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

IRBIS Administrative Review Update:

Summary of Changes

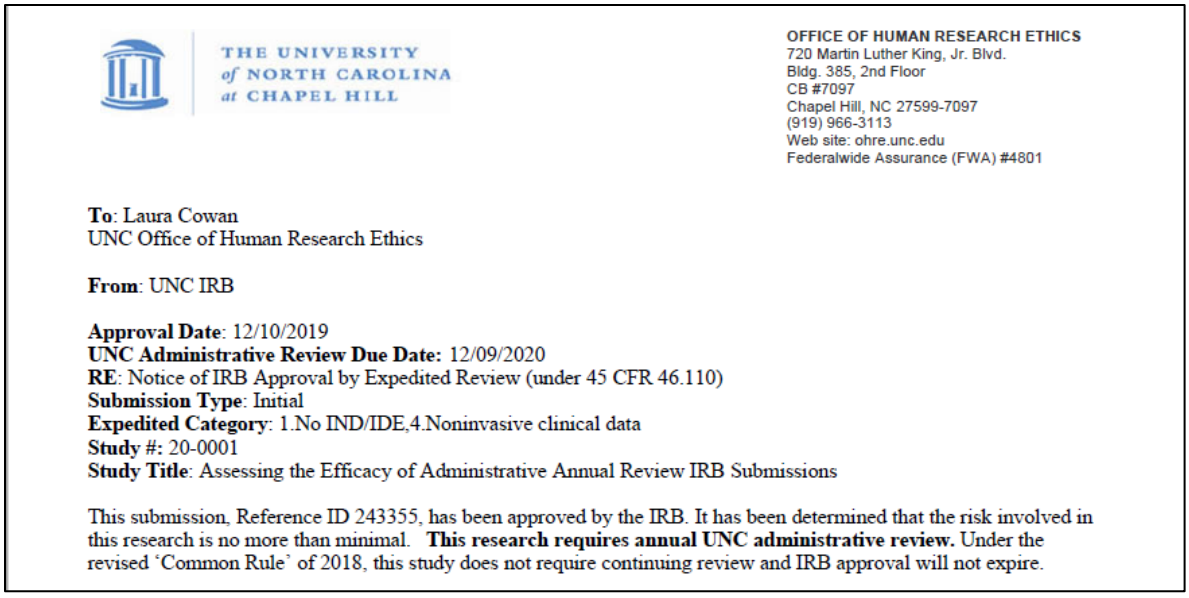
Administrative Review Background

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

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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

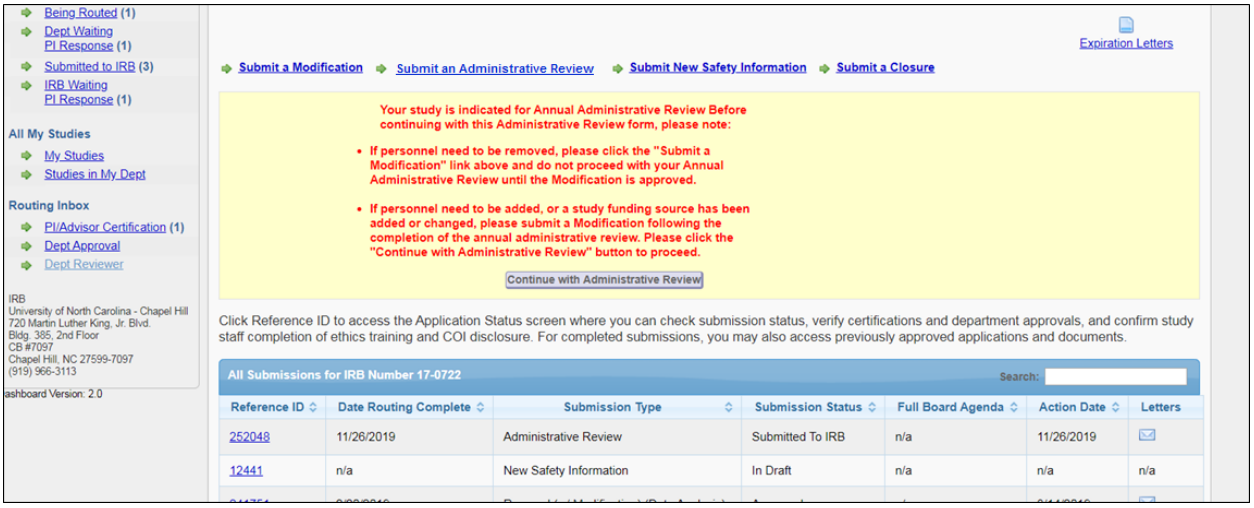
Similarly to the traditional Continuing Review Renewal process, you will receive an email reminder that your UNC Administrative Review Due Date is approaching 60 days prior. At that time, you should confirm that your Research Project Personnel and Funding Source information is up to date on your IRB 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.

