

LINKING & ACCESSING HUMAN SUBJECTS APPROVALS IN eRA

Created: 04/27/2016

Purpose

The Human Subjects (HS) and Proposal Tracking (PT) modules are linked in *Boulder eRA*. Creating a link between a proposal in PT to a protocol in HS allows users to access statuses in real time. This document details the procedures to link a protocol in HS with a proposal in PT from within either module. This document also describes the procedures to access the approval letter.

Data Needed to Complete this Process

- PSR form with protocol number (if linking from PT)
- HRP-211 Initial Application (eForm) with proposal number (if linking from HS)



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I. Link a Protocol to a Proposal in PT (*OCG staff*)

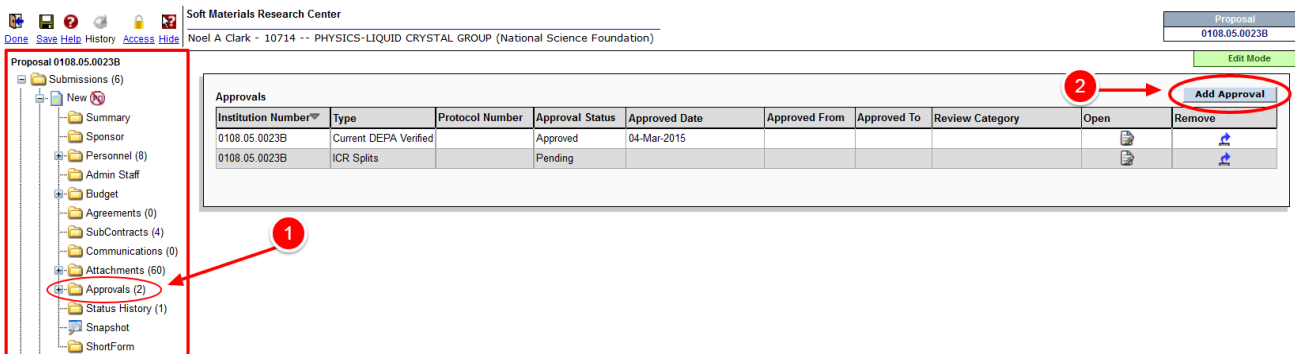
1) Locate and Open the Proposal in PT.

2) Open PT > Submissions > [*PT Record*] > Approvals.

Be sure to open the **Approvals** folder within the appropriate PT record (e.g. **New, Renewal...**) and not the parent **Approvals** folder. *Opening the parent Approvals folder (showing approvals attached to ALL records associated with the main proposal) limits permissions to view-only mode.*

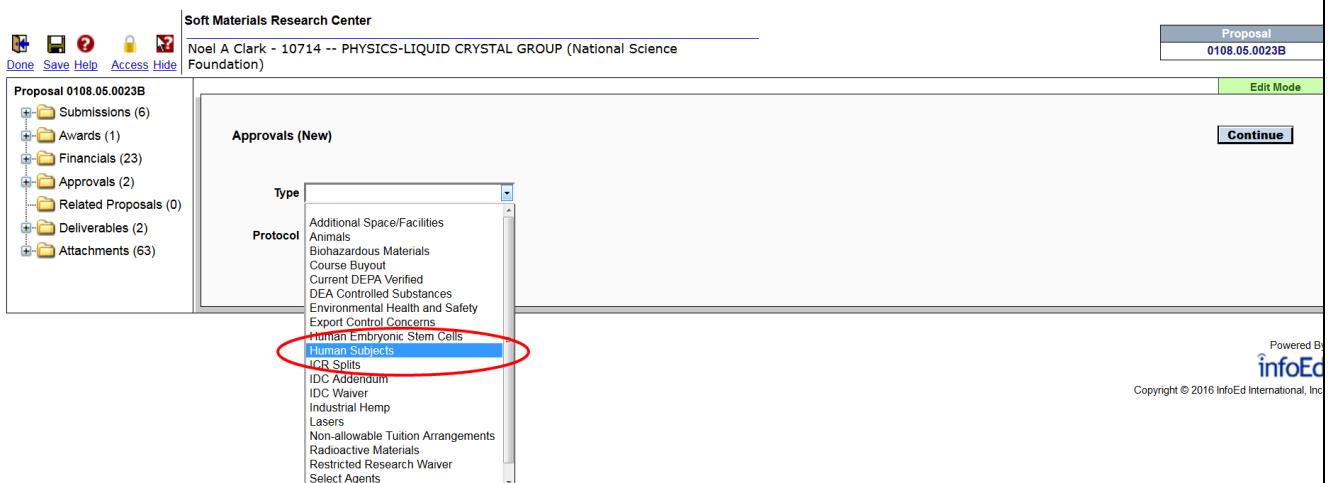
3) Add Approval with Attached Protocol.

3-1 Click **Add Approval**.



