

Combined Form Buck-IRB Submission Instructions:

For initial IRB submissions:

- Check “Informed Consent – Form” on the Informed Consent Process page and upload the combined document into the informed consent upload box.
- On the HIPAA Research Authorization page, select “Written Authorization,” click “Save & Continue.” On the General Authorization Forms page, select the appropriate documents from the list that contain both consent and HIPAA language. Do not upload another copy of the combined consent and authorization form here.
- The final version of the combined consent and HIPAA authorization form will be maintained as an approved document in Buck-IRB.

For amendment submissions:

For projects with an approved consent process involving separate consent and HIPAA research authorization forms, an amendment is required to use the combined consent and HIPAA authorization form.

- If no other changes are requested, create an amendment in Buck-IRB, check “Yes” to the “Are there any other changes you would like to make...” on the “Scope of changes” page and upload the combined consent and HIPAA authorization form in the Informed Consent Process upload box on the Document Changes page. No boxes need to be checked on the Proposed Changes page for this change. As this is a new document, there is no need to submit a tracked version of the original consent form.
- On the Document Changes page, find the HIPAA authorization form upload box and select the appropriate documents from the list that contain both consent and HIPAA language combined. Do not upload another copy of the combined consent and authorization form here
- Insert the following text in answer to the first question on the “Supplemental Questions” page and adapt as appropriate:

This amendment is to [add a new combined consent and HIPAA authorization form/transition from the stand-alone HIPAA authorization form to the combined consent and authorization form]. We [will/will not] continue using the previously approved consent document and stand-alone HIPAA authorization form for new study enrollment.

Note: If the combined consent and HIPAA authorization form is added by amendment, re-consent is not necessary for participants already enrolled using the previously approved separate informed consent and HIPAA authorization process.