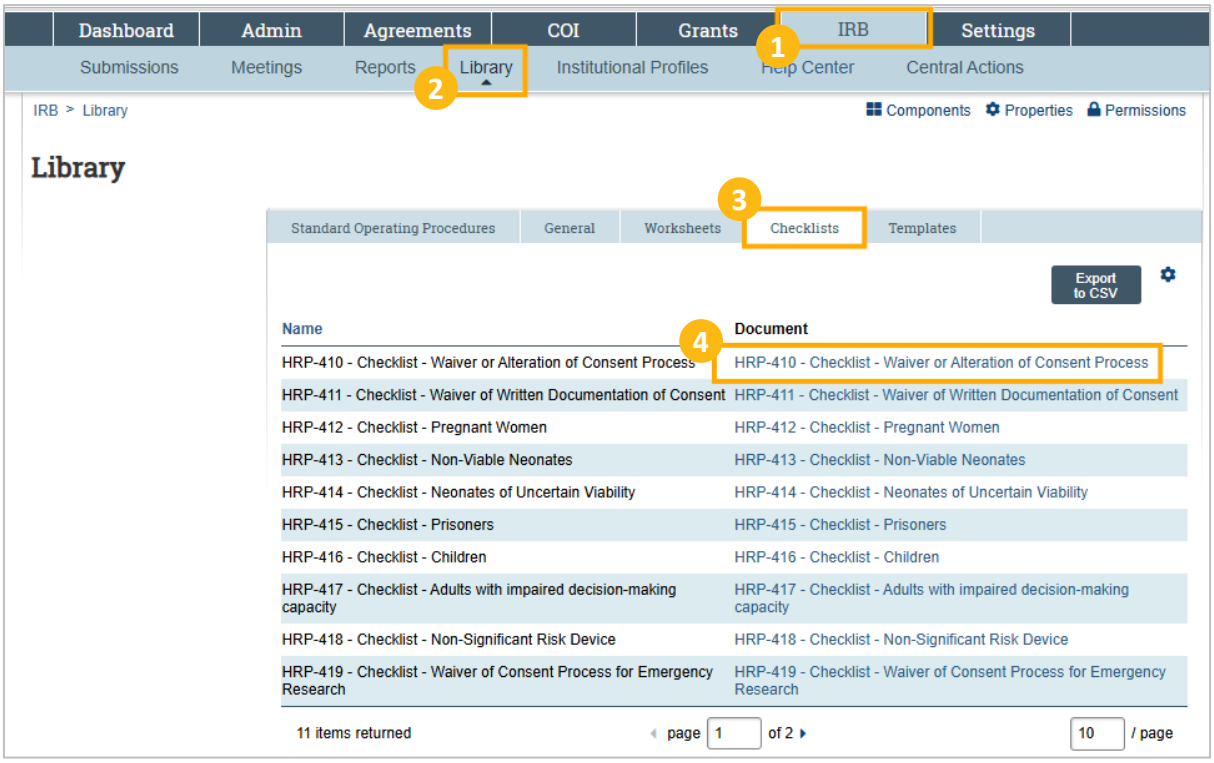
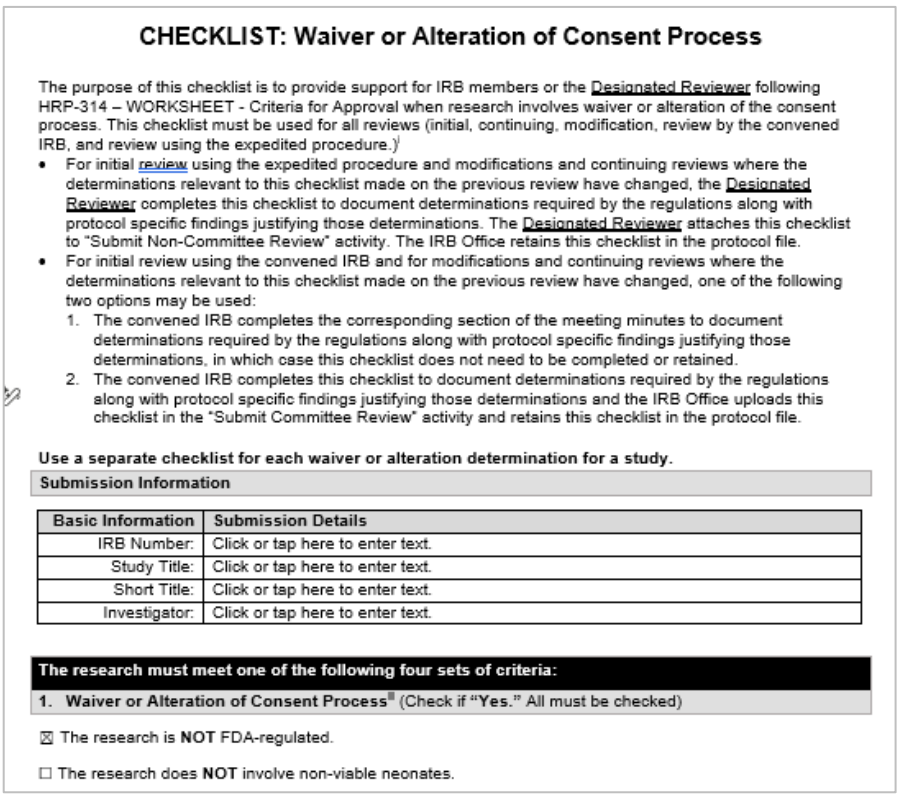
Working with Checklists

