

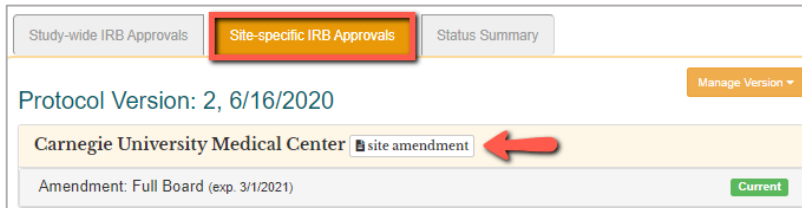
HOW TO UPLOAD A SITE AMENDMENT APPROVAL IN IREx

IREx can be used to document and communicate the approval of **Site Amendments** that only affect a single site, such as PI changes. Study-wide Amendments are also captured in IREx and include changes to the protocol or other study materials that apply to ALL sites (see [quick guide](#)).

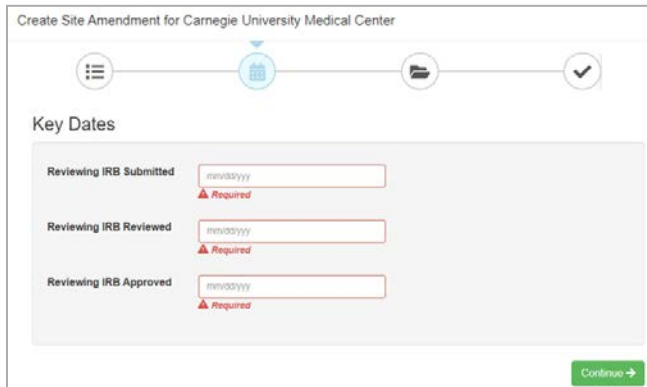
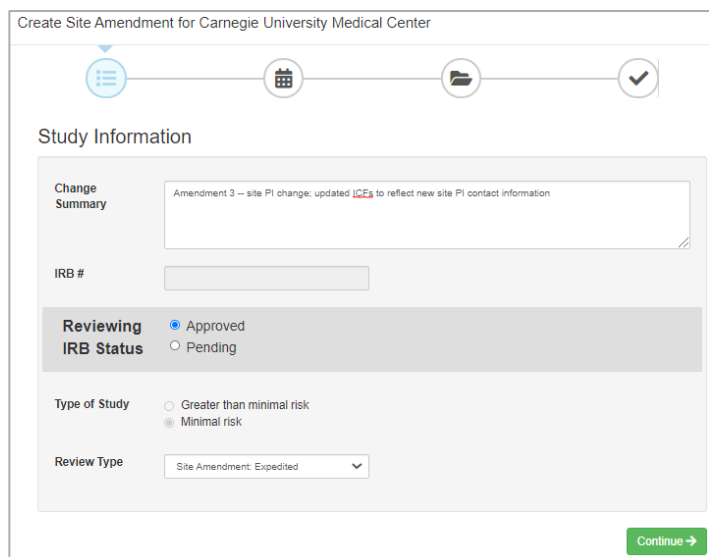
UPLOADING A SITE AMENDMENT

Follow the steps below to upload a site amendment for a site that already has initial approval in IREx.

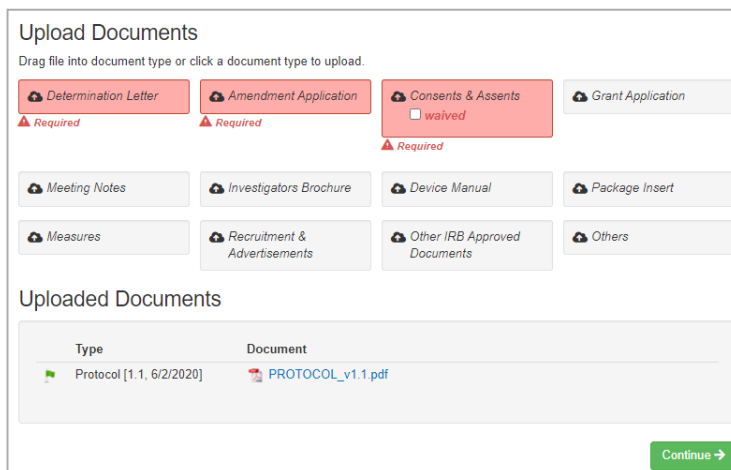
- From the Site-specific IRB Approvals tab, click **site amendment** beside the site's name.



- In the Create Site Amendment dialog:
 - Enter a **Change Summary** describing the changes.
 - Change the Reviewing IRB Status to **Approved**.
 - Select the appropriate **Review Type**, Site Amendment: Full Board/Expedited
 - Click **Continue**.
- Enter the Key Dates Reviewing IRB *Submitted*, *Reviewed*, *Approved*, and click **Continue**.

- Upload the **Determination Letter** for the amendment and any other new or updated documents for the site. Be sure to remove any documents that are no longer in use or approved. Then click **Continue**.



- Review the study information. If required fields are missing, the section will be highlighted.
- Click **Save**. IREx will notify the following users of the new approval:
 - Reviewing IRB Liaisons
 - site Liaison(s)
 - the IREx Study Manager(s)
 - site study contacts in IREx

The documents will appear on the Site-specific IRB Approvals tab.