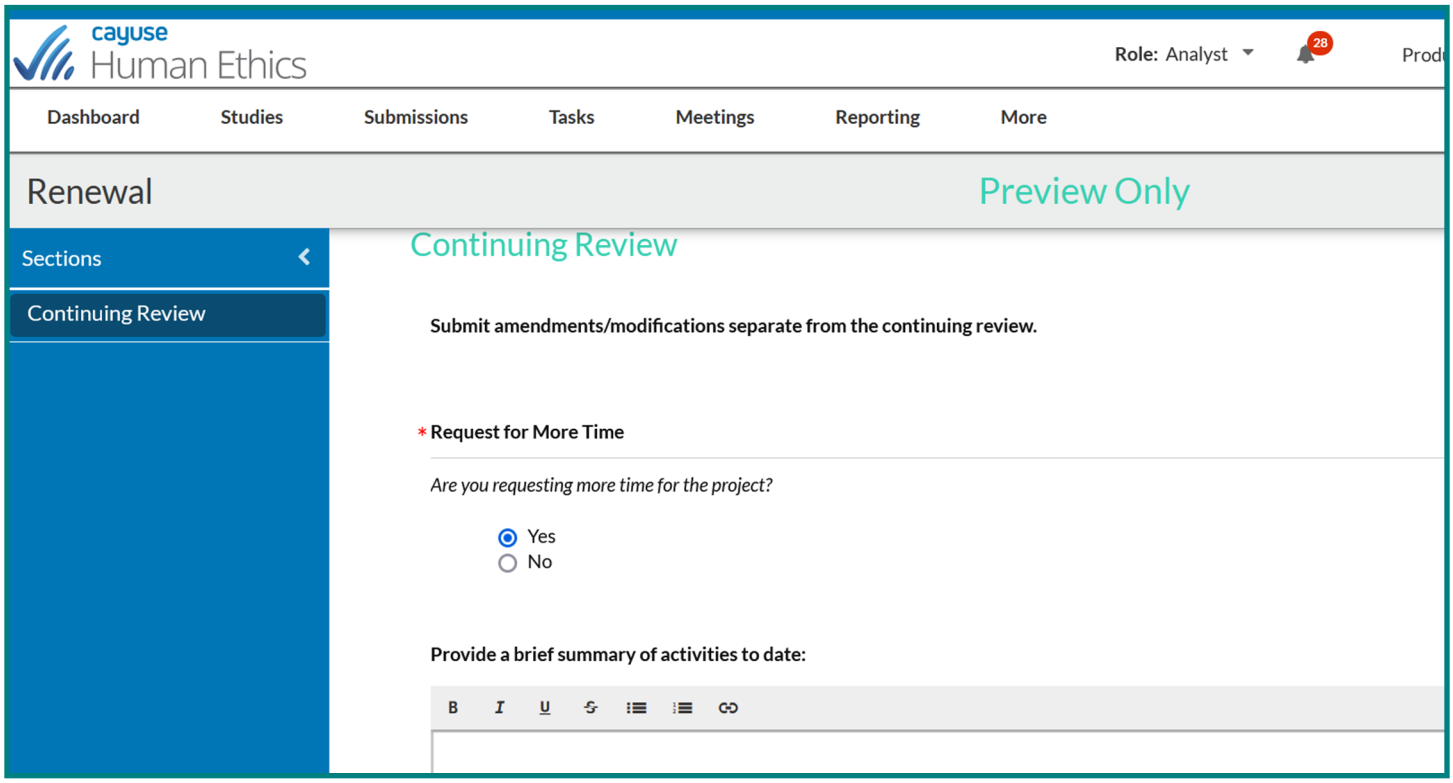
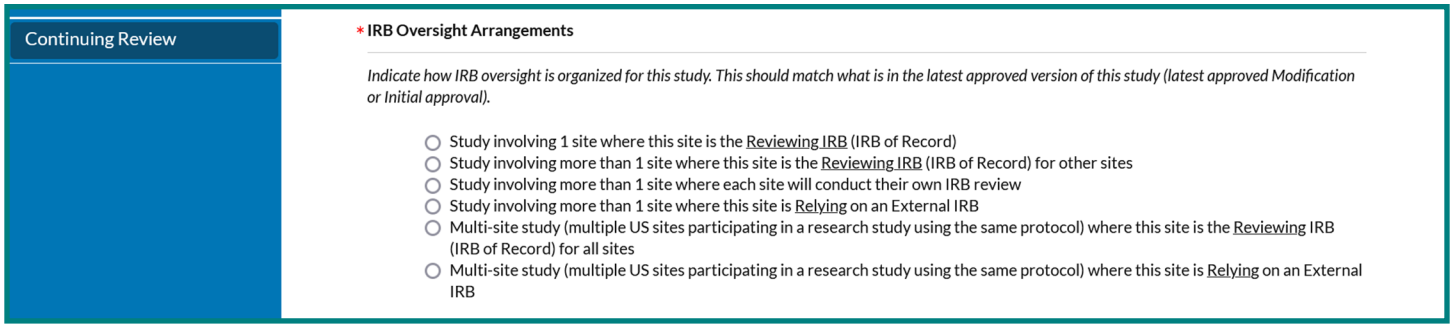
