

CREATING AND SUBMITTING A NEW PACKAGE AFTER PACKAGE #1

A package must be completed for each submission to the IRB or ORA. Only IRB documents should be submitted to the IRB. Only ORA documents should be submitted to the ORA. Repeat this submission process for each package submitted to the IRB or ORA.

CREATE A NEW PACKAGE

1. Find the Project on “My Projects,” and click on the “Project Title.”

USER PROFILE LOGOUT

Welcome to IRBNet
Susan Daley

My Projects

Projects that you have created or that have been shared with you:

Search: Search Clear

1 - 10 of 86 10

IRBNet ID	Project Title	Principal Investigator	Submission Type	Status	Effective Date
44707-2	Project 123	Doe		Work in progress	
44701-1	Title On the Protocol (TOP)	PI's Last Name	New Funding	Pending Review	
44692-1	tbd	mitchell		Work in progress	

2. You will be automatically taken to the “Project Overview” page. On the left side navigation bar, click “Project History.”

IRBNet ID: 44701-1 USER PROFILE LOGOUT

Welcome to IRBNet
Susan Daley

Project Overview

[44701-1] Title On the Protocol (TOP)

You have Full access to this project. (Edit)

Research Institution	Florida Hospital, Orlando, FL
Title	Title On the Protocol (TOP)
Principal Investigator	PI's Last Name, PI's Proper Name, 1 Degree
Status	Pending Review
Lock Status	Locked
Keywords	Jane Doe John Smith Stephanie Jackson
Sponsor	Sponsor's Name (Sponsor's Protocol #)
Internal Reference Number	Cost Center #

The documents for this project can be accessed from the Designer.

Submitted to:
Florida Hospital Office of Research Administration (ORA) 04/24/2011 Pending Review. Review details.

My Projects
Create New Project
My Reminders (3)

Project Administration

- Project Overview
- Designer
- Share this Project
- Sign this Package
- Submit this Package
- Delete this Package
- Send Project Mail
- Reviews
- Project History**

Messages & Alerts (1)

3. On the Project History page, click “Create New Package.”

The screenshot shows the IRBNet interface for user Susan Daley. The top navigation bar includes 'USER PROFILE' and 'LOGOUT'. The main content area is titled 'Project History' and displays information for package [44701-1]. A table lists the available document packages:

Pkg #	Package Type	Status	Create Date	Submission Date	Review Date
1	New Funding	Pending Review	04/24/2011	04/24/2011	

Below the table, a 'Create New Package' button is highlighted with a red box. The left sidebar contains navigation options such as 'My Projects', 'Project Administration', and 'Other Tools'.

4. The new Package will appear in the table on the “Project History” page. Notice that the IRBNet ID # is now preceded by “-2,” which signifies the second Package.

The screenshot shows the IRBNet interface with the 'Project History' page updated. The title is now '[44701-2] Title On the Protocol (TOP)'. The table now lists two packages:

Pkg #	Package Type	Status	Create Date	Submission Date	Review Date
2	New Document Package	Work in progress	04/24/2011		
1	New Funding	Pending Review	04/24/2011	04/24/2011	

The table indicates '2 Packages found, displaying all Packages.' The 'New Document Package' row is highlighted with a red box. The left sidebar remains the same.

5. Click “New Document Package,” or on the left side navigation bar, click “Designer.”

The screenshot shows the IRBNet interface with the 'Project History' page. The title is '[44701-2] Title On the Protocol (TOP)'. The table lists two packages, with the 'New Document Package' row highlighted. In the left sidebar, the 'Designer' link under 'Project Administration' is highlighted with a red box.

6. Assemble your Package on the “Designer” page.
 - a) Go to Step 1 and download the blank form(s) for the submission.
 - i) Select the library.
 - ii) Select the correct form.
 - iii) Click “Download” to download the document to the location the department currently saves ORA and IRB documents. This will allow you to fill out the form and later attach it to the package. Use the filename format: IRBNet ID #, Document Description, Version (if applicable), and Date (if applicable).
 2. Once the form(s) and supporting documents are ready to be submitted, go to Step 2 to upload the documents to the Package.
 - i) Click “Add New Document.”
 - ii) Select Document Type (see Appendix A for a list of Document Types).
 - iii) Select File: click “Browse,” choose the file for the document that has been saved on the computer drive and is ready to be submitted, and click “Open.”
 - iv) Leave Description blank – the document’s filename will automatically populate this field.
 - i) Click “Attach.”

