

# PROTECT Tip Sheet for Research Teams:

## “Tips & Tricks: Preparing Continuing Reviews and Study Closures”

### Access to read/write/submit:

- For Continuing Reviews, only **those listed on the study team** for that protocol will have the ability to **create** a continuing review submission and only **the PI/PI proxy** can **submit** continuing reviews.
- If someone is only listed as a Guest or as a Primary Contact on the study, they will only be able to **view** items related to that study. They will not be able to create, edit or submit any form for that protocol (except for RNIs, any user of the system can submit an RNI).
- If an ancillary review is added to a Continuing Review, once the ancillary review is managed, those on the committee will have **read only access** to the Continuing Review form, documents, and the entire study workspace.

### Continuing Review Submission Form:

- The Continuing Review submission form is now more abbreviated and only contains items specific to the IRB for review.

You Are Here: COX in Neurodegenerative Brain... > \_IRBSubmission

### Creating New: IRB Submission

**Modification / Continuing Review / Study Closure**

\* What is the purpose of this submission? ?

Continuing Review

Modification / Update

Modification and Continuing Review

[Clear](#)

**Active Modification For This Study**

Modification / Update #4 for Study COX in Neurodegenerative Brain Disease

\* Does this action require review by your IC DEC office?

Yes  No [Clear](#)

- Questions 1, 2 and 3 are where you will input your enrollment totals for your protocol. We **NO LONGER** include the CIER data table that was used previously in the Continuing Review Form. The CIER data is submitted each year to OPS for tracking via the [PQS system](#). Click the question mark 'Help' icons ? at the end of the questions for tips on how to answer each question.

You Are Here: COX in Neurodegenerative Brain... > Continuing Review for Study CO...

### Editing: CR000752

**Continuing Review / Study Closure Information**

1. \* Specify enrollment totals at this investigator's sites: ?

2. \* Specify enrollment totals at this investigator's sites since last approval: ?

3. \* Specify enrollment totals study-wide: ?

- We do not track CT.gov recruitment status in the PROTECT system, only the study status. Question 4 on the CR form is the **only place** in the PROTECT system that indicates your recruitment status which is answered at the time of Continuing Review.

**4. Research milestones:** (select all that apply)

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information/biospecimens is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information/biospecimens is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

**i Important!** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

- If a study, for example, transitions to data analysis, the study team will only update OPS on this via [PQS](#) and will wait until their next Continuing Review to update the IRB using the Continuing Review Form.
- Number 5 of the Continuing Review form is where you will indicate any important information that has occurred since the previous CR. Leave items **unchecked** that occurred since the past CR. If any items are left unchecked, upload a Word Document in the “attach files” section with an explanation of each item left unchecked. (You do not need one document for each explanation. A summary of all events in one single document is fine.) Redacted consents, if there was enrollment in the past year, should also be attached here.

**5. Check the items that are true since the last IRB approval for all sites involved in the study:** (initial review or last continuing review)

- NO subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- NO subjects withdrew from the study
- NO unanticipated problems involving risks to subjects or others
- NO complaints about the study
- NO publications in the literature relevant to risks or potential benefits
- NO interim findings
- NO multi-center trial reports
- NO data safety monitoring reports
- NO regulatory actions that could affect safety and risk assessments
- NO other relevant information regarding this study, especially information about risks
- In the opinion of the PI, the risks and potential benefits are unchanged
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted
- NO short form has been used
- NO non-compliance has occurred (including minor or major deviations)

**6. Attach supporting documents:** (include an explanation of each item left unchecked above)

Name
There are no items to display

If your study was approved with the use of a consent form document(s), and subjects have been enrolled since the last review, a redacted copy of the consent, normal volunteer, assent) must be uploaded. Redacted consents are full copies of signed consent forms with blacked out patient identifiers.

Please REDACT:  
Participant's name, initials, signature, identification number/barcode, and date of birth.

Please DO NOT REDACT:  
Participant's signature date.  
Principal Investigator's signature and signature date.

*Study Closure Submissions:*

- To submit a Study Closure, you will use the same CR form and choose “Continuing Review” as you would do for a standard CR submission:

- Where you indicate a study is being closed is number 4 on the CR form. If the first four boxes apply to the status of your study, all four must be checked off to initiate a study closure.

- Once all are checked, a question will be generated asking you to acknowledge that your study will be closed. This takes your submission down the pathway of being considered for closure by the IRB and ultimately to the 'Closed' state if it is determined to be eligible for closure.

- Continue to fill out the CR form as applicable.
- NOTE: if you have any actions that have not been closed out yet, the system will prompt you that the study cannot be closed until these have been resolved:

ID	Name	State
MOD003602	Modification / Update #5 for Study PSYCHOBIOLOGY OF TEMPERAMENT	Non-Committee Review

Once you have closed the study in PROTECT, this **cannot** be undone by the IRBO. You will have to start over in PROTECT. PLEASE be sure you only submit a study closure when you are absolutely sure you want to close it. Closing a study means that study is completely done. A study closure is not the same as closed to data analysis only. If your study is in data analysis, then it should NOT be closed.