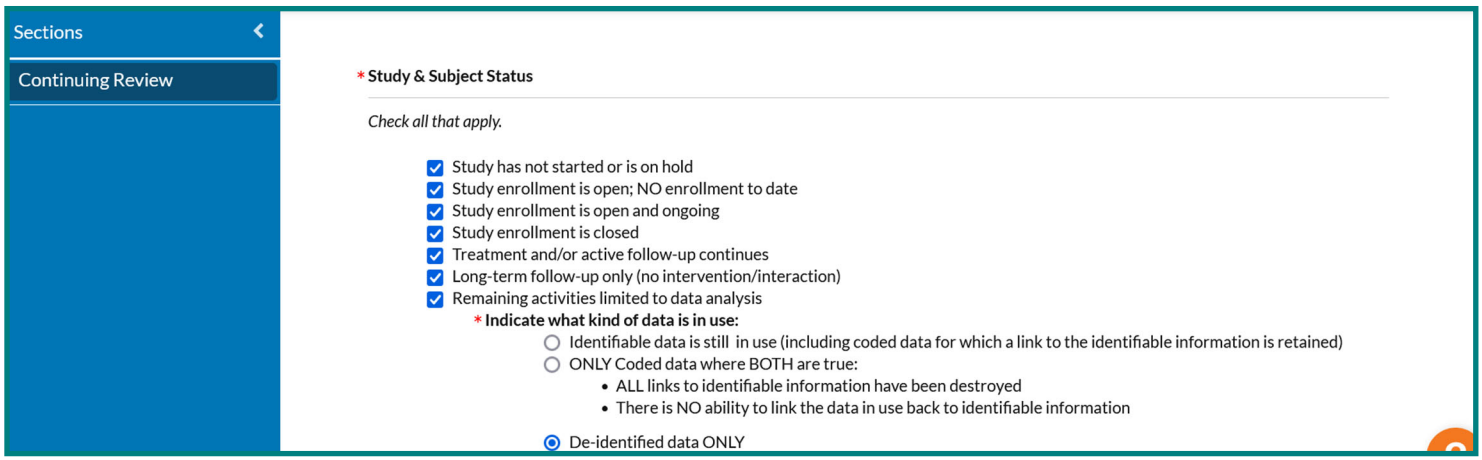
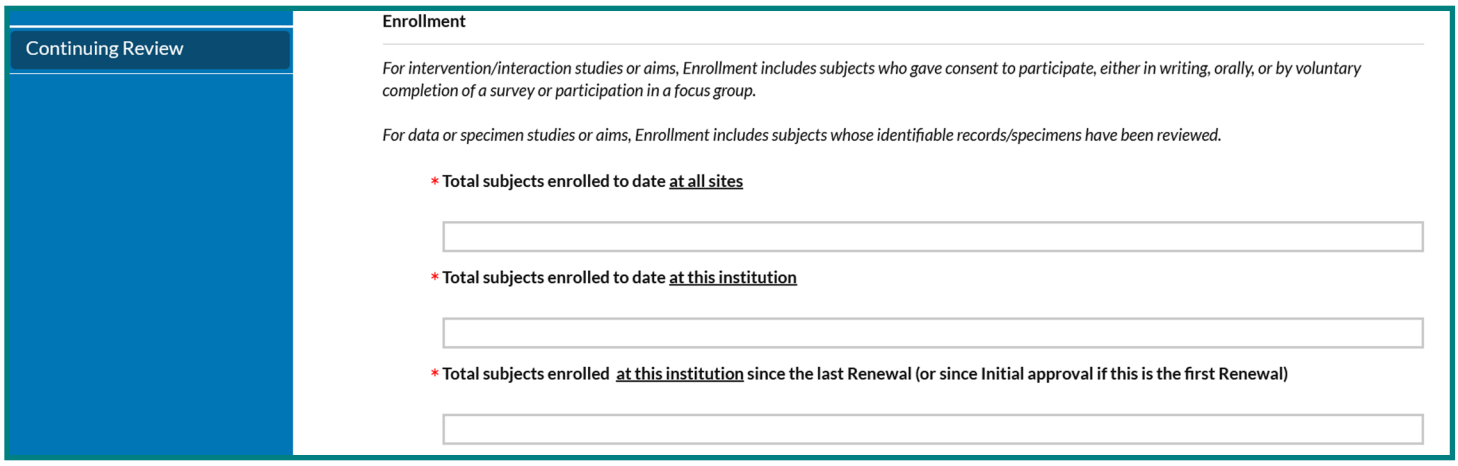
Renewal/Continuing Review

