

## IRBIS changes, effective 7:00 PM, December 10, 2019

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### IRBIS Administrative Review Update:

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### Administrative Review Background

IRBIS is being updated to provide an Administrative Annual Review process.

With the revised "Common Rule", The Office of Human Research Ethics (OHRE) at UNC-Chapel Hill over the last several months has been reviewing studies that meet the regulatory requirements and determining "administrative review" instead of the previous continuing review as applicable as part of the burden reducing provisions from the Office of Human Research Protection (OHRP). The OHRE has been updating its processes, forms, and IRBIS based on these revisions. At this time more than 1400 studies meet the requirements to be reviewed administratively, as these studies are now becoming due for their first "administrative review" the IRB will be deploying the "Administrative Review" submission.

### How to identify if your study requires continuing review vs Administrative Review

In your renewal letters from 2019 or future letters, you will see the UNC Administrative Review Due Date, rather than an Expiration date:



THE UNIVERSITY  
of NORTH CAROLINA  
at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS  
720 Martin Luther King, Jr. Blvd.  
Bldg. 385, 2nd Floor  
CB #7097  
Chapel Hill, NC 27599-7097  
(919) 966-3113  
Web site: ohre.unc.edu  
Federalwide Assurance (FWA) #4801

**To:** Laura Cowan  
UNC Office of Human Research Ethics

**From:** UNC IRB

**Approval Date:** 12/10/2019

**UNC Administrative Review Due Date:** 12/09/2020

**RE:** Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)

**Submission Type:** Initial

**Expedited Category:** 1.No IND/IDE,4.Noninvasive clinical data

**Study #:** 20-0001

**Study Title:** Assessing the Efficacy of Administrative Annual Review IRB Submissions

This submission, Reference ID 243355, has been approved by the IRB. It has been determined that the risk involved in this research is no more than minimal. **This research requires annual UNC administrative review.** Under the revised 'Common Rule' of 2018, this study does not require continuing review and IRB approval will not expire.

## When should study teams submit for administrative review

Similarly to the traditional Continuing Review Renewal process, you will receive an email reminder that your UNC Administrative Review Due Date is approaching 60 days prior. At that time, you should confirm that your Research Project Personnel and Funding Source information is up to date on your IRB application. If not, we recommend that you submit a Modification submission at this time.

Annual COI disclosures will be automatically generated at 45 days prior to the UNC Administrative Review Due Date for all Research Project Personnel. These disclosures will automatically be transitioned into the Administrative Annual Review submission at the time it is created.

An additional email reminder will be sent that your UNC Administrative Review Due Date is approaching 30 days prior.

## How to submit for administrative review, including new IRBIS form

If your study is indicated for annual review, you will see a link for an Administrative Review submission where the Renewal link is located:

[Being Routed \(1\)](#)  
[Dept. Waiting PI Response \(1\)](#)  
[Submitted to IRB \(3\)](#)  
[IRB Waiting PI Response \(1\)](#)

[My Studies](#)  
[My Studies](#)  
[Studies in My Dept](#)

**Routing Inbox**  
[PI/Advisor Certification \(1\)](#)  
[Dept Approval](#)  
[Dept Reviewer](#)

IRB  
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Dashboard Version: 2.0

[Expiration Letters](#)

[Submit a Modification](#)  
 [Submit an Administrative Review](#)  
 [Submit New Safety Information](#)  
 [Submit a Closure](#)

Your study is indicated for Annual Administrative Review Before continuing with this Administrative Review form, please note:

- If personnel need to be removed, please click the "Submit a Modification" link above and do not proceed with your Annual Administrative Review until the Modification is approved.
- If personnel need to be added, or a study funding source has been added or changed, please submit a Modification following the completion of the annual administrative review. Please click the "Continue with Administrative Review" button to proceed.

[Continue with Administrative Review](#)

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.

Reference ID	Date Routing Complete	Submission Type	Submission Status	Full Board Agenda	Action Date	Letters
<a href="#">252048</a>	11/26/2019	Administrative Review	Submitted To IRB	n/a	11/26/2019	
<a href="#">12441</a>	n/a	New Safety Information	In Draft	n/a	n/a	n/a

You will then see some instructional text which notes that your study is indicated for Administrative Annual Review. Before proceeding, please review if any personnel or funding source changes are required.

The Administrative Annual Review form is very brief. The first two sections contain two study status options and a short progress report form:

**Item List**

**Admin Annual Review Submission**

[Administrative Annual Review Submission](#)

[COI Disclosures / IRB Training](#)

**Submission Routing**

[Submit Form](#)

[PI Certification Needed](#)

**Submission Management**

[View Submission](#)

[View History](#)

[View PDF](#)

[Delete Submission](#)

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**>> Administrative Annual Review**

IRB Number: <b>20-0000</b>	Study Status: Approved	Admin Annual Review Date: 03/13/2021
PI: <a href="#">Cowan, Laura</a>	IRB: Non-Biomedical	
Sponsor:		
Study Title: Annual Administrative Review Demonstration Study		
Reference Id: <a href="#">253070</a>	Submission Status: Unsubmitted	
Date Submitted: Not Submitted	Date PI Certified: Not Certified	

**>> Administrative Annual Review Submission**

**>> Current Study Status**

**1. Choose only one: \***

A) Data collection continues (e.g. abstracting more data from medical records, receiving data from other study, subjects completing surveys, blood drawn at further time points)

B) All data has been collected/obtained (interaction/intervention complete, data abstraction complete). Only data analysis remains.

