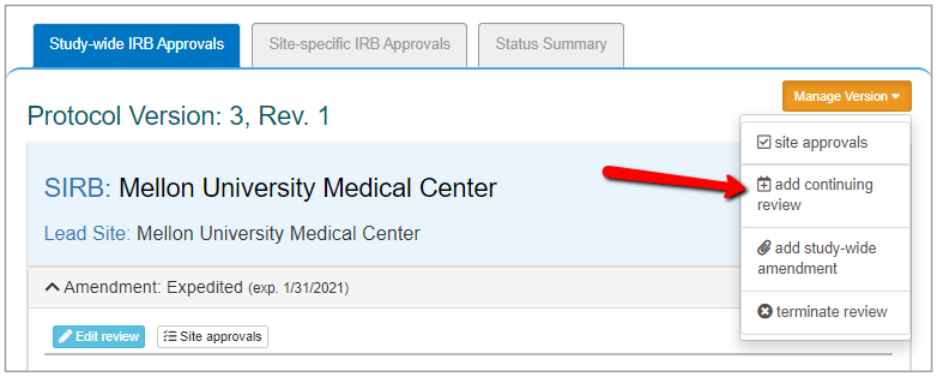
IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

HOW TO UPLOAD CONTINUING REVIEW APPROVALS IN IREx – STUDY MANAGERS

IRB Reliance Exchange ("IREx") can be used to document and communicate the continuing review approval for participating sites. However, IREx does not currently capture the information the Reviewing IRB needs to conduct the continuing review for participating sites. This information is captured outside of IREx.

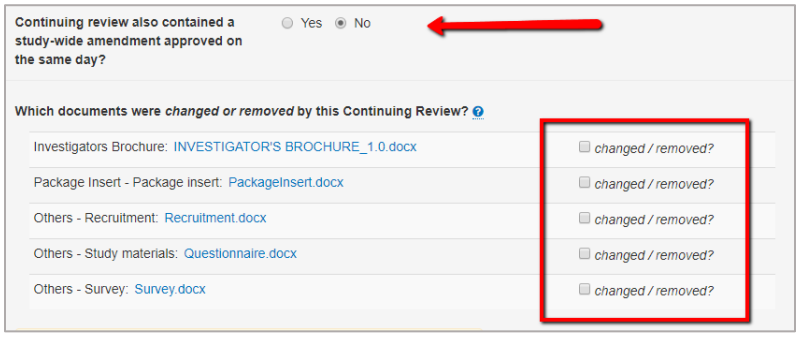
UPLOADING CONTINUING REVIEW APPROVALS FOR THE OVERALL STUDY

As of March 2020, the Reviewing IRB or ****NEW** Study Manager (SM)** can upload the lead site or overall study approval at continuing review, which must be uploaded before site approvals can be uploaded.



A. On the Study-wide IRB Approvals tab, click the **Manage Version** button and select **add continuing review**.

B. Before adding the information about the review and approval, a pop-up will ask if the continuing review also included a study-wide amendment – Yes/No. If yes, provide the required information about whether the protocol was changed and a change summary.



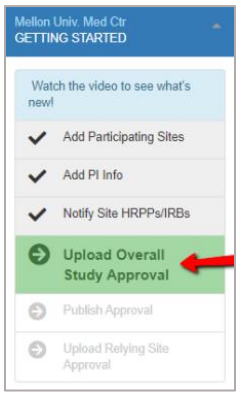
C. The pop-up also asks what *documents changed* at continuing review. These documents will remain in archived versions, but will not be carried forward into the new approval.

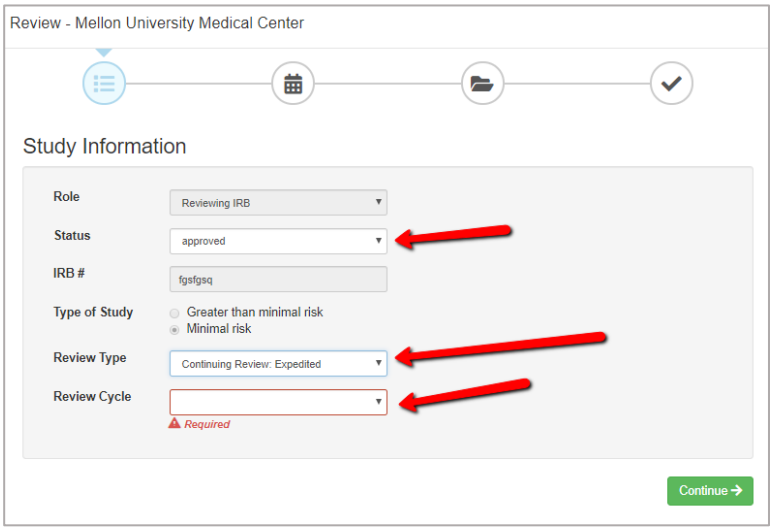
Tip: Previously approved consents will be automatically removed. You can upload the newly stamped consents and new documents in the steps ahead.

D. Click **Save**.

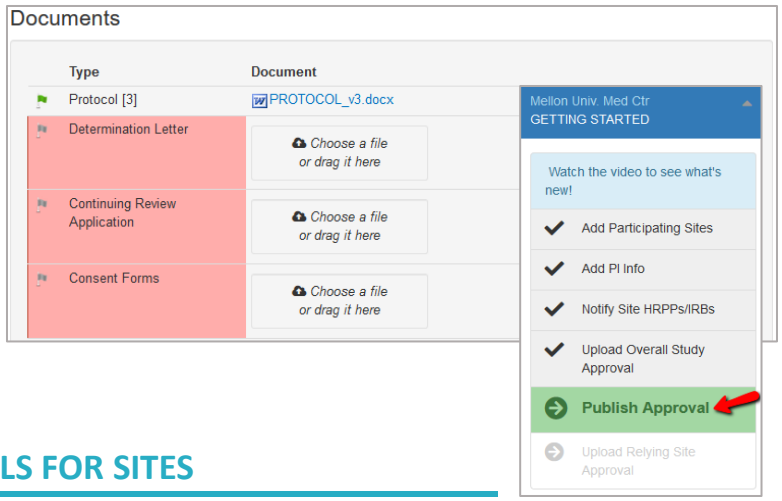
The continuing review has been created. You can now upload the approval for the lead site/ overall study.