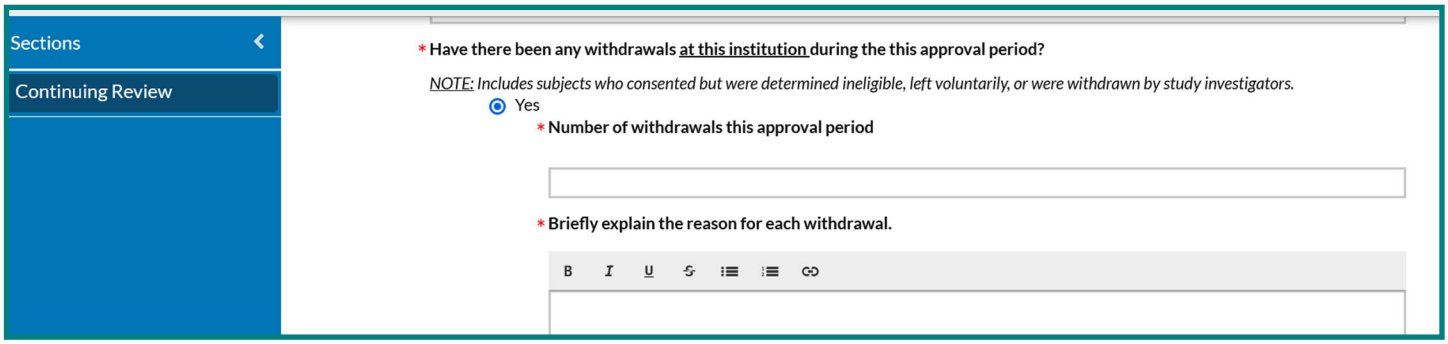
Some changes have been made to the form after initial upload of Legacy data. There may be some variations between a legacy submission and later submissions.