Institution Number	Type	Protocol Number	Approval Status	Approved Date	Approved From	Approved To	Review Category	Open	Remove
0108.05.0023B	Current DEPA Verified		Approved	04-Mar-2015					
0108.05.0023B	ICR Splits		Pending						

3-2 Select **Human Subjects** from the *Type* drop-down menu.



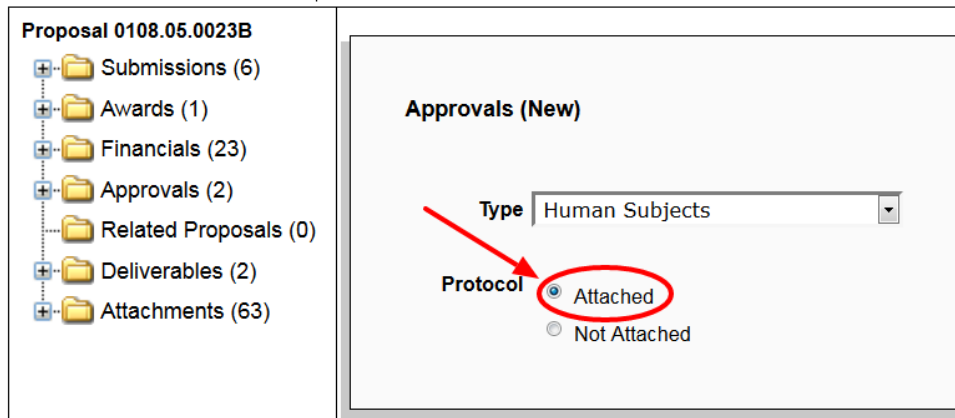
Approvals (New)

Type: **Human Embryonic Stem Cells**

Protocol:

Additional Space/Facilities
 Animals
 Biohazardous Materials
 Course Buyout
 Current DEPA Verified
 DEA Controlled Substances
 Environmental Health and Safety
 Export Control Concerns
 Human Embryonic Stem Cells
 ICR Splits
 IDC Addendum
 IDC Waiver
 Industrial Hemp
 Lasers
 Non-allowable Tuition Arrangements
 Radioactive Materials
 Restricted Research Waiver
 Select Agents

3-3 Set Protocol as **Attached**.



Proposal 0108.05.0023B

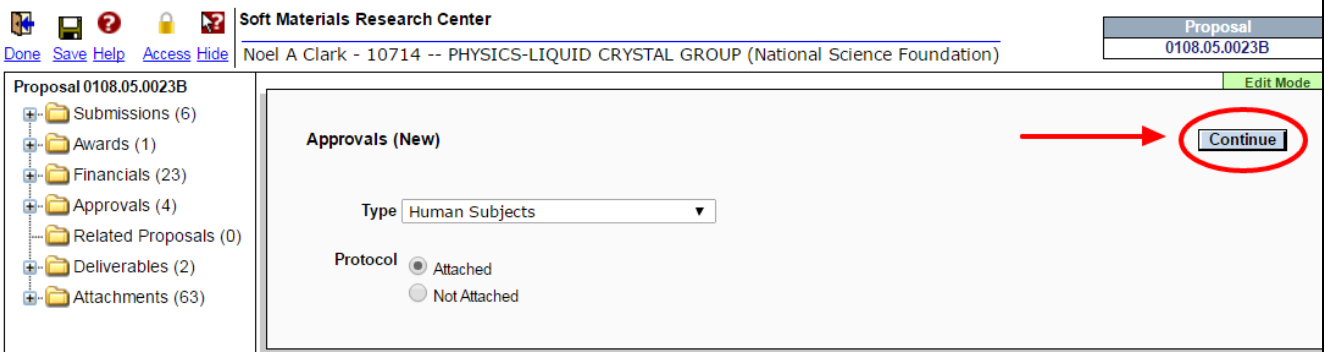
- Submissions (6)
- Awards (1)
- Financials (23)
- Approvals (2)
- Related Proposals (0)
- Deliverables (2)
- Attachments (63)

Approvals (New)

Type: Human Subjects

Protocol: Attached Not Attached

3-4 Click **Continue**.



Done Save Help Access Hide | **Soft Materials Research Center** | Proposal 0108.05.0023B Edit Mode

Noel A Clark - 10714 -- PHYSICS-LIQUID CRYSTAL GROUP (National Science Foundation)

Proposal 0108.05.0023B

- Submissions (6)
- Awards (1)
- Financials (23)
- Approvals (4)
- Related Proposals (0)
- Deliverables (2)
- Attachments (63)

Approvals (New)

