How to Create and Submit a Continuing Review

ePIRATE Training



This tutorial shows you how to create and submit a continuing review in ePIRATE.

Continuing reviews include information about the status of the study, including updates on enrollment and progression of research subjects (or their data in secondary analyses).

Continuing review is not required for all studies following an update to the common rule (implemented January 2019). Studies that display an expiration date on the main study workspace require continuing review and the ePIRATE system will send reminder emails periodically leading up to the expiration date.

The process for extending the expected end date (applies to most studies approved after the previously mentioned rule change) is completed via amendment.

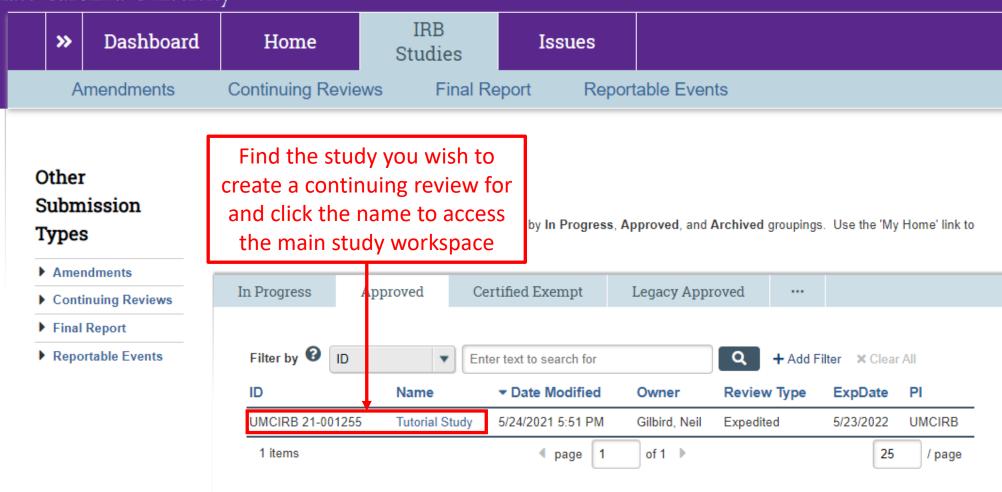
Studies granted an exempt certification do not expire.



***9.11.2020: Existing research studies that are changing their method of paying

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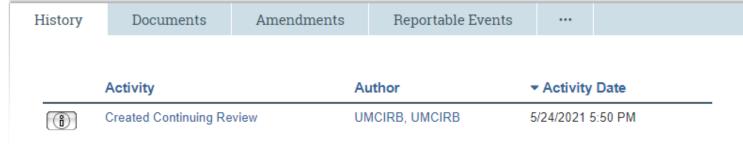
East Carolina University Hello, UMCIRB UMCIRB ▼ **IRB** Dashboard >> Home **Issues** Studies Final Report Reportab Amendments Continuing Reviews If the study has expired it will be found in the "Expired" tab which you Other IRB Studies may need to click the three Submission Click on "Approved" buttons below to find. Welco ies by In Progress, Appre link Types to see the list of submissions related to you. Amendments ••• In Progress Approved Certified Exempt Legacy Approved Continuing Reviews Final Report Reportable Events Filter by 3 Enter text to search for + Add Filter ➤ Clear All Date Review PΙ Name State ID Owner Modified Type MS1 UMCIRB 21-Expedited 5/25/2021 11:15 Gilbird. **UMCIRB Tutorial Study** Amendment 001255 AM Neil Open UMCIRB 18-001624 Test Study 3/4/2021 1:44 Pre **UMCIRB** Exempt PMSubmission 7/6/2020 12:32 **UMCIRB** UMCIRB 14-001022 Neil study Pre Exempt PMSubmission UMCIRB 18-000600 Copy of Neil's Template 3/2/2018 2:09 **UMCIRB** Pre Submission PM UMCIRB 17-002837 Whole Group Instruction verses 11/29/2017 9:37 Pre **UMCIRB** Small Group Instruction PM Submission 11/29/2017 9:33 **UMCIRB** UMCIRB 17-002835 Whole Group Instruction verses Pre Expedited Small Group Instruction PMSubmission How to Upload Documents in 9/8/2017 4:16 **UMCIRB** UMCIRB 15-001136 Pre **ePIRATE** PMSubmission





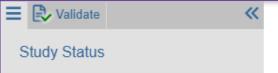






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Number of **Participants**

Reportable Event Details

Research Results

Final Page

The numbers of subjects reported in the continuing review should be accurate at the time of submission and be consistent with any previous continuing reviews.