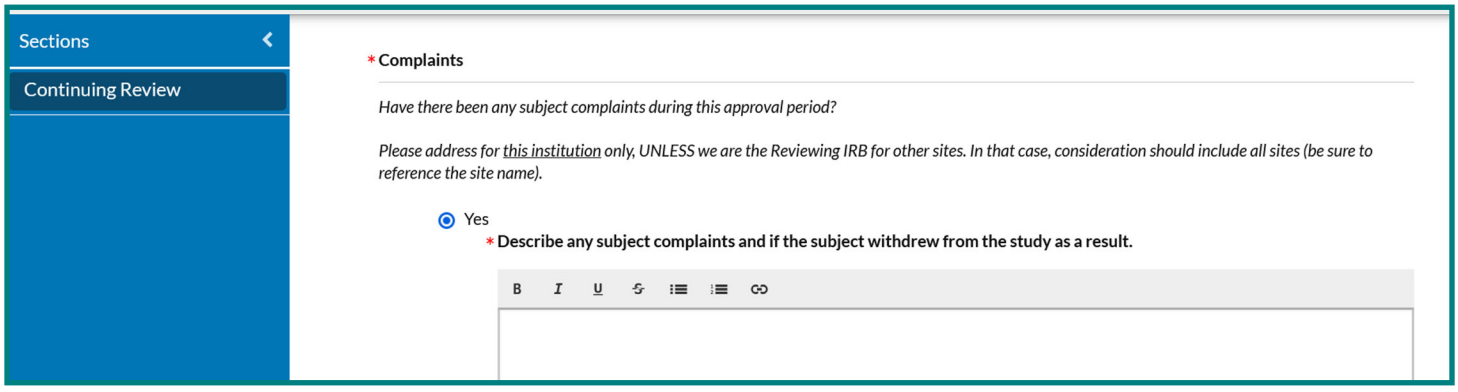


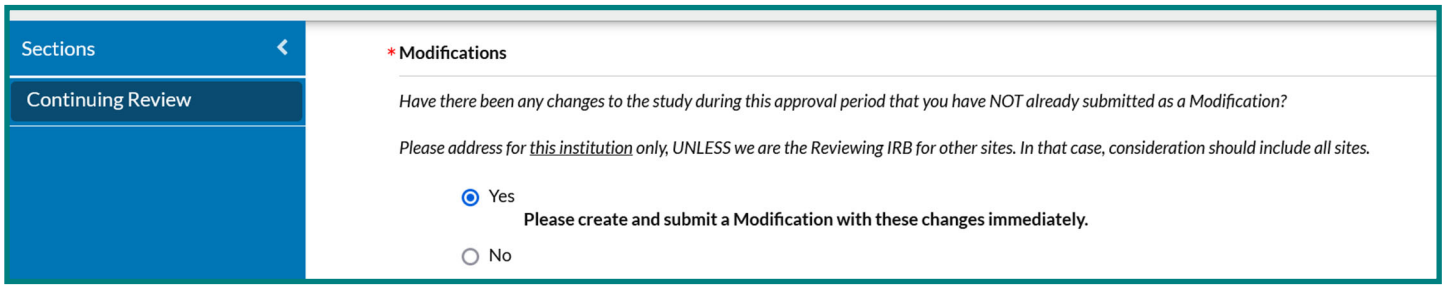


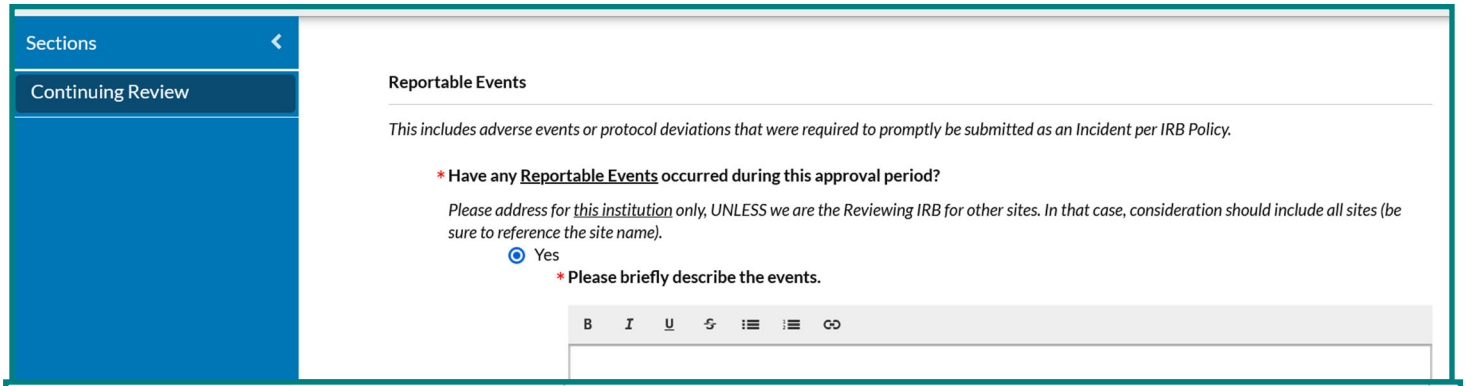


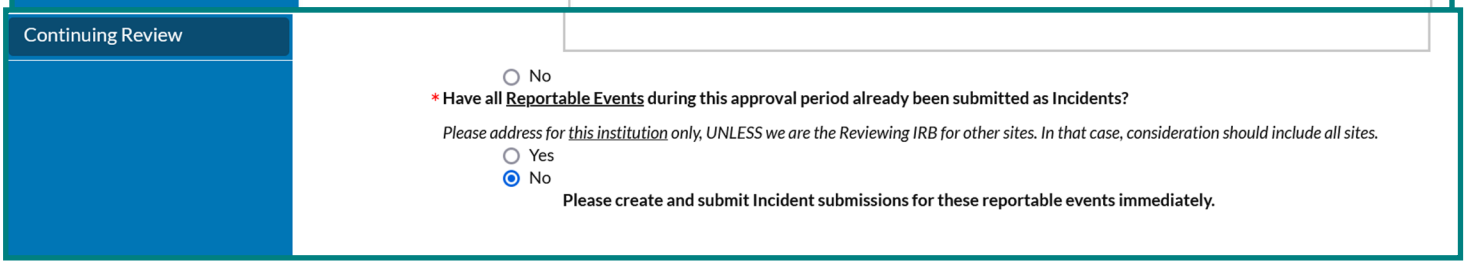

Continuing Review
Enrollment
For intervention/interaction studies or aims, Enrollment includes subjects who gave consent to participate, either in writing, orally, or by voluntary completion of a survey or participation in a focus group.
For data or specimen studies or aims, Enrollment includes subjects whose identifiable records/specimens have been reviewed.
* Total subjects enrolled to date at all sites
