Notes for Researchers and Study Coordinators:
Submitting a Revised Project Package

You may be asked to submit a revised project package, with updated information, for your local committee's review. Example submissions may include: a continuing review, modifications required for approval, changes to the study team, or another reason. The following steps will help ensure a smooth submission, while maintaining an organized set of Project Documents.

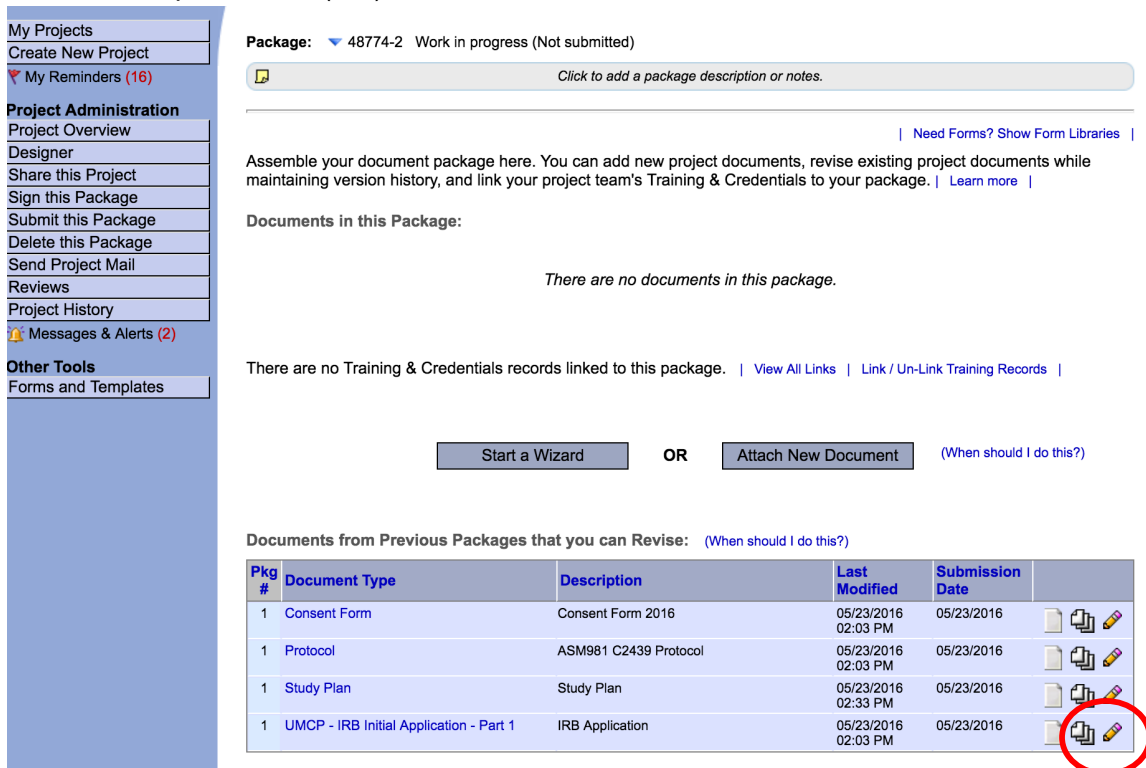## Create a New Package for an Existing Project in IRBNet

1. Log into IRBNet.
2. Click on the Project Title, from the My Projects page, to access the Project Overview page.
3. Click the 'Create New Package' button to the left of the page.
4. Click the 'Designer' button to work on documents for the new package via two methods:
   - **Revise** a previously submitted document; or
   - **Attach** a new document to the package.

Revise a Previously Submitted Document for Review (Designer page)

Revising a document is very important for developing a Document Revision History, as it associates separate documents within the same Document Type.

Refer to the 'Documents from Previous Packages' section at the bottom of the Designer page.

1. To revise or include a **Document Wizard** from a previous package:

   - Click on the pencil icon (✏️) to revise an online Document Wizard document.

- Make any necessary changes to previously entered information and save. The document will move to the 'Documents in this Package' section.

Documents in this Package:

Document Type ▲	Description	Last Modified	
UMCP - IRB Initial Application - Part 1	IRB Application	10/27/2016 04:03 PM	📄 🗐 ✏ ✕

Document Revision History | Help | ☒

Pkg #	Document Type	Description	Last Modified	Submission Date	
2	UMCP - IRB Initial Application - Part 1	IRB Application	10/27/2016 04:03 PM		📄
1	UMCP - IRB Initial Application - Part 1	IRB Application	05/23/2016 02:03 PM	05/23/2016	📄

There are no Trai...   this?)

