

Amendment Submission Checklist

NOTE: Grey highlighted documents are **MANDATORY**. Other documents required for an amendment submission depend on what is being changed; see examples below. Please submit the track changes version of any revised documents, do not submit “clean” copies. Edited documents must be uploaded creating a version trail in IRBNet. All documents are located in the [IRB Library](#).

✓	Document	Document Type (in IRBNet)	Notes
*	Amendment Application	Application Form	Submit as PDF only; must be signed by PI.
**	All revised documents using track changes and new version date	As appropriate	Submit as Word doc; may include protocol, consent form, recruitment materials, data collection instruments
**	New documents requiring IRB review and approval before use	As appropriate	

* Required ** Required if applicable

Examples of Amendments

Scenario	Include in Application	Supporting Documents/Notes
1 Changes to Protocol (e.g. increase enrollment number, modify recruitment strategies, revising/removing instruments, changing procedures)	<ul style="list-style-type: none"> Identify the documents being changed Itemized list of all changes If adding procedures or increasing risk, provide justification 	<ul style="list-style-type: none"> ✓ Revised protocol with track changes and new version date ✓ Revised consent form with track changes to reflect protocol changes with new version date ✓ Upload revised documents in IRBNet to show a version trail by clicking on the pencil icon next to the currently approved version of the document to upload the edited document
2 Change the PI of record	<ul style="list-style-type: none"> Change the current PI Name to new PI Name; also update name in IRBNet “Project Overview” Identify the documents that need to be changed as a result Include an itemized list of all changes 	<ul style="list-style-type: none"> ✓ New PI’s CV, CITI Completion Report and COI Mgmt. Plan, if applicable ✓ Revised documents to reflect new PI with track changes and new version dates ✓ Updated project team form to reflect new PI and remove old PI (if applicable) ✓ Upload revised documents in IRBNet to show a version trail by clicking on the pencil icon next to the currently approved version of the document to upload the edited document
3 Adding new data collection procedures	<ul style="list-style-type: none"> Identify the documents being added and/or changed Include an itemized list of the changes 	<ul style="list-style-type: none"> ✓ New data collection instruments ✓ Revised protocol with track changes and new version date ✓ Upload revised documents in IRBNet to show a version trail by clicking on the pencil icon next to the currently approved version of the document to upload the edited document