* Total subjects enrolled to date at this institution
* Total subjects enrolled at this institution since the last Renewal (or since Initial approval if this is the first Renewal)

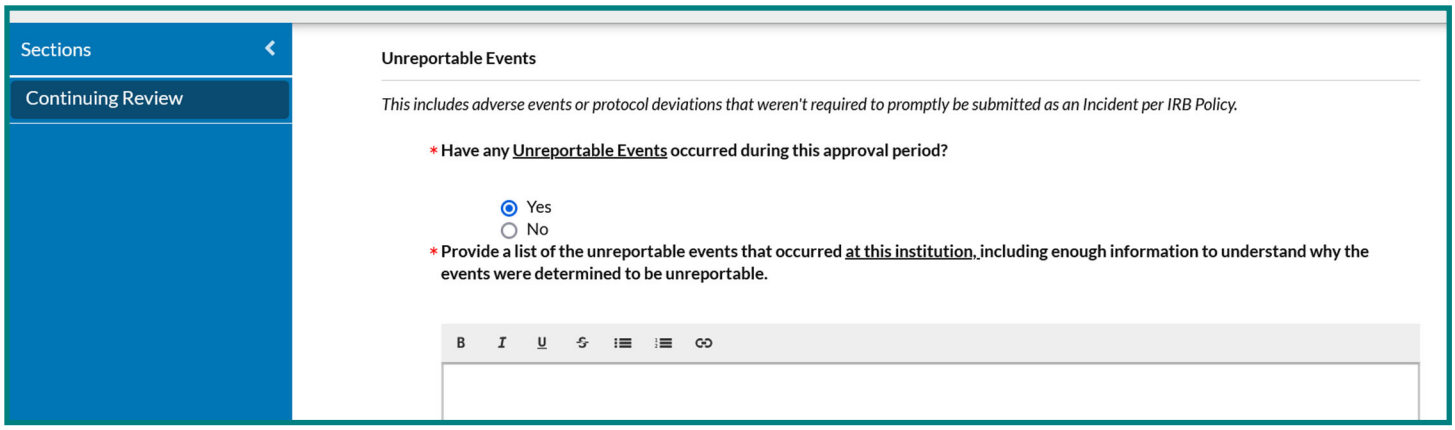

Sections
Continuing Review
* Have there been any withdrawals at this institution during the this approval period?
NOTE: Includes subjects who consented but were determined ineligible, left voluntarily, or were withdrawn by study investigators.
Yes
* Number of withdrawals this approval period
* Briefly explain the reason for each withdrawal.