You Are Here: Tutorial Study > 2022 Review for UMCIRB 21-001...

Editing: CR00009264



R Help

Numbers of Participant Activity

(if this is a record/chart review, this section should include the numbers of records/charts reviewed)

- Total enrollment requested for local site:
- Total individuals who have signed the informed consent at this
- Total individuals who have signed informed consent for this site since last continuing review (if this is the first continuing review, this number will be the same as in question 2.0 above):
- Total who have completed all research related interventions or 4.0 interactions required by study:
- Total continuing to receive research related interventions or 5.0 interactions:

Total in follow-up (e.g., not receiving research related intervention, but study team may still have contact with the participant for follow-up or access a participant's medical record to collect clinical data):

The UMCIRB needs to know how many subjects have been enrolled and where they are in the study. If the study is only utilizing secondary data, include the number of records accessed by the study team.

Provide any comments/clarifications regarding the number of participants above:

* Has the entire project or local site exceeded the proposed sample size? O Yes O No !

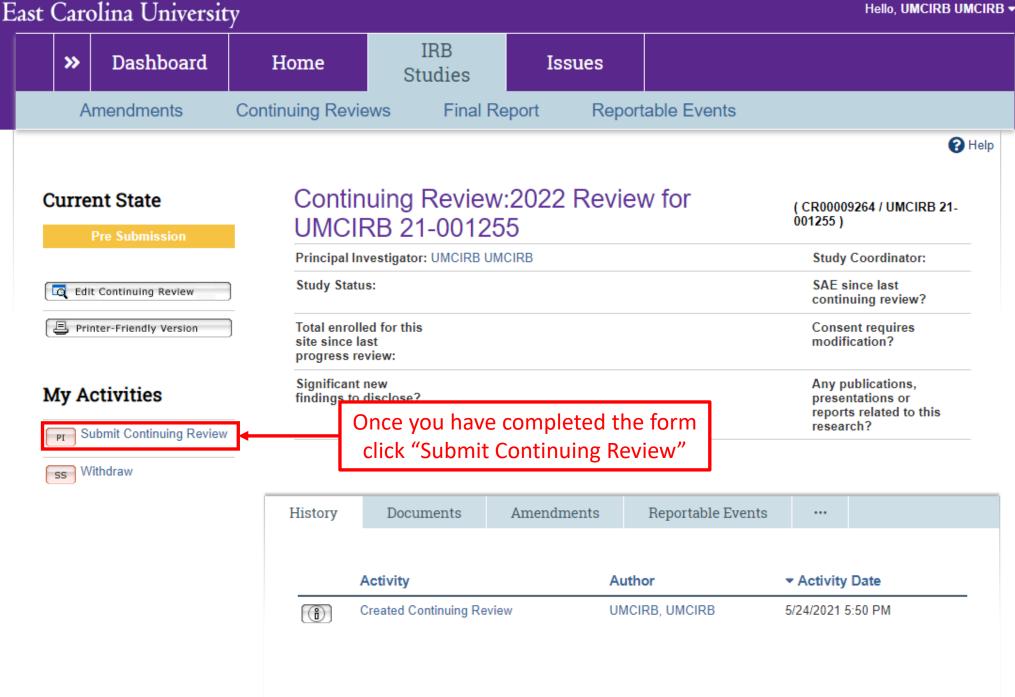


3 Exit



■ Save

Continue 🔿



Submit Continuing Review

Use this form to submit your **completed continuing review**. If you click **ok**, you are no longer able to modify the continuing review. You will be notified about the review result by email. If you are not ready for submission, click **cancel**.

Click "OK" to submit the continuing review for review

Cancel