**>> Progress Report**

**2. Number of Subjects Involved through direct contact or use of their data (for multi-site studies, include only subjects covered by this IRB)**

A. Total number as currently approved by IRB: \*  
600 (Read-Only Prior Response)

B. Total number of subjects included/enrolled to date (do NOT include 'screen failures'): \*

C. Number of subjects included/enrolled since last renewal: \*

D. Number to be included/enrolled in upcoming year: \*

E. Since initial approval, have any subjects been enrolled who are members of vulnerable/protected groups (children, pregnant women, nonviable neonates or neonates of uncertain viability, prisoners, cognitively impaired)? \*  
 Yes  No

F. Since initial approval, have you enrolled any individuals using an Informed Consent Short Form? \*  
 Yes  No

If you select the second option, that your study is in data analysis, we present the option to close your study, if appropriate.

<b>Item List</b>  <b>Admin Annual Review Submission</b> ✓ <a href="#">Administrative Annual Review Submission</a> ✓ <a href="#">COI Disclosures / IRB Training</a>  <b>Submission Routing</b> ⚠ <a href="#">Submit Form</a> ⚠ <a href="#">PI Certification Needed</a>  <b>Submission Management</b> ➡ <a href="#">View Submission</a> ➡ <a href="#">View History</a> ➡ <a href="#">View PDF</a>  ⚠ <a href="#">Delete Submission</a>  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	<b>&gt;&gt; Administrative Annual Review</b>
	IRB Number: <a href="#">20-0000</a> Study Status: Approved      Admin Annual Review Date: 03/13/2021
	PI: <a href="#">Cowan, Laura</a> IRB: Non-Biomedical
	Sponsor: Study Title: Annual Administrative Review Demonstration Study
Reference Id: <a href="#">253070</a> Submission Status: Unsubmitted	
Date Submitted: Not Submitted      Date PI Certified: Not Certified	
<b>&gt;&gt; Administrative Annual Review Submission</b>	
<b>&gt;&gt; Current Study Status</b>	
<b>1. Choose only one: *</b>	
<input type="checkbox"/> A) Data collection continues (e.g. abstracting more data from medical records, receiving data from other study, subjects completing surveys, blood drawn at further time points)	
<input checked="" type="checkbox"/> B) All data has been collected/obtained (interaction/intervention complete, data abstraction complete). Only data analysis remains.	
NOTE: the study may be closed if: • All identifying information has been destroyed (review A.9.1. of your application) and there is no longer any way to match data back to an individual, OR • Analysis of identifiable data is complete and you were approved to store identifiers beyond closure of your study (review A.12.1. of your application), <a href="#">Click here to close the study.</a>	

Sections E. and F. of the progress report expand to ask for additional details. Finally, in the Study Updates section, some additional instructions are provided regarding additional changes to your research project, New Safety Information (NSI) reporting, and protocol deviations:

**>> Progress Report**

**2. Number of Subjects involved through direct contact or use of their data (for multi-site studies, include only subjects covered by this IRB)**

A. Total number as currently approved by IRB: \*  
 (Read-Only Prior Response)

B. Total number of subjects included/enrolled to date (do NOT include 'screen failures'): \*

C. Number of subjects included/enrolled since last renewal: \*

D. Number to be included/enrolled in upcoming year: \*

E. Since initial approval, have any subjects been enrolled who are members of vulnerable/protected groups (children, pregnant women, nonviable neonates or neonates of uncertain viability, prisoners, cognitively impaired)? \*  
 Yes  No

F. Since initial approval, have you enrolled any individuals using an Informed Consent Short Form? \*  
 Yes  No

**>> Study Updates**

If there are changes to any of the following that have not been submitted to the IRB, please submit a modification at this time.

- Changes to funding.
- Changes to project personnel.
- Changes to study materials.
- Other changes to that are not reflected in the IRB application.

**New Safety Information**

If there are any events that meet the reporting requirements of New Safety Information (NSI) as defined in OHRE [SOP 1401](#) that has not yet been reported, please submit an [NSI](#) at this time.

All other deviations should be documented in your study records in a Protocol Deviation Tracking Log. A template is available [here](#).

Once the brief form has been completed, you are ready to submit for review. A confirmation screen will advise you that the Principal Investigator, and Faculty Advisor (if applicable) are required to certify the submission:

>> Progress Report

**2. Number of Subjects involved through direct contact or use of their data (for multi-site studies, include only subjects covered by this IRB)**

A. Total number as currently approved by IRB: \*  
 (Read-Only Prior Response)

B. Total number of subjects included/enrolled to date (do NOT include 'screen failures'): \*

C. Number of subject

D. Number to be incl

E. Since initial approv  
 nonviable neonates c  
 Yes  No

F. Since initial approv  
 Yes  No

Submit Administrative Review for IRB Number 17-0722 - Reference Id 253070

**Are you ready to submit this Administrative Annual Review Form?**

**The final step in this process is to have the Administrative Annual Review Form certified by the Principal Investigator (and Faculty Advisor, if applicable); the IRB will not receive this form until the PI/FA has certified.**

**Submit to Routing**

>> Study Updates

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**New Safety Information**

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All other deviations should be documented in your study records in a Protocol Deviation Tracking Log. A template is available [here](#).

Following certification, if all COIs have been completed, you will receive a new letter noting your UNC Administrative Review Due Date for the following year.