Designer

[44701-2] Title On the Protocol (TOP)

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

Select a Library:

Select a Document:

Step 2:
Assemble your document package.

New and Revised Documents in this Package:

There are currently no documents in this package.

IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. [Learn more.](#)

(When should I do this?)

Attach Document

[44701-2] Title On the Protocol (TOP)

You may attach documents to this package by clicking the “Browse...” button to locate a document and then by clicking “Attach”. The “Document Type” and optional “Description” are informational fields to assist you in managing your attached documents.

Document Type *

Description

File *

* required fields

SIGN THE NEW PACKAGE

At this time, only the person submitting a Package to the IRB or ORA is required to sign electronically in IRBNet. (All other required signatures must be present on the attached PDF forms.)

1. On the left side navigation bar, click “Sign this Package.”

The screenshot shows the IRBNet Designer interface. On the left, a navigation bar lists various options, with "Sign this Package" highlighted in red. The main content area is titled "Designer" and shows a package titled "[44701-2] Title On the Protocol (TOP)". It includes two steps: Step 1 (Download blank forms) and Step 2 (Assemble your document package). A table lists documents in the package, including Application Form, Consent Form, and Protocol. There is also an "Add New Document" button.

2. Select the role of the person submitting the Package.

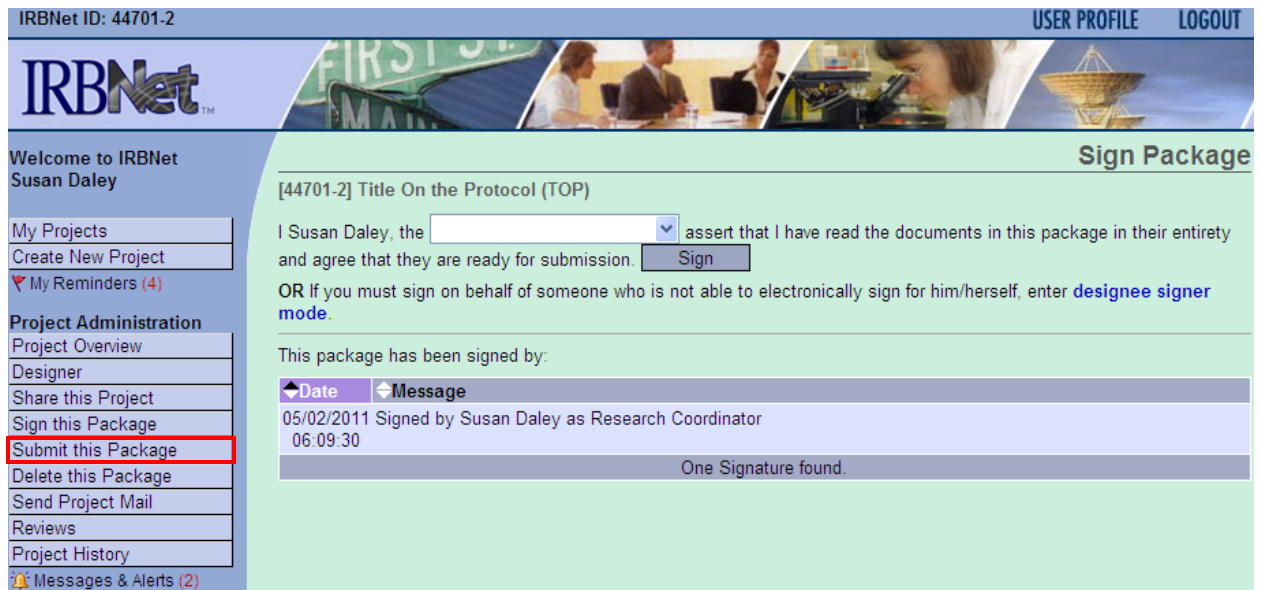
The screenshot shows the "Sign Package" interface. A dropdown menu is open, listing various roles such as Research Coordinator, Advisor, Administrative Reviewer, Auditor, Co-Investigator, Department Head, Department Representative, Institutional Official, Monitor, Other Signatory, Principal Investigator, Scientific Reviewer, Sponsor, Sub-Investigator, and Team Member. The "Research Coordinator" role is selected and highlighted in blue. The text "I Susan Daley, the Research Coordinator" is visible, along with a "Sign" button.