Documents from

Pkg #	Document Ty...				
1	Consent Form				📄 🗐 ✏
1	Protocol	ASM981 C2439 Protocol	05/23/2016 02:03 PM		📄 🗐 ✏

2. To **revise a previously uploaded document** (.docx, .xlsx, .pdf, etc.) in an older package:
   - Download the most recent document by clicking on Document Type or the paper icon (📄).
   - Make any necessary changes and save the revised document to your computer.
   - Click on the pencil icon to upload the revised document into IRBNet.

Documents in this Package:

Document Type ▲	Description	Last Modified	
UMCP - IRB Initial Application - Part 1	IRB Application	10/27/2016 04:03 PM	📄 🗐 ✏ ✕

There are no Training & Credentials records linked to this package. | View All Links | Link / Un-Link Training Records |

[Start a Wizard]   **OR**   [Attach New Document]   (When should I do this?)

Documents from Previous Packages that you can Revise: (When should I do this?)

Pkg #	Document Type	Description	Last Modified	Submission Date	
1	Consent Form	Consent Form 2016	05/23/2016 02:03 PM	05/23/2016	📄 🗐 ✏
1	Protocol	ASM981 C2439 Protocol	05/23/2016 02:03 PM	05/23/2016	📄 🗐 ✏
1	Study Plan	Study Plan	05/23/2016 02:33 PM	05/23/2016	📄 🗐 ✏

- Browse your computer, select your revised document to upload, make necessary changes to 'Document Type' and 'Description' (below), and click the Update button. Note the system remembers the 'Document Type' and 'Description'.

[48774-2] UT Dallas Research Project

You are updating an attachment. To help you identify the file that was attached:

- This attachment was loaded from the file **Consent Form - Spinal Motion.doc**.
- It was attached on **05/23/2016**.
- It has a size of **93184** bytes.

Document Type *	Consent Form ▴▾
Description	Consent Form 2016 v2
File *	Choose File Consent Form… Motion.doc
	Update Cancel

* required fields

- When you click the 'Update' button, the revised document will appear in the current document package ('Documents in this Package') with a new Document Revision History which indicates document versions (see below).

Designer

[48774] UT Dallas

Package: ▾ 487

Document Revision History | Help | ☒

Pkg #	Document Type	Description	Last Modified	Submission Date	
2	Consent Form	Consent Form 2016 v2	10/27/2016 04:03 PM		
1	Consent Form	Consent Form 2016	05/23/2016 02:03 PM	05/23/2016	

rm Libraries |

Assemble your do   while
maintaining versio

Documents in th

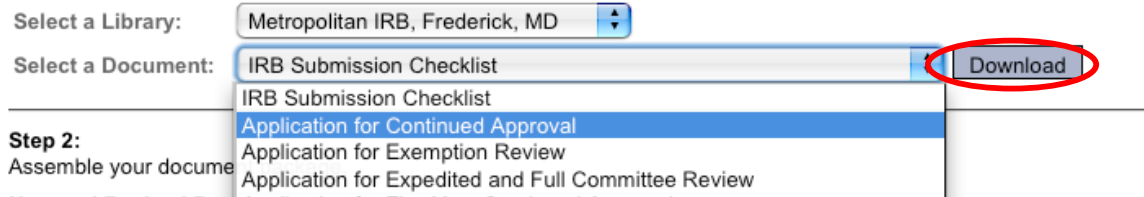| **Document Type**			
▾ Consent Form	Consent Form 2016 v2	10/27/2016 04:03 PM	📄 🗐 ✏ ✗
UMCP - IRB Initial Application - Part 1	IRB Application	10/27/2016 04:03 PM	📄 🗐 ✏ ✗

There are no Training & Credentials records linked to this package. | View All Links | Link / Un-Link Training Records |

Attach a New Document to the Submission Package

1. Download the document template and related instructions from the Document Library (if the document is not already prepared and on your computer).

Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: Metropolitan IRB, Frederick, MD

Select a Document: IRB Submission Checklist ◆ Download

    IRB Submission Checklist
    Application for Continued Approval
    Application for Exemption Review
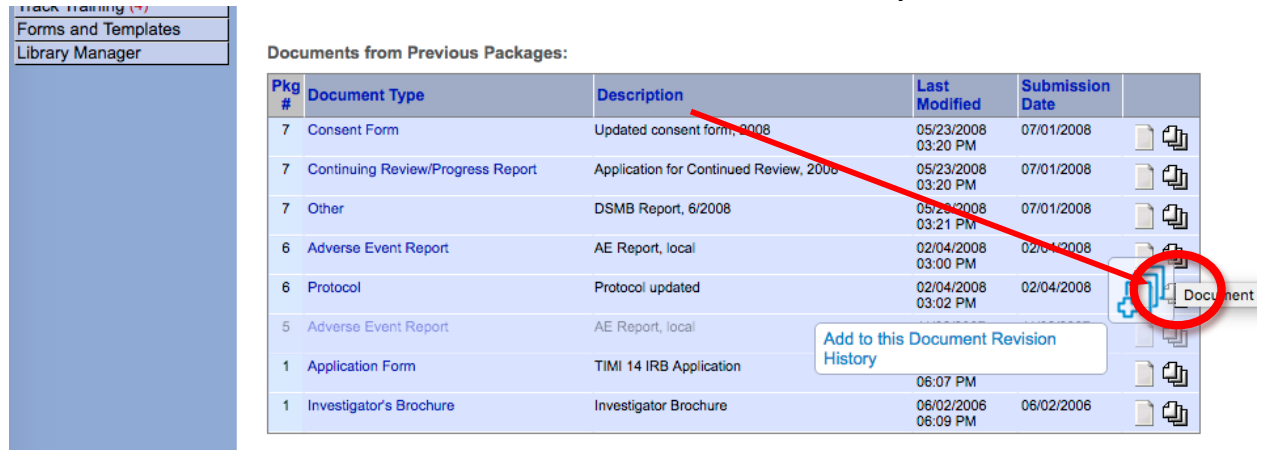   Application for Expedited and Full Committee Review