This guide demonstrates how to find and complete and checklist and upload that checklist to the meeting.

1. **To find all available checklists, click on the IRB tab, then the Library tab, and click on Checklists to see a list of all available checklists. Click on the name of a checklist to download it to your computer. For a list of all checklists and when to use them, see the HRPP Toolkit section of the *IRB Guide for Campus and HRPP*.**



2. **After opening the checklist, carefully read over the instructions at the top of the page, and fill out the checklist.**



CHECKLIST: Waiver or Alteration of Consent Process

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 – WORKSHEET - Criteria for Approval when research involves waiver or alteration of the consent process. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.

Use a separate checklist for each waiver or alteration determination for a study.

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.

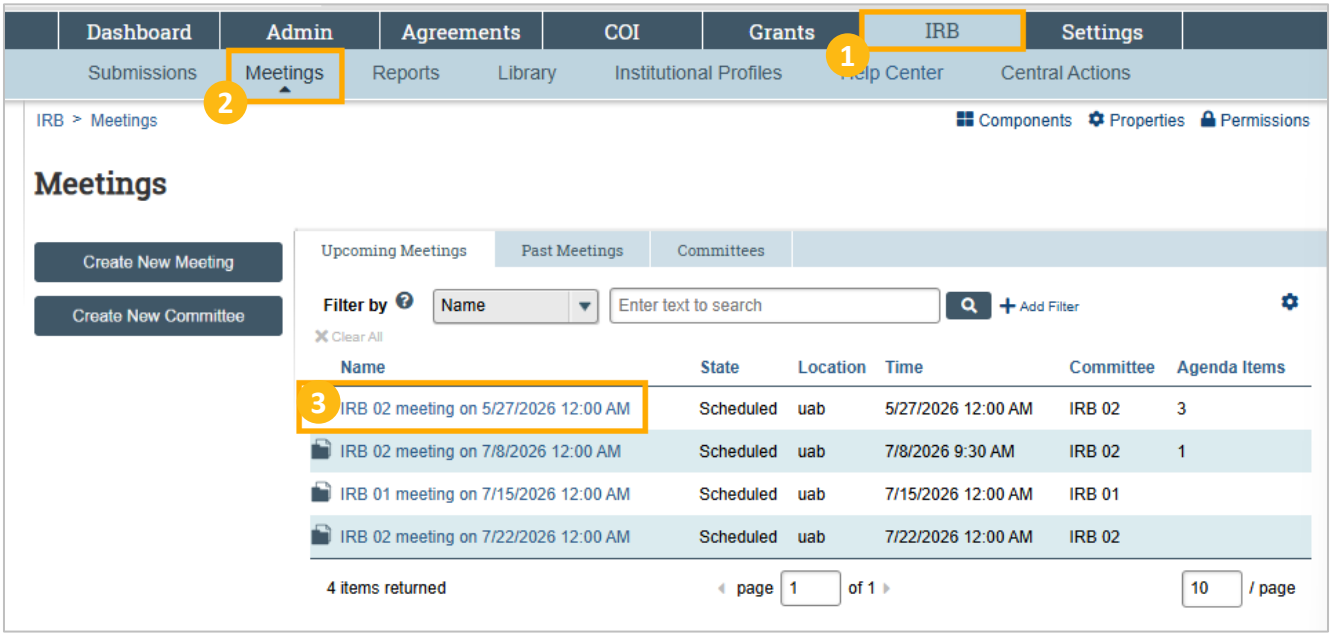
The research must meet one of the following four sets of criteria:

1. Waiver or Alteration of Consent Process (Check if "**Yes.**" All must be checked)

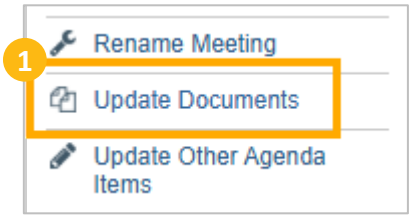
☒ The research is **NOT** FDA-regulated.

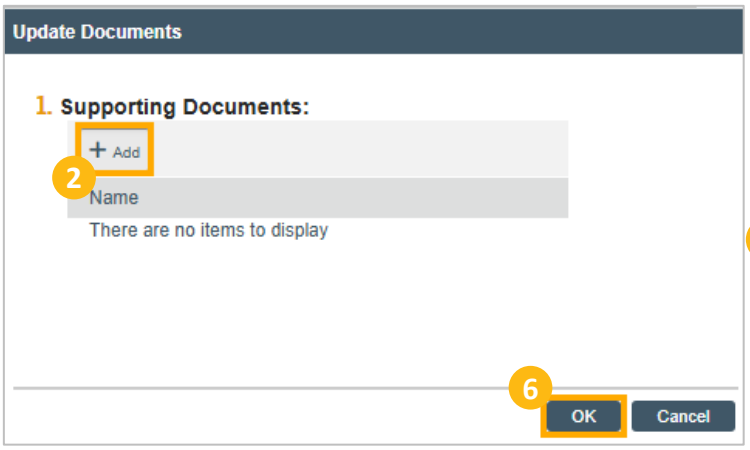
☐ The research does **NOT** involve non-viable neonates.

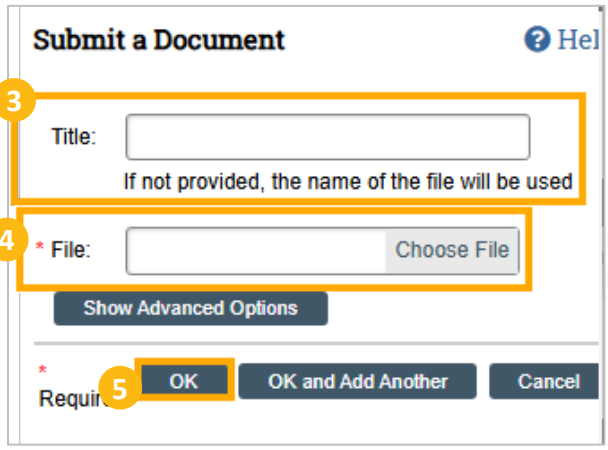
3. **After completing the checklist, you will need to upload it to the associated meeting. To do this, click on the IRB tab, then the Meetings tab, and click on the name of the meeting you'd like to add your checklist to open the meeting workspace.**



4. **Once on the meeting workspace, click on the Update Documents activity to upload your checklist, click Add to upload the checklist, fill out the title (optional), upload the file, and click OK or OK and Add Another.**







5. **The file will appear under the Supporting Documents tab of the meeting workspace.**