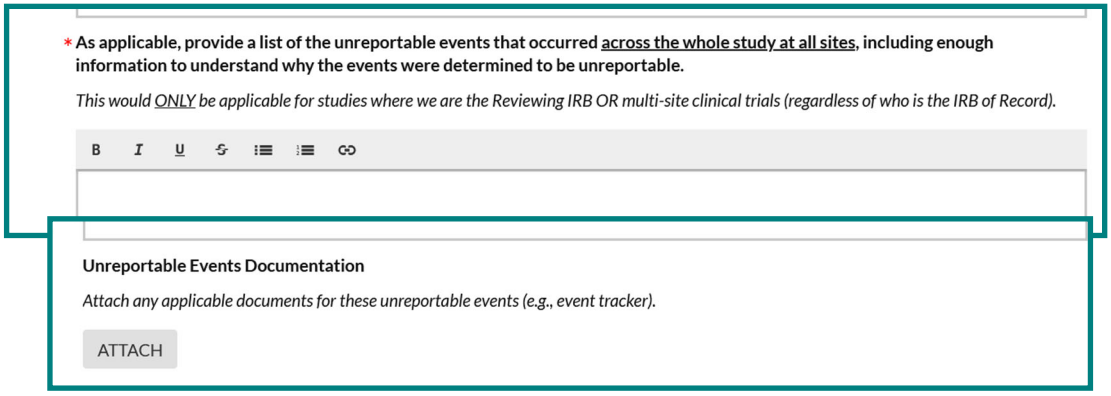

Sections
Continuing Review
* Complaints
Have there been any subject complaints during this approval period?
Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites (be sure to reference the site name).
Yes
* Describe any subject complaints and if the subject withdrew from the study as a result.


Sections
Continuing Review
* Modifications
Have there been any changes to the study during this approval period that you have NOT already submitted as a Modification?
Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites.
Yes
Please create and submit a Modification with these changes immediately.
No

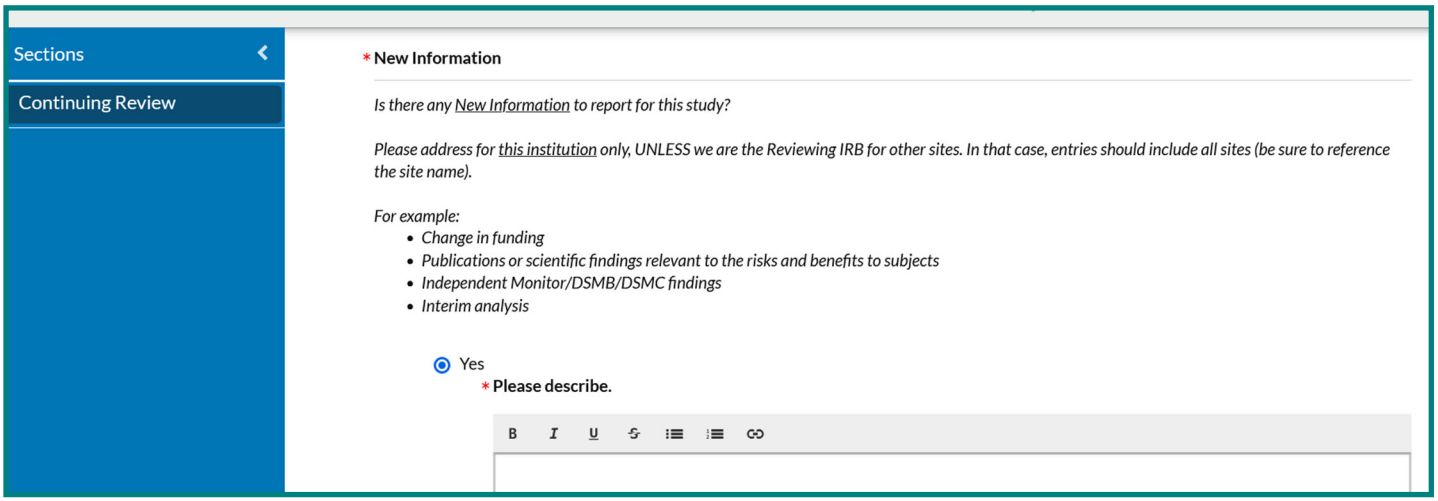

Sections
Continuing Review
Reportable Events
This includes adverse events or protocol deviations that were required to promptly be submitted as an Incident per IRB Policy.
* Have any Reportable Events occurred during this approval period?
Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites (be sure to reference the site name).
Yes
* Please briefly describe the events.