Type: Human Subjects

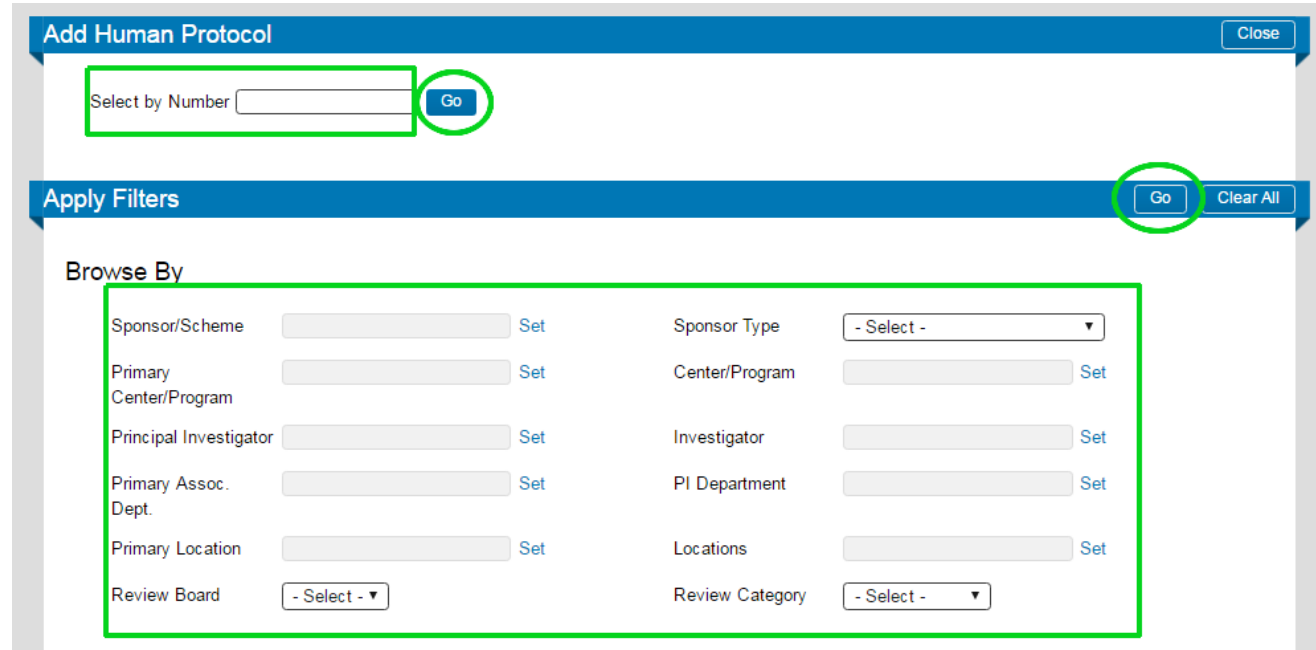
Protocol: Attached Not Attached

Continue

3-5

Enter the protocol number in the field at the top of the page. Click **Go**.

- *If the protocol number is not readily available, search/browse by another parameter (e.g. PI or Department).*



Add Human Protocol Close

Select by Number Go

Apply Filters Go Clear All

Browse By

Sponsor/Scheme <input type="text"/> Set	Sponsor Type - Select - ▼
Primary Center/Program <input type="text"/> Set	Center/Program <input type="text"/> Set
Principal Investigator <input type="text"/> Set	Investigator <input type="text"/> Set
Primary Assoc. Dept. <input type="text"/> Set	PI Department <input type="text"/> Set
Primary Location <input type="text"/> Set	Locations <input type="text"/> Set
Review Board - Select - ▼	Review Category - Select - ▼

3-6

Scroll down to the bottom of the page.

3-7

Select the protocol by checking the box.

3-8

Click **Select**.



Converted Default Status Revised Budget Request Submitted to OIC Initial Contact Under Development Reviewed

1 Records Found. Displaying pages 1 through 1 of 1

Number	Title	Sponsor/Scheme	PI
15-07-0005	Paintable Heat-reflective Coatings for Low-cost Energy Efficient Windows	Department of Energy	Miyake, Garret Morgan Dr. Ph.D.

↓
Select
↑

The window will close and a screen for the Approval/Protocol just added will appear.

3-7

Review the **Status** and **Approved Dates**.

- As the IRB processes the protocol, the status and dates will be automatically updated.

Soft Materials Research Center

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Proposal: 0108.05.0023B

Done Save Help History Access Hide

Proposal 0108.05.0023B

- Submissions (6)
- Awards (1)
- Financials (23)
- Approvals (3)
- Related Proposals (0)
- Deliverables (2)
- Attachments (63)

Approvals

Number: 0606.20	Status: Closed	PI: Liane G Pedersen-Gallegos	Department: 10219 -- SOCIOLOGY
Approved Date: 13-Jul-2006	Approved From:	Approved To: 31-Jul-2009	
Title: "Evaluation of RESESS: Reserach and Education in Solid Earth Sciences for Students"			Mode: <input checked="" type="radio"/> Attached <input type="radio"/> Not Attached

Submission(s)

Review Type	Review Category	Decision	Submission Date	Approved Date	Approved From	Approved To
Initial Application		Closed				

