

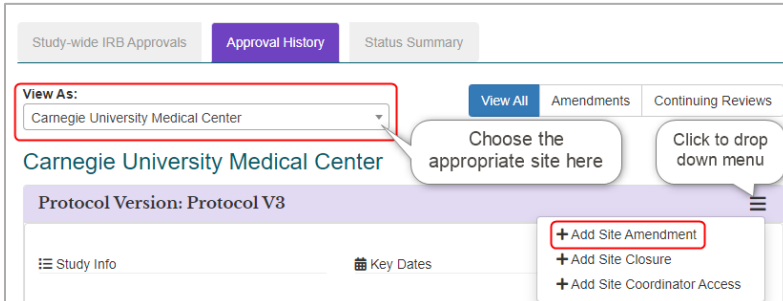
HOW TO UPLOAD A SITE AMENDMENT APPROVAL IN IREx

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, which are changes affecting ALL sites, are also captured in IREx (see [quick guide](#)).

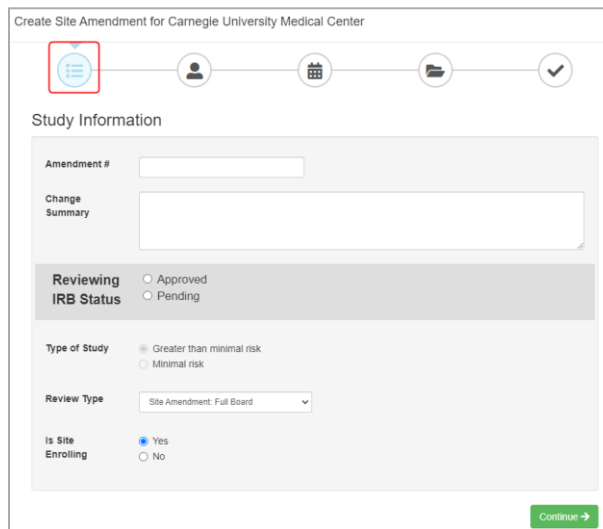
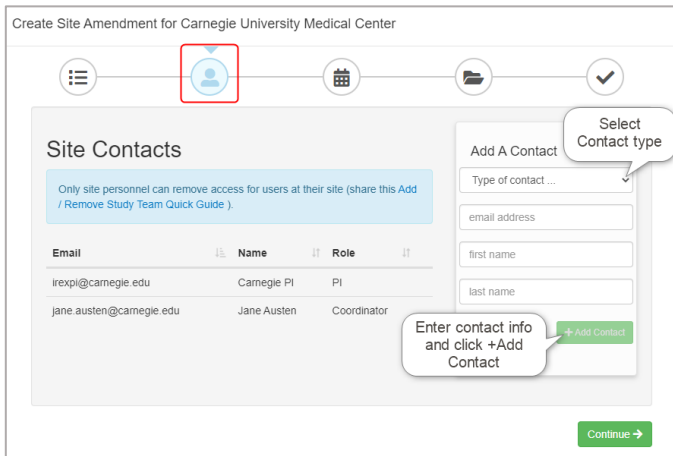
UPLOADING A SITE AMENDMENT

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

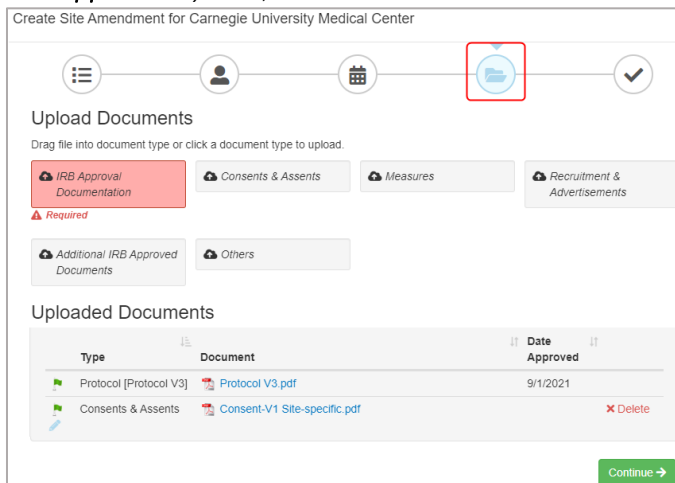
1. From the **Approval History** tab **View As** menu, select a site
2. From the menu (stacked lines) click **+ Add Site Amendment**.



3. In the Create Site Amendment dialog,
 - a. Enter a **Change Summary** describing the changes;
 - b. Change the **Reviewing IRB Status** to Approved; and
 - c. Complete the remaining required fields (marked in red).
4. ****NEW**** Continue to update new **Site Contacts**. If a new PI was approved in the site amendment, you can add the new PI. New site coordinators can also be added.

5. Enter the Key Dates: **Submitted** to Reviewing IRB, **Reviewed**, and **Approved** by sIRB, and click **Continue**.
6. Upload the **IRB Approval Documentation** for the amendment and any other new or updated documents for the site. Remove any documents that are no longer in use or approved. (Documents that are removed remain available in previous approvals.) Then click **Continue**.
7. Review the approval information. Any section with missing information will be highlighted. Click **Save**.



| Type | Document | Date Approved |
|------------------------|------------------------------|---------------|
| Protocol [Protocol V3] | Protocol V3.pdf | 9/1/2021 |
| Consents & Assents | Consent-V1 Site-specific.pdf | |

IREx will notify the Reviewing IRB Liaison, IREx Study Manager, Site Liaison(s) and site's study contacts of the new approval. The documents will appear on the site's **Approval History** tab.