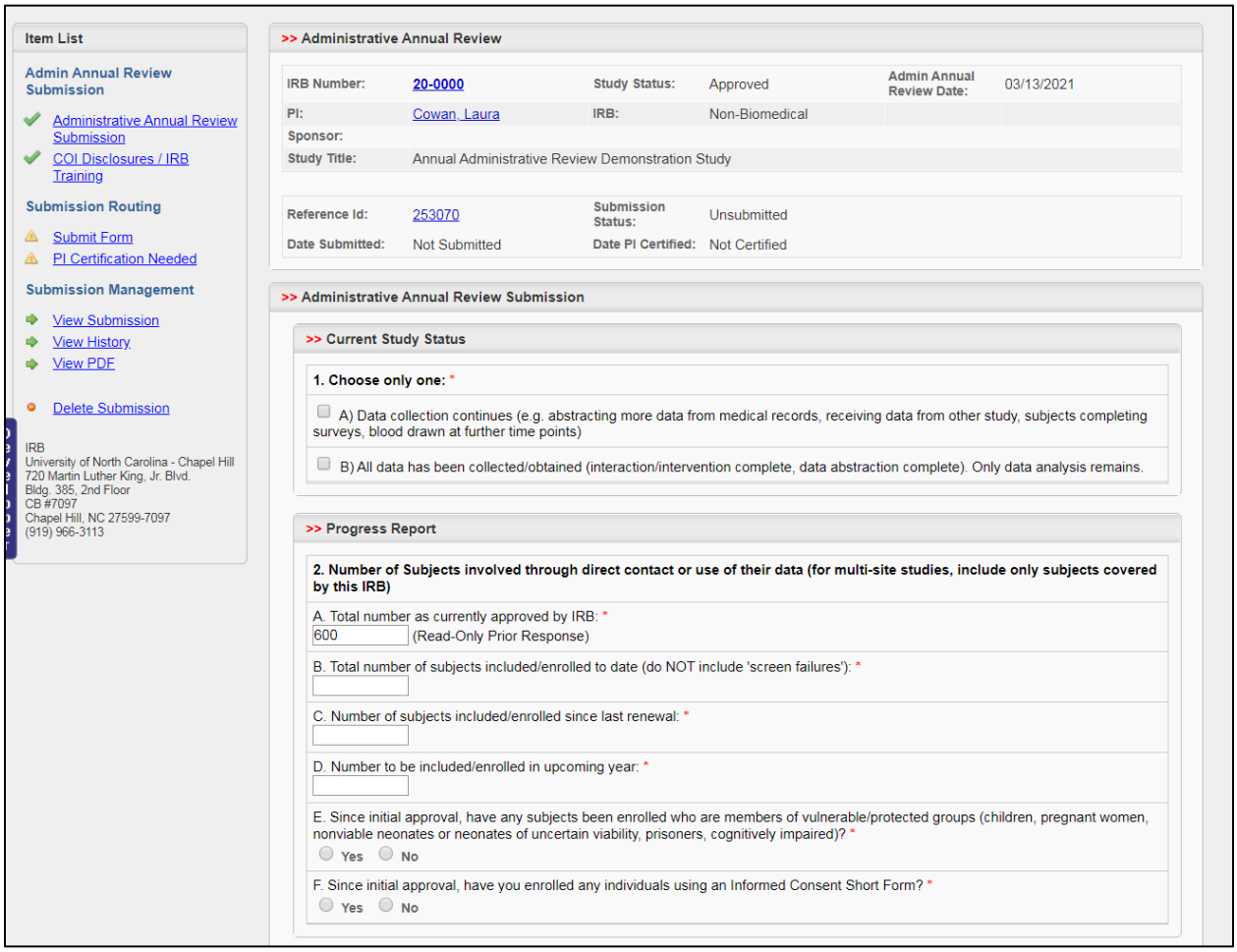
How to submit for administrative review, including new IRBIS form