1) From the Getting Started Checklist, click **Upload Overall Study Approval**.
2) Change the Status to **approved** and complete the required fields (highlighted in red) on each page, clicking continue to move forward.





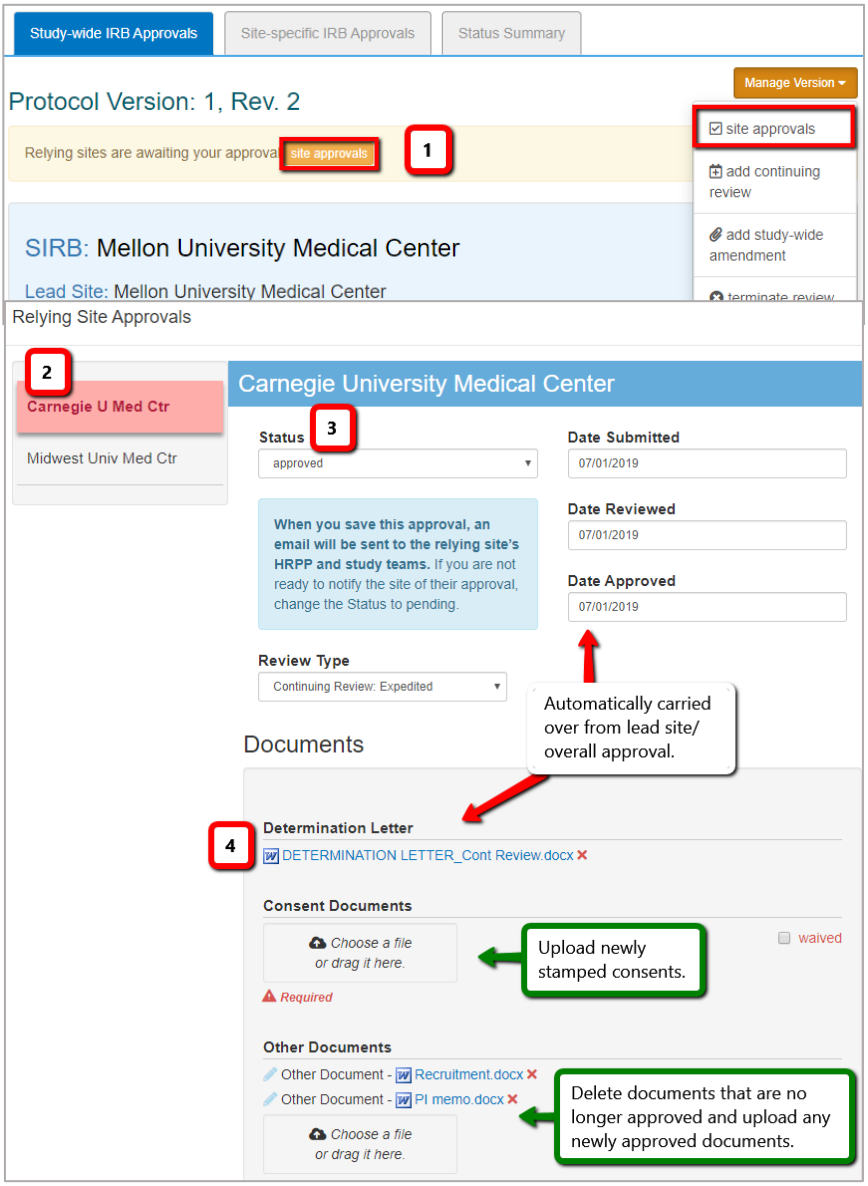
3) Upload the newly approved documents, like the *determination letter, continuing review application, newly stamped consent documents,* and any other new or updated documents for the lead site/overall study. Required documents will be marked in red.
4) Review the study information and click **Save**.
5) Click **Publish Approval** on the Getting Started Checklist to make the documents visible to sites. Tip: Sites are not notified of the new overall, approval. They are notified when their site-specific approval documents are uploaded in the next step.



UPLOADING CONTINUING REVIEW APPROVALS FOR SITES

AFTER the continuing review approval has been uploaded for the lead site/ overall study, site approvals can be added.

1) Click on the orange **site approvals** button on the Study-wide IRB Approvals tab or select it from the Manage Version menu.
2) In the Relying Site Approvals dialog, select the **name of the site** for which you are uploading approval.
   Tip: The dates and determination letter from the overall study approval will be auto-populated for all sites that had approval on the previous version. Other site-specific documents that were approved in the previous version will also be carried forward.
3) Change the Status to **approved** and ensure the correct *Review Type* is selected.
   Tip: All sites who have ceded review appear in the Relying Site Approvals dialog, but only sites approved on the previous version will have a have a review type of Continuing Review: Full/Expedited.
4) **Upload the new consent forms and ensure the correct versions of all other approved documents are listed for the site.**
5) Click **Save**.



IREx will notify the (1) Reviewing IRB Liaisons, (2) site Liaison(s), (3) the IREX Study Manager(s), and (4) site study contacts in IREx of the new approval. The documents will appear on the Site-specific IRB Approvals tab.

Tip: You can upload approvals for more than one participating site at a time. Select another site name and complete steps 2-5 before saving.