Step 2:
Assemble your docume

2. Complete downloaded forms or documents to be submitted.
3. Use the 'Attach New Document' button, or drag the document from your desktop to the Designer page, to upload the document into the current package.
4. Assign a 'Document Type'.

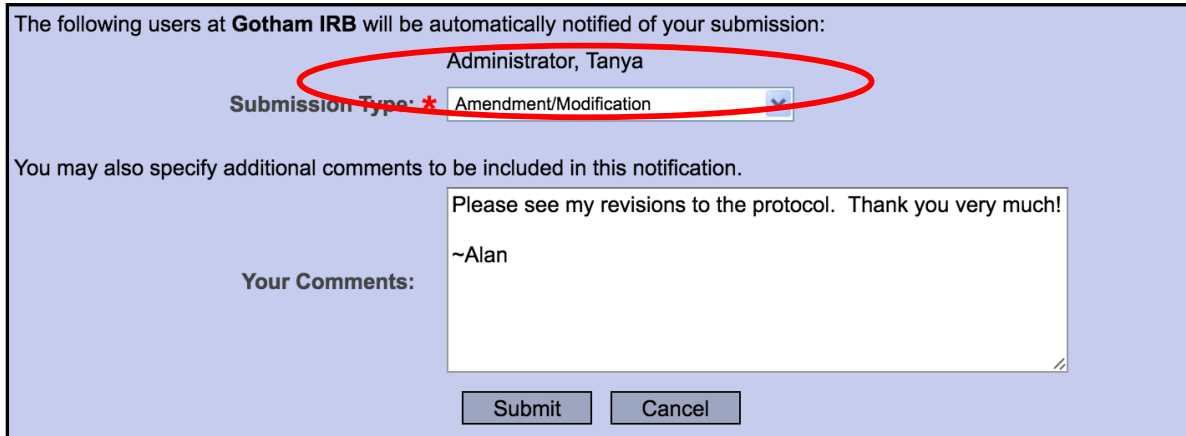**TIP**: If the document uploaded is meant to be part of a Document Revision History you may:

- Assign a Document Type via drop down

- Drag the new Document onto the Document Revision History ( ) icon of the older document to create a Document Revision History.

Track Training (4)
Forms and Templates
Library Manager

Documents from Previous Packages:

Pkg #	Document Type	Description	Last Modified	Submission Date		
7	Consent Form	Updated consent form, 2008	05/23/2008 03:20 PM	07/01/2008		
7	Continuing Review/Progress Report	Application for Continued Review, 2008	05/23/2008 03:20 PM	07/01/2008		
7	Other	DSMB Report, 6/2008	05/23/2008 03:21 PM	07/01/2008		
6	Adverse Event Report	AE Report, local	02/04/2008 03:00 PM	02/04/2008		
6	Protocol	Protocol updated	02/04/2008 03:02 PM	02/04/2008		Document
5	Adverse Event Report	AE Report, local				
1	Application Form	TIMI 14 IRB Application	06:07 PM			
1	Investigator's Brochure	Investigator Brochure	06/02/2006 06:09 PM	06/02/2006		

Add to this Document Revision History

Points to Remember

When you have attached all the required documents, please remember to sign the package as instructed by your local committee.

Submit the revised package to your committee. Be sure to select the appropriate Submission Type (below).

The following users at **Gotham IRB** will be automatically notified of your submission:

Administrator, Tanya

Submission Type: * [Amendment/Modification ▾]

You may also specify additional comments to be included in this notification.

Your Comments:
Please see my revisions to the protocol. Thank you very much!

~Alan

[Submit] [Cancel]

Note: All documents required for committee review should be included in the current package. It is not necessary to attach copies of historical, unchanged project documents (such as the previously approved consent form) unless directed by your local committee for their review purposes. These historical documents will always be available in the Designer for consideration by the committee.