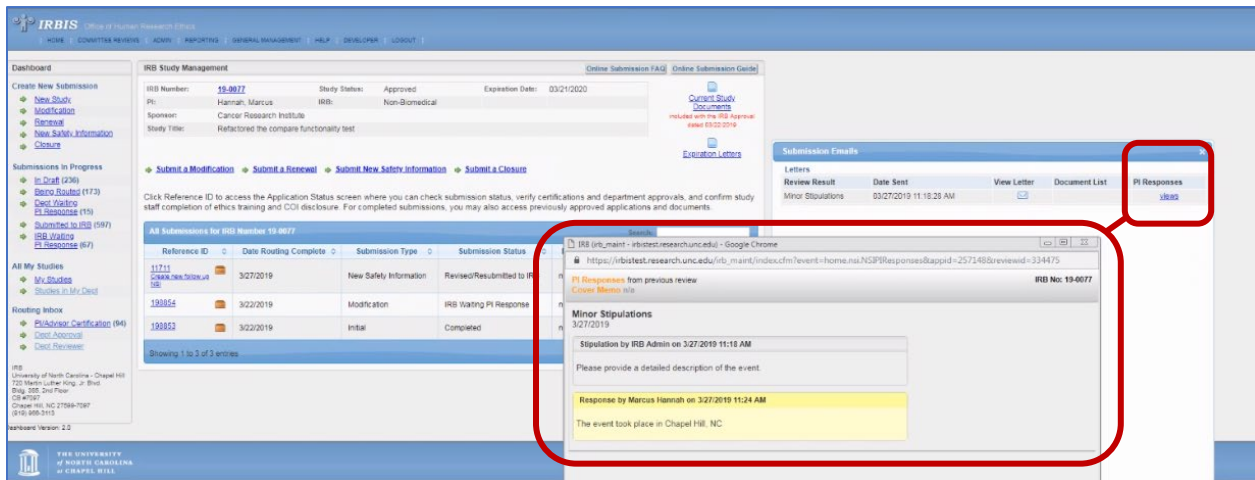
This screenshot shows the 'New Safety Information Stipulations' section of the IRBIS system. The left-hand menu has 'Resubmit' highlighted in yellow. The main content area features a yellow box with instructions: 'Please review and respond to the stipulations as follows. 1. Respond to each stipulation in the response field and click save. If the stipulations are not prepopulated, please copy and paste the stipulations into the response field. 2. Make any requested changes to the NSI application. 3. Upload requested attachments. 4. When all changes AND responses are complete, please click the yellow Resubmit button, on the left navigation bar.' Below the instructions, there is a text area for 'Please provide a detailed description of the event.' and a rich text editor with the text 'The event took place in Chapel Hill, NC'.

To view a comparison of the revised NSI and the prior submission, click the View Revisions button on the left-hand menu. This will display a tracked changes view of the NSI report responses and any attachment revisions.



5) New NSI Stipulation Letters and Responses View

NSI Stipulation responses will now be available to view via the IRB Study Management Screen, Letter icon, similarly to stipulation responses for other submissions.



6) OHRE Initiated NSI Modifications

OHRE now has the ability to administratively initiate an NSI Modification if they are requesting application changes as a result of information submitted in the NSI report. The administrative NSI Modification will not be visible to you when it is in draft. If you attempt to start a submission while the administrative NSI Modification is in draft, you will receive the following hard stop message:

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

IRB Number:	18-0123	Study Status:	Approved	Expiration Date:	03/26/2019
PI:	Hannah, Marcus	IRB:	Non-Biomedical		
Sponsor:	Cancer Research Institute				
Study Title:	TESTING NSI				

[Current Study Documents](#)
 included with the IRB Approval dated 03/27/2018
[Expiration Letters](#)

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

New submissions, other than NSI, are not possible at this time as OHRE has an administrative submission pending for IRB Number 18-0123. Please contact the OHRE/IRB to discuss any urgent issues.

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 18-0123							Search: <input type="text"/>
Reference ID	Date Routing Complete	Submission Type	Submission Status	Full Board Agenda	Action Date	Letters	
10532 <small>as follow up to 10510 Create new follow up NSI</small>	3/8/2019	New Safety Information	IRB Waiting PI Response	n/a	3/12/2019		

7) Updated Function of the Existing NSI Follow-Up Report

The existing NSI Follow-up report option should now only be used to provide follow-up information after the initial NSI report has been finalized (noted) by the IRB.

To submit a follow-up, choose the Follow-Up option from the NSI management section, or the IRB Study Management screen

<ul style="list-style-type: none"> Protocol/Consent Forms Corrective Action NSI Attachments NSI Routing PI Certification Needed NSI Management <ul style="list-style-type: none"> View NSI Follow Up History View PDF Delete NSI <p>IRB University of North Carolina - Chapel Hill 720 Martin Luther King, Jr. Blvd. Bldg. 385, 2nd Floor CB #7097 Chapel Hill, NC 27599-7097 (919) 966-3113</p>	<p>Date Submitted: 06/01/2018 Date PI Certified: Not Certified</p> <p>>> New Safety Information Submission</p> <p>>> Brief Description of New Safety Information</p> <p>This is a test.</p> <p>>> Does This New Safety Information Need to be Reported?</p> <p>A1) Did this event occur at a site for which a UNC-Chapel Hill IRB has direct oversight responsibility or involve a research participant at one of those sites? Yes</p> <p>A2) Was the event unexpected in nature, severity, or frequency? Yes</p> <p>If yes, please explain: <input type="text" value="Sample"/></p> <p>A3) Do you think the event was related or possibly related to this research? Yes</p> <p>If yes, please explain:</p>
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To provide feedback or additional suggestions, please contact: IRBIS@unc.edu