3. Click “Sign.”

The screenshot shows the "Sign Package" interface with the "Sign" button highlighted in red. The text "I Susan Daley, the Research Coordinator" is visible, along with the "Sign" button.

SUBMIT THE NEW PACKAGE

1. On the left side navigation bar, click “Submit this Package.”



IRBNet ID: 44701-2 USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
Susan Daley

Sign Package

[44701-2] Title On the Protocol (TOP)

I Susan Daley, the assert that I have read the documents in this package in their entirety and agree that they are ready for submission.

OR If you must sign on behalf of someone who is not able to electronically sign for him/herself, enter **designee signer mode**.

This package has been signed by:

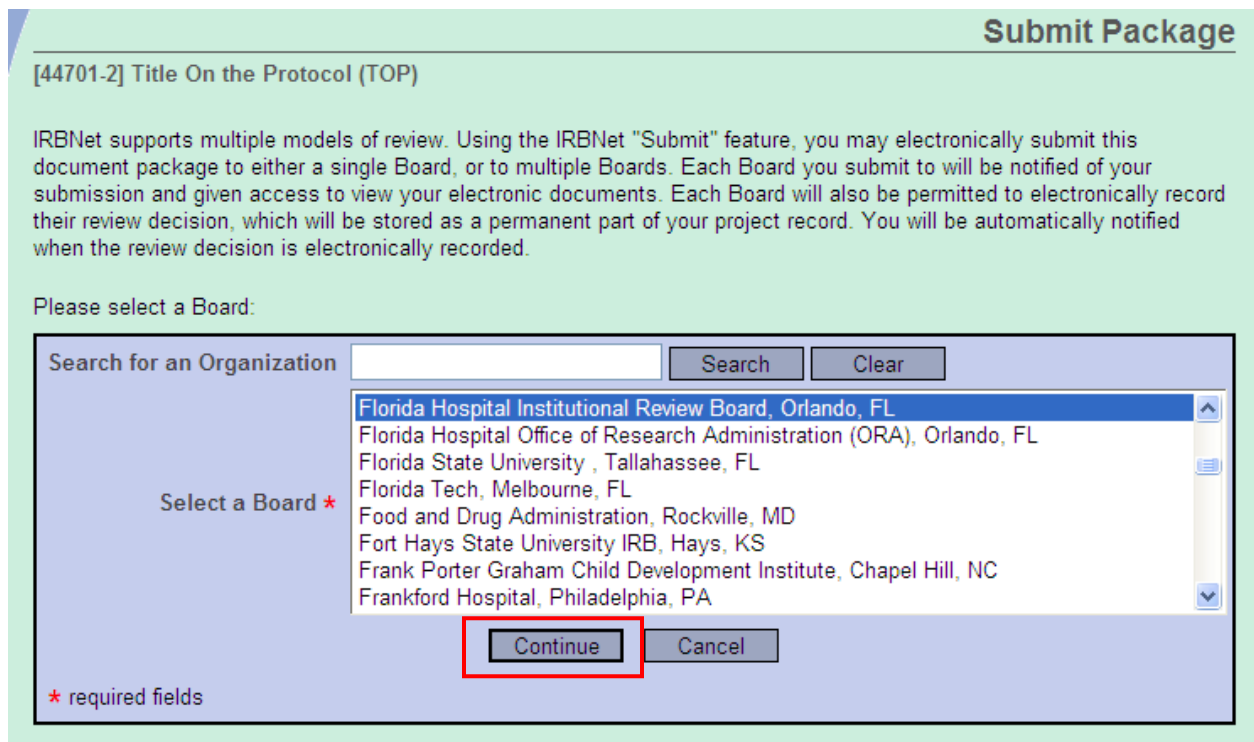
Date	Message
05/02/2011 06:09:30	Signed by Susan Daley as Research Coordinator

One Signature found.