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

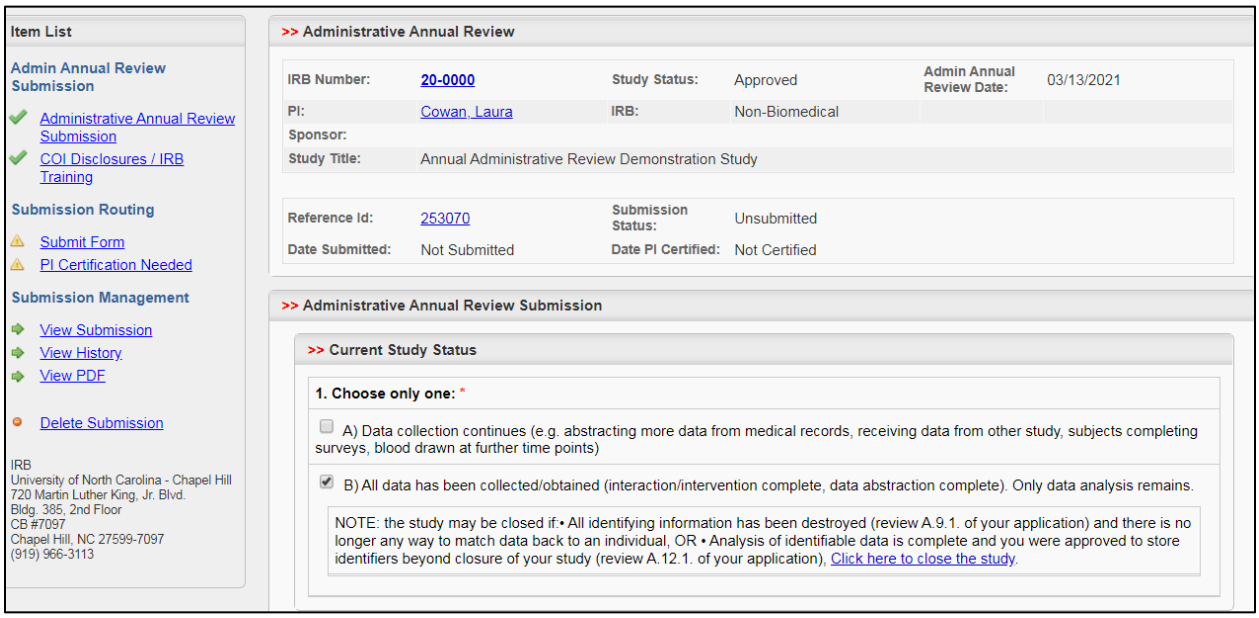


You will then see some instructional text which notes that your study is indicated for Administrative Annual Review. Before proceeding, please review if any personnel or funding source changes are required.