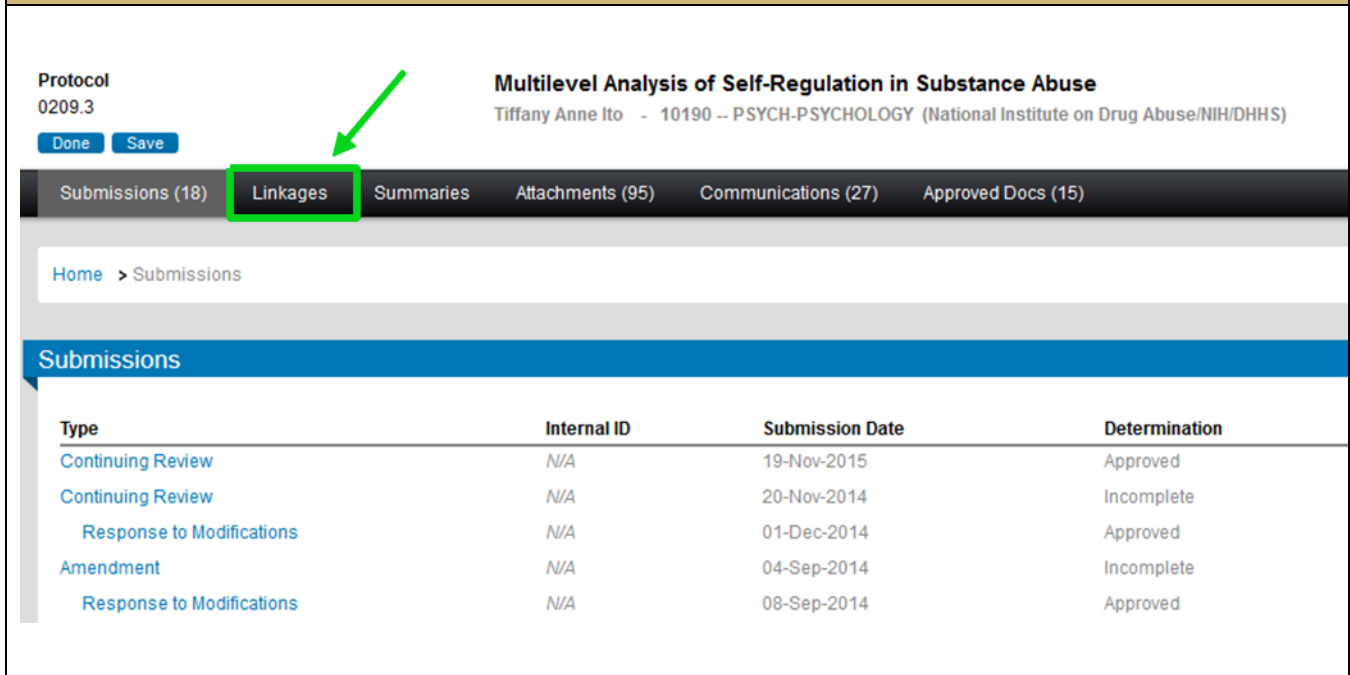
Other Approval Details

Comments

II. Link a Proposal to a Protocol in HS (*IRB staff*)

1) Locate and Open the Protocol in HS.

2) Click on the Linkages Tab.



