# 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.

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

* Required ** Required if applicable

## Examples of Amendments

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Include in Application</th>
<th>Supporting Documents/Notes</th>
</tr>
</thead>
</table>
| 1 Changes to Protocol (e.g. increase enrollment number, modify recruitment strategies, revising/removing instruments, changing procedures) | • Identify the documents being changed  
• Itemized list of all changes  
• If adding procedures or increasing risk, provide justification | ✓ 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 | • 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 | ✓ 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 | • Identify the documents being added and/or changed  
• Include an itemized list of the changes | ✓ 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 |