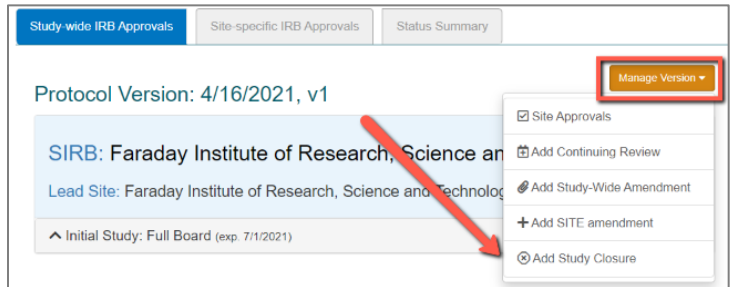


IREx can be used by sIRB Liaisons or Study Managers to document and communicate the closure of a study, when appropriate. *Closing a study* ensures all sites are aware that the study has ended, but retains a record of the reliance and a history of sIRB site approvals. The study remains accessible to all sites, but all past approvals are read-only. Only the study closure documents can be downloaded.

**Note:** ‘Study Closure’ is not used when studies are ongoing, but closed to enrollment, as sites need to retain access sIRB approvals.

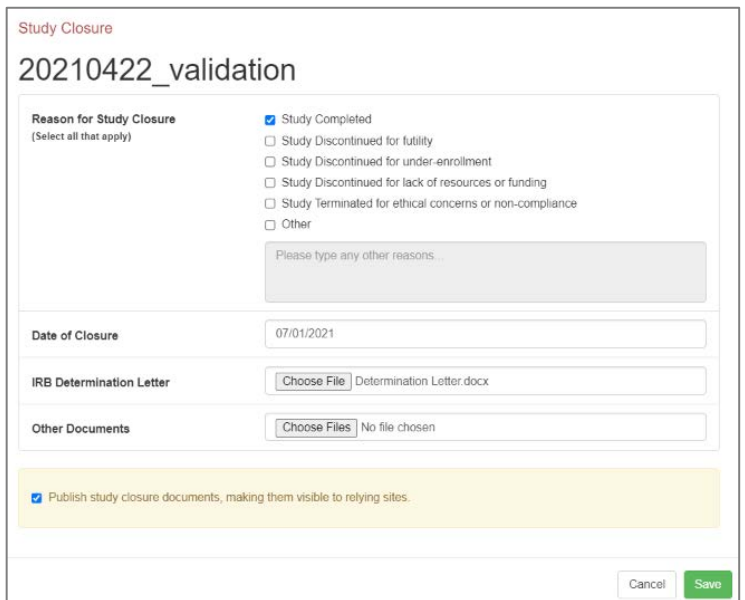
## HOW DO I CLOSE A STUDY?

1. Navigate to the **Manage Version** box on the study page, and click **Add Study Closure**.



The screenshot shows the 'Study wide IRB Approvals' tab selected. The 'Manage Version' dropdown menu is open, and 'Add Study Closure' is highlighted. Other options include Site Approvals, Add Continuing Review, Add Study-Wide Amendment, Add SITE amendment, and Initial Study: Full Board (exp. 7/1/2021).

2. In the **Study Closure** dialog:
  - a. Check the reason(s) for the closure; include more information in the ‘Other’ text box if needed.
  - b. Input the **Date of Closure**.
  - c. Attach the **IRB Determination Letter**.
  - d. Attach other documents, as needed.
3. To publish the study closure immediately, notifying sites and making the closure documents visible, check the **Publish study closure documents...** box and click **Save**.



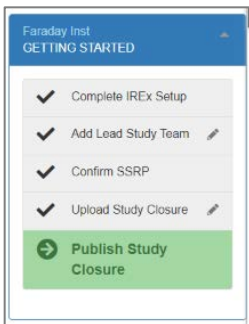
The 'Study Closure' dialog for study 20210422\_validation shows the following fields and options:

- Reason for Study Closure** (Select all that apply):
  - Study Completed
  - Study Discontinued for futility
  - Study Discontinued for under-enrollment
  - Study Discontinued for lack of resources or funding
  - Study Terminated for ethical concerns or non-compliance
  - Other
- Date of Closure:** 07/01/2021
- IRB Determination Letter:** Choose File | Determination Letter.docx
- Other Documents:** Choose Files | No file chosen
- Publish study closure documents, making them visible to relying sites.

Buttons: Cancel, Save

4. If you are not ready to publish the study closure yet, simply click Save after entering your information. You can return to the Study Closure via the **Getting Started Checklist** to publish when you are ready.

**\*Tip\*** A notification is sent to each site (individually) that the study was closed. Sites retain access to the study closure, and a history of past approvals (dates) is still available. However, outside of the study closure documents, no past approval documents can be downloaded.



The 'Getting Started Checklist' for Faraday Inst. shows the following items:

- Complete IREx Setup
- Add Lead Study Team
- Confirm SSRP
- Upload Study Closure
- Publish Study Closure