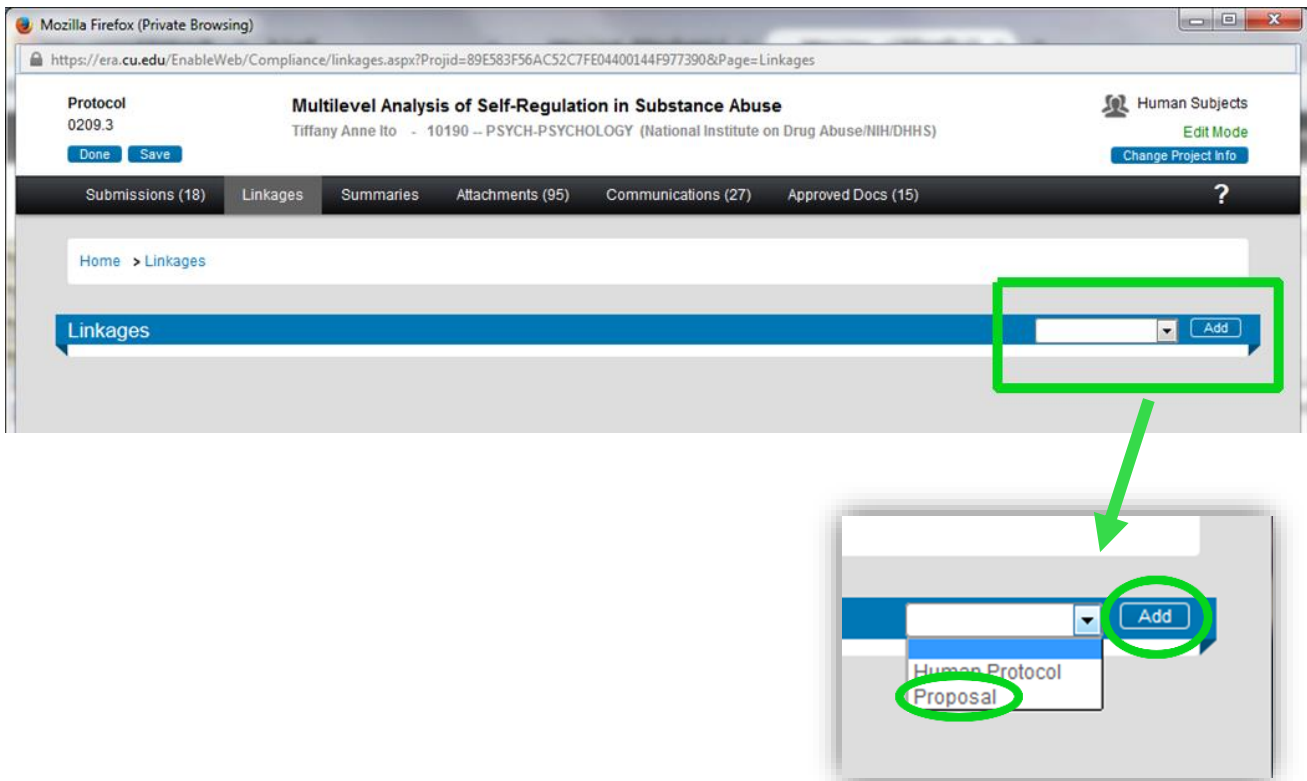
The screenshot displays the eRA system interface for a specific protocol. At the top left, the protocol number is 0209.3. The protocol title is "Multilevel Analysis of Self-Regulation in Substance Abuse" by Tiffany Anne Ito, with internal ID 10190, under the department of PSYCH-PSYCHOLOGY at the National Institute on Drug Abuse/NIH/DHHS. Below the title are "Done" and "Save" buttons. A navigation bar contains tabs for "Submissions (18)", "Linkages", "Summaries", "Attachments (95)", "Communications (27)", and "Approved Docs (15)". The "Linkages" tab is highlighted with a green box, and a green arrow points to it from the left. Below the navigation bar is a breadcrumb trail: "Home > Submissions". A blue header bar reads "Submissions". Below this is a table with the following data:

Type	Internal ID	Submission Date	Determination
Continuing Review	N/A	19-Nov-2015	Approved
Continuing Review	N/A	20-Nov-2014	Incomplete
Response to Modifications	N/A	01-Dec-2014	Approved
Amendment	N/A	04-Sep-2014	Incomplete
Response to Modifications	N/A	08-Sep-2014	Approved

3) Add Proposal.

3-1 From the drop-down menu, select **Proposal**.

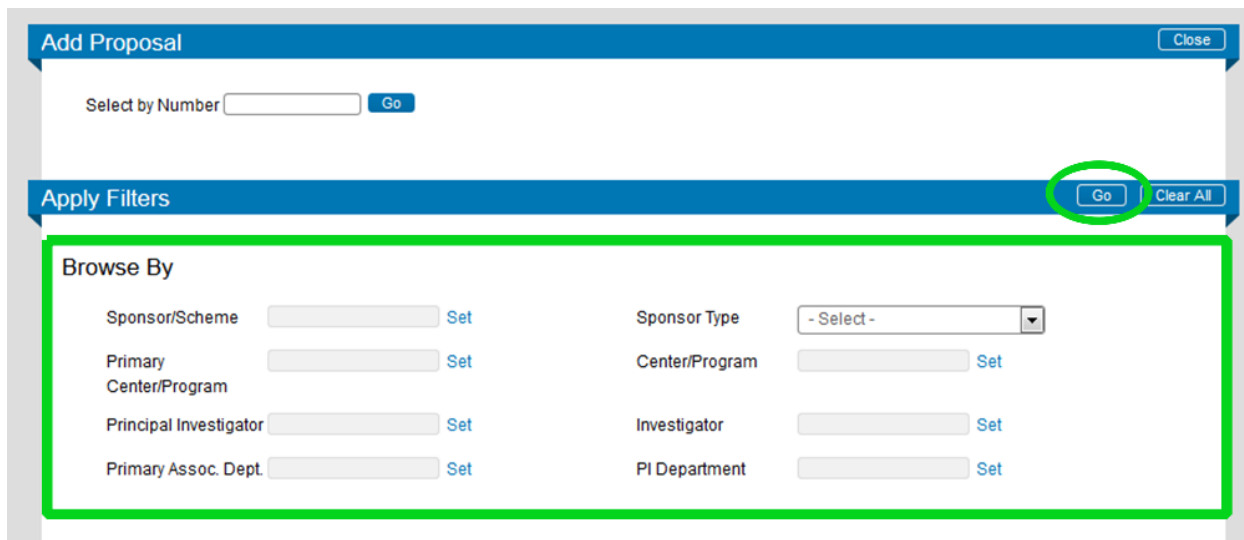
3-2 Click **Add**.