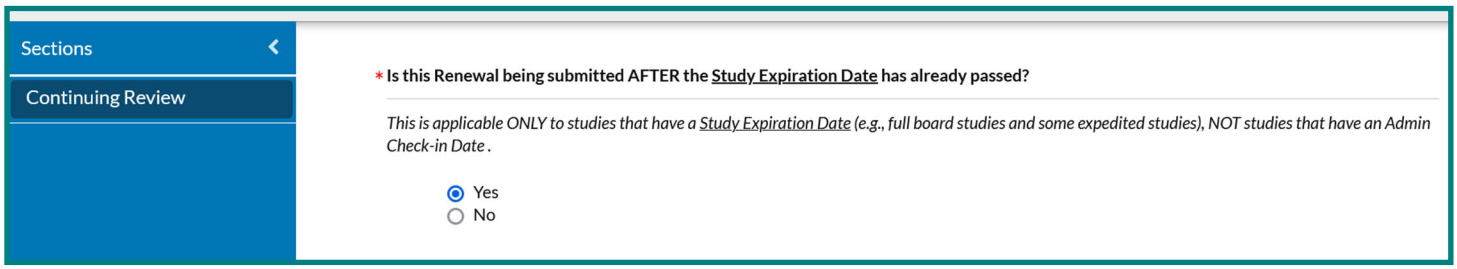

Continuing Review
No
* Have all Reportable Events during this approval period already been submitted as Incidents?
Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites.
Yes
No
Please create and submit Incident submissions for these reportable events immediately.

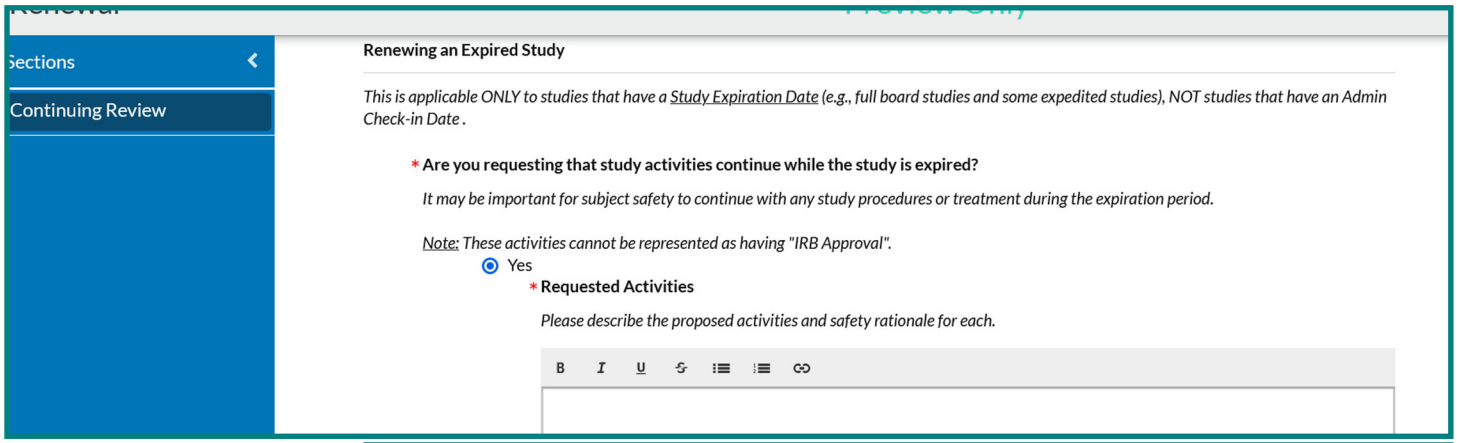

Sections
Continuing Review
Unreportable Events
This includes adverse events or protocol deviations that weren't required to promptly be submitted as an Incident per IRB Policy.
* Have any Unreportable Events occurred during this approval period?
Yes
No
* Provide a list of the unreportable events that occurred at this institution, including enough information to understand why the events were determined to be unreportable.

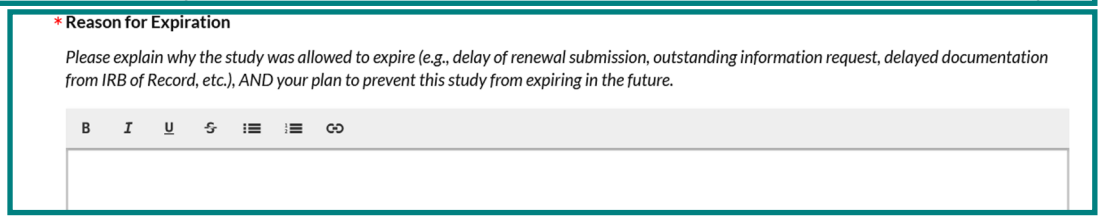

* As applicable, provide a list of the unreportable events that occurred across the whole study at all sites, including enough information to understand why the events were determined to be unreportable.
This would ONLY be applicable for studies where we are the Reviewing IRB OR multi-site clinical trials (regardless of who is the IRB of Record).