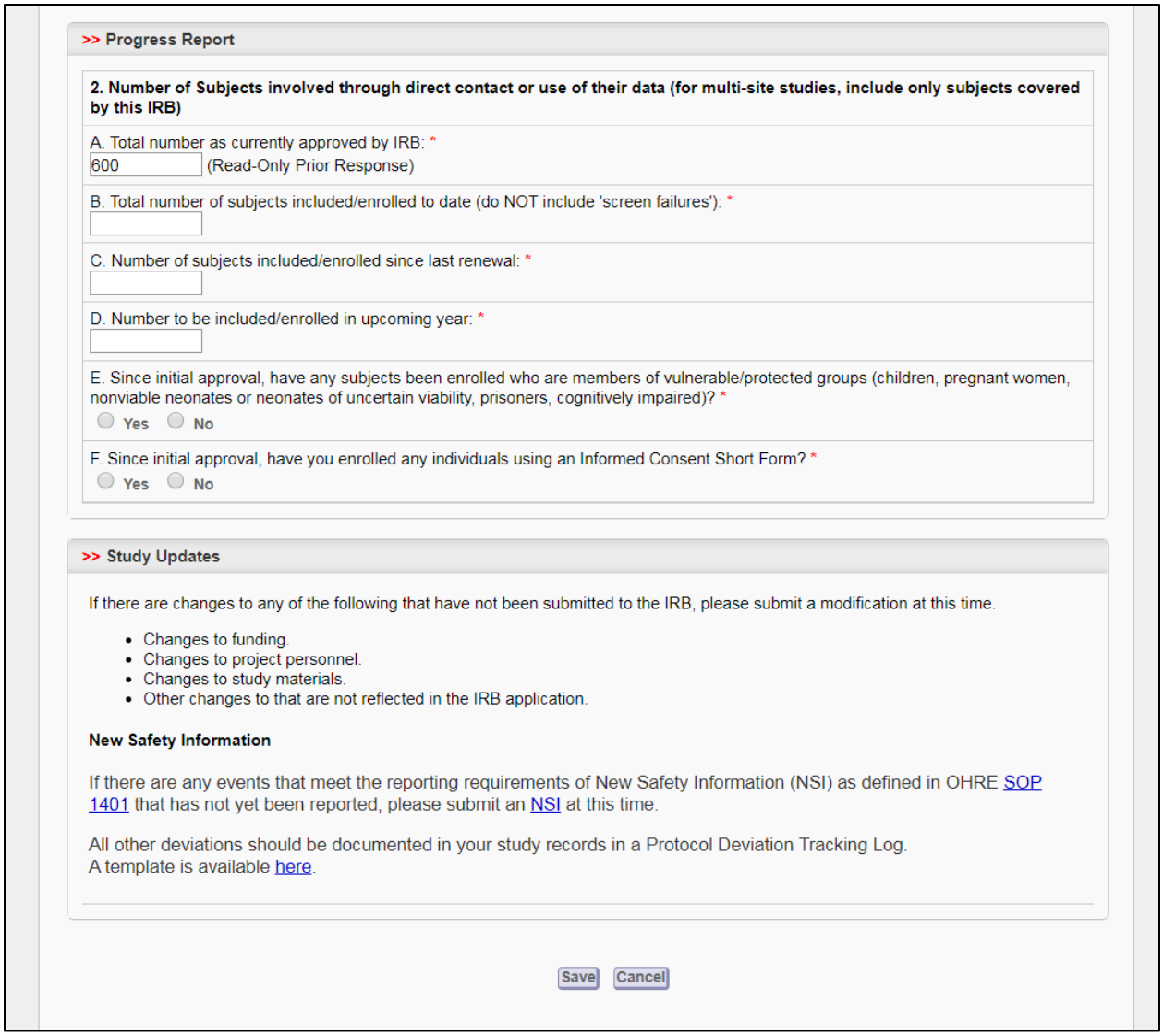
The Administrative Annual Review form is very brief. The first two sections contain two study status options and a short progress report form:



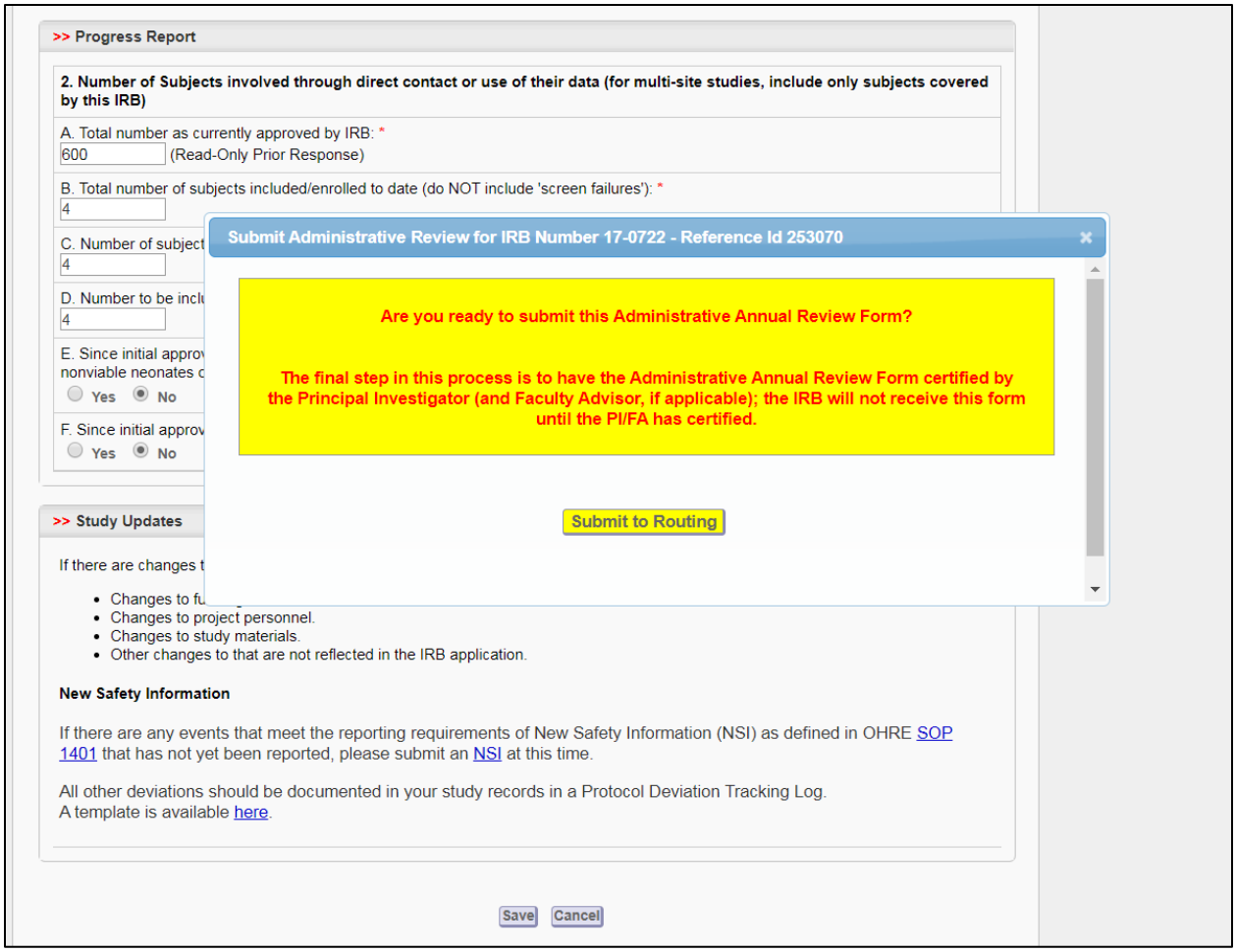
If you select the second option, that your study is in data analysis, we present the option to close your study, if appropriate.



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:



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:



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.