3-3a Enter proposal number (from HRP-211 Initial Application).
 ▪ If proposal number is not available, see step 3-3b.



3-3b Locate the proposal by browsing by PI, Department, etc. Click **Go** to search.



Add Proposal Close

Select by Number Go

Apply Filters Go Clear All

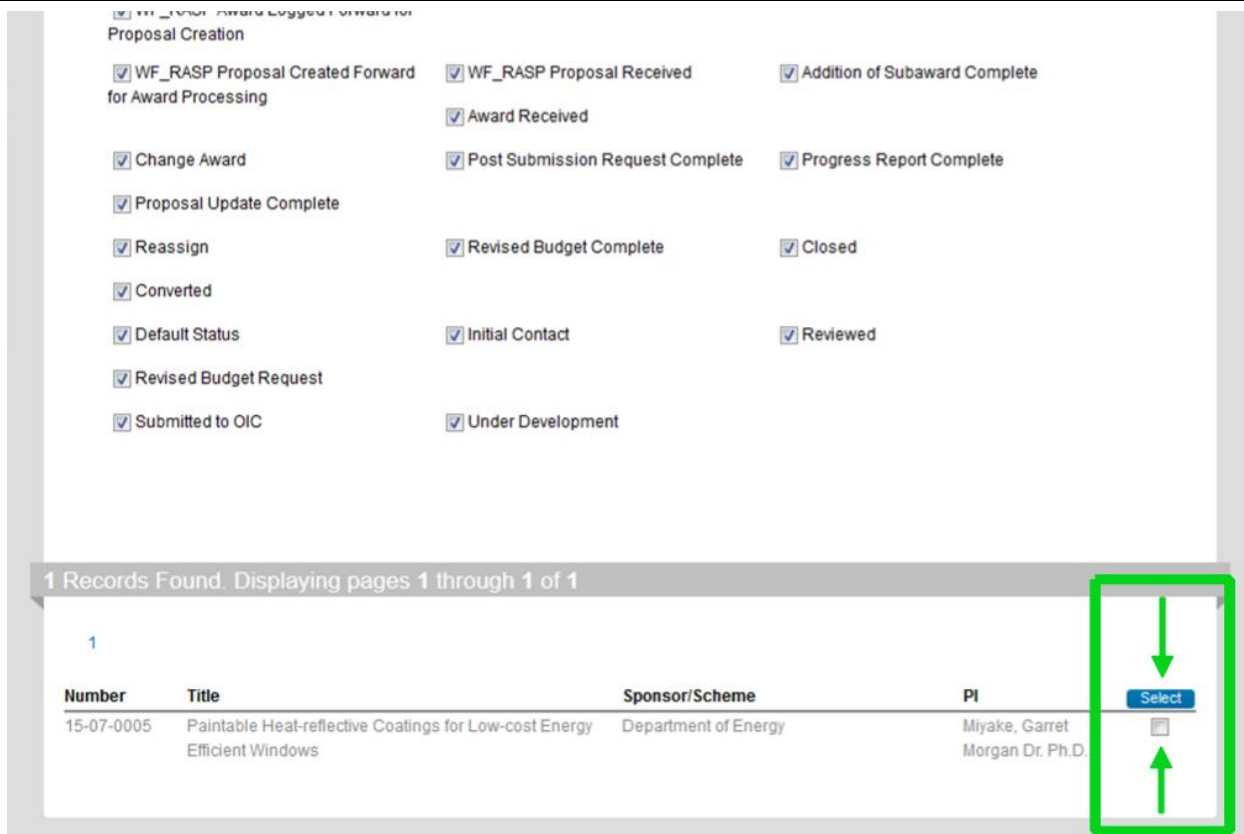
Browse By

Sponsor/Scheme <input type="text"/> Set	Sponsor Type - Select -
Primary Center/Program <input type="text"/> Set	Center/Program <input type="text"/> Set
Principal Investigator <input type="text"/> Set	Investigator <input type="text"/> Set
Primary Assoc. Dept. <input type="text"/> Set	PI Department <input type="text"/> Set

3-4 Scroll down to the bottom of the page.

3-5 Check the box for the connected proposal.

3-6 Click **Select**.



Proposal Creation

- WF_RASP Proposal Created Forward for Award Processing
- Change Award
- Proposal Update Complete
- Reassign
- Converted
- Default Status
- Revised Budget Request
- Submitted to OIC
- WF_RASP Proposal Received
- Award Received
- Post Submission Request Complete
- Revised Budget Complete
- Initial Contact
- Under Development
- Addition of Subaward Complete
- Progress Report Complete
- Closed
- Reviewed

1 Records Found. Displaying pages 1 through 1 of 1

Number	Title	Sponsor/Scheme	PI	Select
15-07-0005	Paintable Heat-reflective Coatings for Low-cost Energy Efficient Windows	Department of Energy	Miyake, Garret Morgan Dr. Ph.D.	<input checked="" type="checkbox"/>