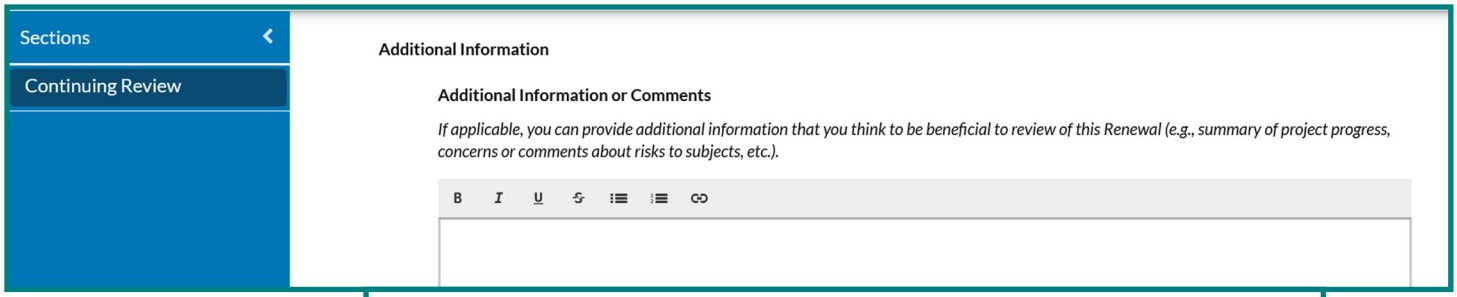
Unreportable Events Documentation
Attach any applicable documents for these unreportable events (e.g., event tracker).
ATTACH

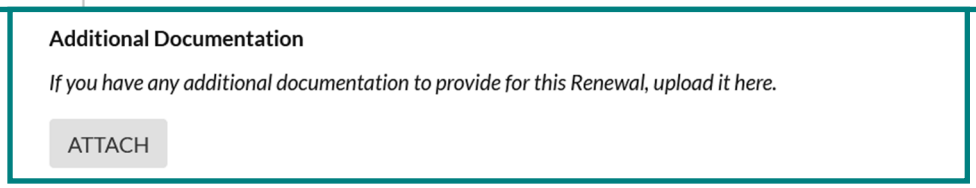

Sections
Continuing Review
* New Information
Is there any New Information to report for this study?
Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, entries should include all sites (be sure to reference the site name).
For example:
Change in funding
Publications or scientific findings relevant to the risks and benefits to subjects
Independent Monitor/DSMB/DSMC findings
Interim analysis
Yes
* Please describe.


Sections
Continuing Review
* Is this Renewal being submitted AFTER the Study Expiration Date has already passed?
This is applicable ONLY to studies that have a Study Expiration Date (e.g., full board studies and some expedited studies), NOT studies that have an Admin Check-in Date .
Yes
No


Sections
Continuing Review
Renewing an Expired Study
This is applicable ONLY to studies that have a Study Expiration Date (e.g., full board studies and some expedited studies), NOT studies that have an Admin Check-in Date .
* Are you requesting that study activities continue while the study is expired?
It may be important for subject safety to continue with any study procedures or treatment during the expiration period.
Note: These activities cannot be represented as having "IRB Approval".
Yes
* Requested Activities
Please describe the proposed activities and safety rationale for each.


* Reason for Expiration
Please explain why the study was allowed to expire (e.g., delay of renewal submission, outstanding information request, delayed documentation from IRB of Record, etc.), AND your plan to prevent this study from expiring in the future.


Sections
Continuing Review
Additional Information
Additional Information or Comments
If applicable, you can provide additional information that you think to be beneficial to review of this Renewal (e.g., summary of project progress, concerns or comments about risks to subjects, etc.).


Additional Documentation
If you have any additional documentation to provide for this Renewal, upload it here.
ATTACH