My Projects
Create New Project
My Reminders (4)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (2)

2. Select the correct Organization (IRB or ORA), and click “Continue.”



Submit Package

[44701-2] Title On the Protocol (TOP)

IRBNet supports multiple models of review. Using the IRBNet "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:

Search for an Organization

Select a Board *

- Florida Hospital Institutional Review Board, Orlando, FL
- Florida Hospital Office of Research Administration (ORA), Orlando, FL
- Florida State University, Tallahassee, FL
- Florida Tech, Melbourne, FL
- Food and Drug Administration, Rockville, MD
- Fort Hays State University IRB, Hays, KS
- Frank Porter Graham Child Development Institute, Chapel Hill, NC
- Frankford Hospital, Philadelphia, PA

* required fields

3. Select Submission Type (see Appendix B for list of submission types); provide package explanation, requests, or special instructions in the Your Comments space provided; and click “Submit.”

4. You will be automatically directed to a Submission Confirmation.

5. On the left side navigation bar, click “Reviews” to see the up-to-date status of the submission’s review.

Pkg #	Submission Date	Submission Type	Ref #	Agenda	Review Type	Status	Effective Date	Project Expiration
2	05/02/2011	New Project	Unassigned		Pending Review			

Pkg #	Submission Date	Submission Type	Ref #	Agenda	Review Type	Status	Effective Date	Project Expiration
1	04/24/2011	New Funding	Unassigned		Pending Review			

This is where you will find approval letters, approved informed consents, and other documents from the IRB/ORA once a review is complete.

APPENDIX A: Document Types

Forms	IRBNet Document Types
Case report forms	Data Collection
Change Request Form	Cover Sheet
Check or proof of payment	Other
Delegation of Responsibilities Log	Other
Determination letters from cooperative review	Letter
Determination letters from other IRB to which you have directly applied for this study	Letter
Device manual	Other
Documentation of other committee review	Letter
FDA letter with assigned IND or IDE number	Letter
Financial Disclosure Forms	Conflict of Interest - Disclosure
Form 1572	Other
Informed consent	Consent Form
Investigator Brochure	Investigator Brochure
IRB Application	Application Form
Major Deviation Report or Minor Dev. Log	Protocol Deviation/Violation Report
Media Release	Publication Material
Monitor letter	Letter
Progress Report	Continuing Review/Progress Report
Protocol	Protocol
Questionnaires, surveys, phone scripts, interview questions, etc.	Questionnaires/Surveys
Recruitment material	Advertisement
Reviews Prep to Research forms	Other
Sponsor's letter of Non-Sig Risk determination	Other

APPENDIX B: Submission Types

Submissions	IRBNet Submission Type
Addendum	Other
Adverse Event	Unanticipated Problem (UP)
Advertisement	Other
Amendment	Amendment/Modification
CIRB Acceptance	New Project
CIRB Amendment	Amendment/Modification
CIRB Progress Report	Continuing Review/Progress Report
CIRB Revision	Revision
Consent Modification	Revision
Deviation	Protocol Deviation/Violation
DSMB report	Other
Editorial/Administrative changes	Revision
Initial Submission	New Project
IRB Audit of Investigative Site	Facility Inspection/Program Inspection
Media Release	Other
Monitor Letter	Other
Note to File	Other
Patient Information	Other
Renewal	Continuing Review/Progress Report
Revised IB	Revision
Revised Protocol	Revision
Revision	Revision
Safety Report	Other
Sponsor Letter	Other
Sponsor's Annual Report	Other
Status Change	Revision
Study team changes	Revision
Termination	Closure/Final Report
Title Change	Revision
Update	Amendment/Modification
Withdrawal of Consent	Other