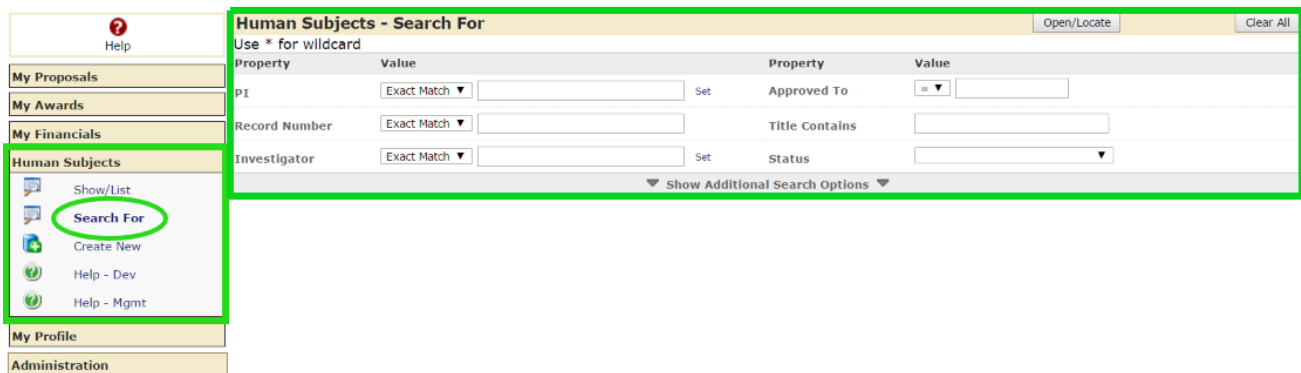
III. Accessing the IRB Approval Letter

1) Locate the Protocol in HS.

1-1 From the eRA dashboard, click on **Human Subjects**.

1-2 From the Human Subjects menu, click **Search For**.

1-3 Enter identifying information from the proposal, such as PI name.



Human Subjects - Search For Open/Locate Clear All







Use * for wildcard

Property	Value	Property	Value
PI	Exact Match <input type="text"/>	Approved To	<input type="text"/>
Record Number	Exact Match <input type="text"/>	Title Contains	<input type="text"/>
Investigator	Exact Match <input type="text"/>	Status	<input type="text"/>

[Show Additional Search Options](#)

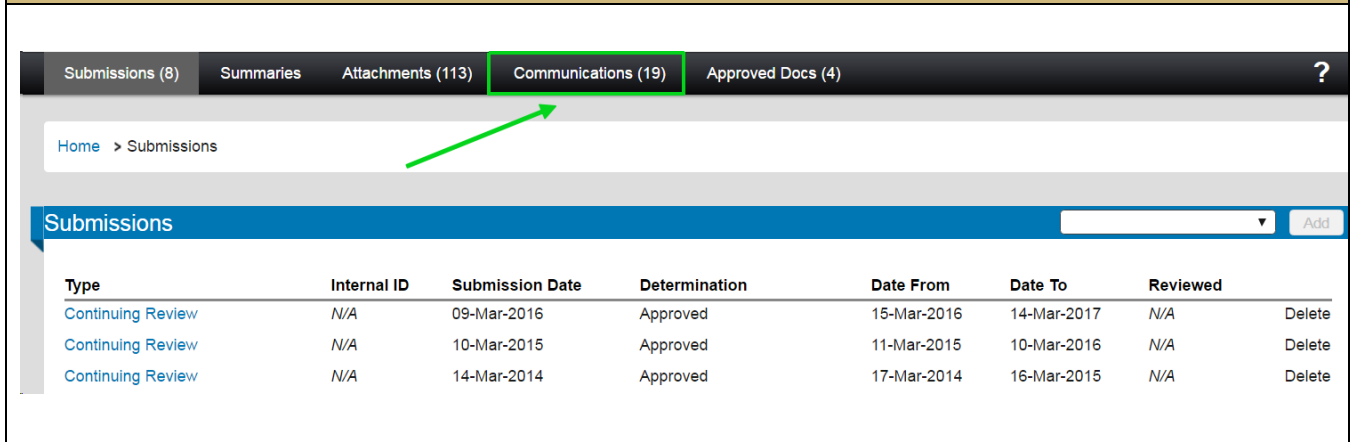
1-4 Click on the yellow folder under **Actions** to open the protocol.

- Notes: Hover over the Quick Status icon to reveal a pop-up with the current status of the protocol.

Actions	Number	Title	Sponsor/PI/Department	Quick Status	Delete
	0106.13 Start:23-Jan-2006	AIDS Pharmaceutical Politics in Argentina, Mexico and Brazil			
	0107.41 Start:13-Feb-2007	Promoting Stress Resilience in College Students			
	0108.10 Start:25-Aug-2010	ELEvATE: Educative Learning Progressions as Tools for Teacher Development	Furtak Erin M 10261 -- EDUCATION		

Protocol Status: Approved
Approved Date: 15-Mar-2016
Approved From: 23-Jan-2006
Approved To: 14-Mar-2017

2) Click on the Communications Tab.