*Continuing Review/Modification Submissions:*

- A new option for researchers in PROTECT is the ability to submit a combined Continuing Review and Modification in the same submission.

- The CR/MOD function will only be available if you don't have any MODs currently being reviewed or if you only have one type of MOD currently being reviewed.

You Are Here: PSYCHOBIOLOGY OF TEMPERAMENT > IRBSubmission

## Creating New: IRB Submission

### Modification / Continuing Review / Study Closure

\* What is the purpose of this submission? ⓘ

Continuing Review  
[Clear](#)

**Active Modification For This Study**  
 Modification / Update #5 for Study PSYCHOBIOLOGY OF TEMPERAMENT

**Modification Type**  
 Other parts of the study  
 Study team member information

You Are Here: Adolescent Depression > IRBSubmission

## Creating New: IRB Submission

### Modification / Continuing Review / Study Closure

\* What is the purpose of this submission? ⓘ

Continuing Review  
 Modification / Update  
 Modification and Continuing Review  
[Clear](#)

**Active Modification For This Study**  
 Modification / Update #4 for Study Adolescent Depression

**Modification Type**  
 Other parts of the study

- Choosing the Modification and Continuing Review option will allow you to fill out the Continuing Review form AND edit your study form based on which type of Modification you choose.

Validate Compare

Modification / Continuing Review

**Continuing Review / Study Closure Information**

Modification Summary

Modification Details

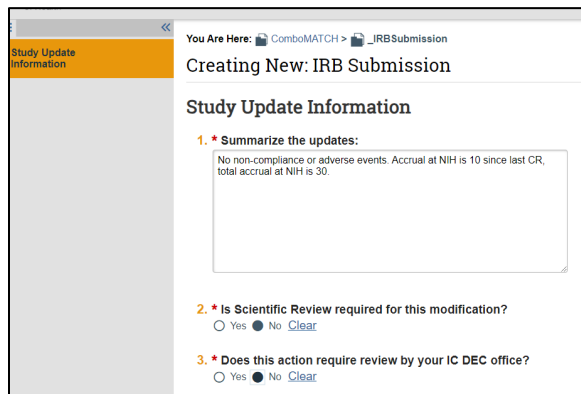
- Whenever you are choosing this option always monitor the expiration date of your protocol. If the expiration date is approaching and you have a significant modification associated with it, the approval of the modification could delay the approval of your Continuing Review and lead to a protocol lapse. In this instance it would be best to submit a **separate** Continuing Review form and Modification form.

### Scientific Review:

- Continuing Reviews are **NOT** linked to any type of Scientific Review submission. The Scientific Review Committees will review the Annual or Quadrennial review that has been submitted to them, not the CR form.

### Continuing Reviews for External IRB studies where NIH is relying on another IRB:

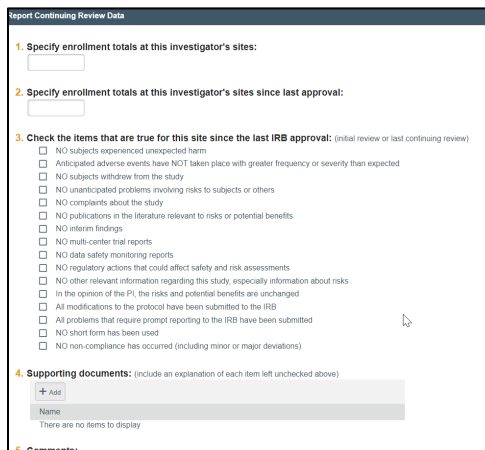
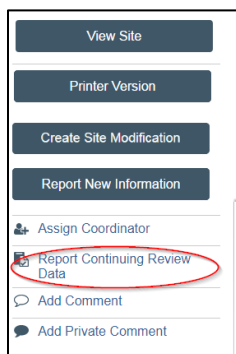
- Continuing Review information for External IRB studies are provided to NIH IRBO through a *Study Update* form.
- In the “Summarize the Updates” section is where you will include a summary of any unanticipated problems (UPs) and/or serious non-compliance that occurred since the last CR or this can be submitted on a separate word document and uploaded as a Supporting Document to the related “Add Comment”.
- You will also include here the number of subjects enrolled at the NIH site since the last CR and the total subject accrual at NIH to date.



- For submissions where the NIH has been closed as a site: Upload the External IRB letter confirming that the NIH site has been closed as a Supporting Document to the “Add Comment”

### Reporting Continuing Review information for Psites where NIH is the Reviewing IRB:

- The enrollment total for participating sites in multi-site studies for which NIH is the reviewing IRB, can be recorded on the site’s page by using the “Report Continuing Review Data” button.



- A form will be generated to input enrollment totals and to report any significant events.