Submissions (8) | Summaries | Attachments (113) | **Communications (19)** | Approved Docs (4) | ?

Home > Submissions

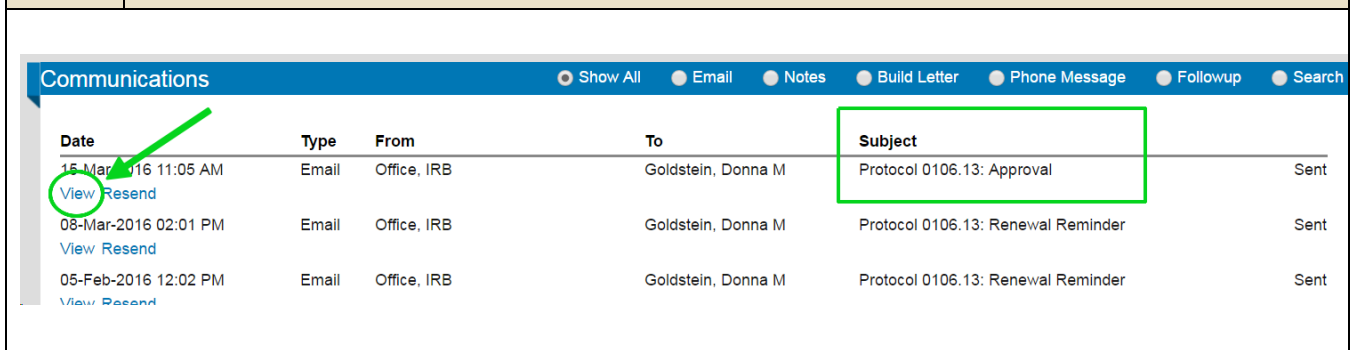
Submissions Add

Type	Internal ID	Submission Date	Determination	Date From	Date To	Reviewed	
Continuing Review	N/A	09-Mar-2016	Approved	15-Mar-2016	14-Mar-2017	N/A	Delete
Continuing Review	N/A	10-Mar-2015	Approved	11-Mar-2015	10-Mar-2016	N/A	Delete
Continuing Review	N/A	14-Mar-2014	Approved	17-Mar-2014	16-Mar-2015	N/A	Delete

3) Open the Approval Letter.

If the protocol has been approved, there will be a Communication titled "Protocol XXXXX: Approval".

3-1 | Open the communication by clicking **View**.



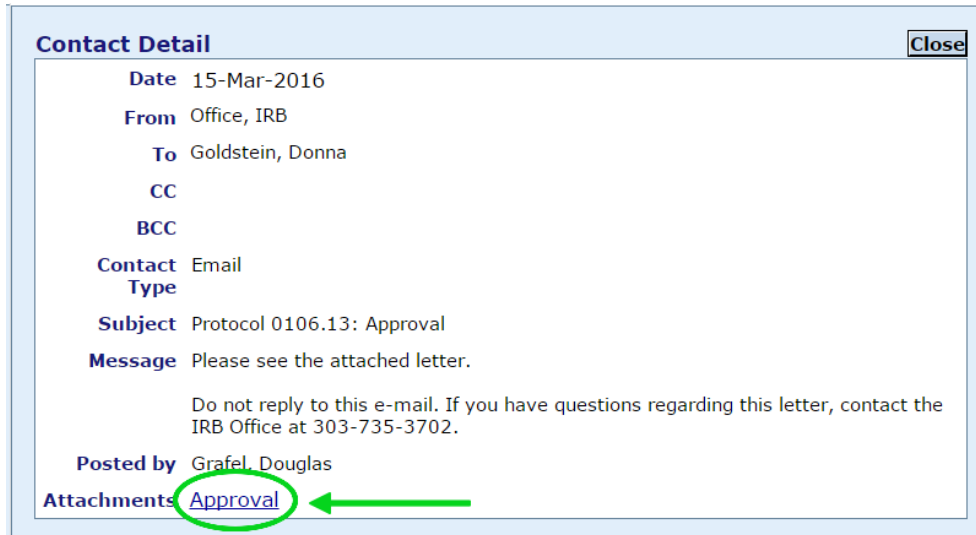
Communications Show All Email Notes Build Letter Phone Message Followup Search

Date	Type	From	To	Subject	
15-Mar-2016 11:05 AM View Resend	Email	Office, IRB	Goldstein, Donna M	Protocol 0106.13: Approval	Sent
08-Mar-2016 02:01 PM View Resend	Email	Office, IRB	Goldstein, Donna M	Protocol 0106.13: Renewal Reminder	Sent
05-Feb-2016 12:02 PM View Resend	Email	Office, IRB	Goldstein, Donna M	Protocol 0106.13: Renewal Reminder	Sent



3-2

At the bottom of the Contact Detail screen, open the Attachments link: **Approval**.



The approval letter will open as a PDF in a new window. Download the file to your computer if desired.