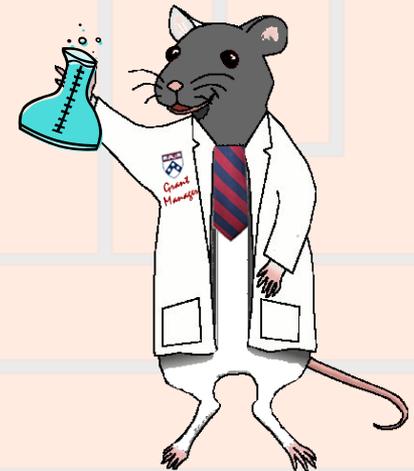
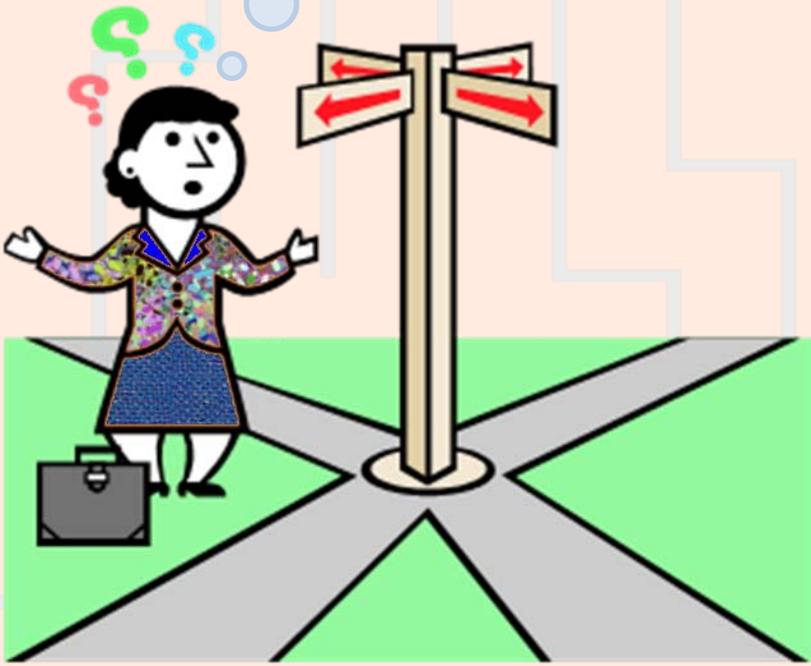


Regulatory Approvals Scenario

What is the status of the regulatory approvals for my outstanding proposals?

The following slide will present you with a few questions to help refine your not-very-specific question into a re-defined business question that can be matched to PennERA Proposals data for an answer!



Regulatory Approvals Scenario – Step 1a

Re-defining Your Question

If your business question is not framed correctly (or completely), you will not be able to define your data query adequately. Here are some questions you should ask (and answer!) BEFORE attempting to write your query. Read them and consider what kinds of answers you might come up with. Besides asking/answering these questions, best practice is to check the cautions in the PennERA Proposal [table documentation](#) as well.

- **What do you mean by “my” proposals?**
 - Proposals that have a particular person listed as responsible for
 - the project as a whole (the Principal Investigator (PI))?
 - for one or more accounts (a co-investigator)?
 - the project and/or one or more accounts?
 - Proposals that cite a particular school/center or ORG
 - as the one responsible for the proposal?
 - as the one responsible for one or more increments of funding?
 - as the one responsible for one or more of the fund codes assigned to the proposal?
 - in one or more of the General Ledger account numbers assigned to the proposal?
 - Some combination of the above?
- **What do you mean by “outstanding” proposals?**
- **What specific information do you want to display in your report?**



Hints
and
Tips

Note: Regulatory approvals are associated with proposals (funding cycles or project periods), not with budget periods or requests for budget period or supplement funding.

Regulatory Approvals Scenario – Step 1b

Re-defining Your Question



Initial question: “What is the status of the regulatory approvals for my outstanding proposals?”

Re-defined question: “One of my responsibilities is to ensure that every proposal for my ORG meets the sponsor’s requirements regarding regulatory approvals. I need a report on proposals for which my ORG (4528, PA-Laboratory Medicine) is responsible. The report should include only proposals whose current status is not 'Withdrawn', 'Unfunded', 'Awarded', 'Not Submitted', or 'Closed' – in other words, proposals that either will be submitted to the sponsor, or that have been submitted but the final funding decision is outstanding.

I would like to review the regulatory approval information for each proposal with the PI to make sure that the regulatory approval status information is correct, and that all of the necessary approvals have been obtained. (We might need to have regulatory approval information updated in PennERA. We also might need to follow up on some aspects so that everything is approved.)

The report should display the proposal’s Institution No., the names of the PI and the sponsor, the project title, the requested project start and end dates, the proposal’s current status, the submitted date, and the information on the regulatory approvals: the regulatory type, approval status, reference number, approval date, approved from and to dates, review category, protocol attached flag, and prot. no. “

All aspects of a proposal that are subject to regulatory oversight must be approved before the proposal is awarded; often, they must be approved even before the proposal is submitted to the sponsor!



Regulatory Approvals Scenario – Step 2

Many of the result objects needed for this report are objects in the **Pennera Proposal** folder, which includes the proposal's current status. The other result objects that you want are in the **Pennera Prop Regulatory Appr** folder. Drag or double click the following objects to make them appear in the **Result Objects panel**:

- **Pennera Proposal:**  
 - Institution No (PROP)
 - Pi Name (PROP)
 - Sponsor Description (PROP)
 - Project Title (PROP)
 - Requested Project Start (PROP)
 - Requested Project End
 - Proposal Status (PROP)
 - Submitted Date (PROP)

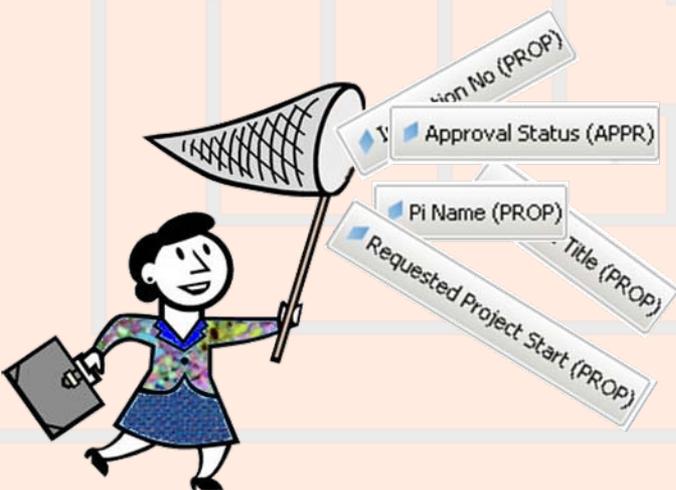
WHY? → This folder provides information about your outstanding proposals.

[More...](#)

- **Pennera Prop Regulatory Appr :**  
 - Regulatory Type (APPR)
 - Approval Status (APPR)
 - Reference No (APPR)
 - Approval Date (APPR)
 - Approved From (APPR)
 - Approved To (APPR)
 - Review Category (APPR)
 - Protocol Attached (APPR)
 - Prot No (APPR)

WHY? → This folder provides information about the regulatory approvals for your outstanding proposals.

[More...](#)



Regulatory Approvals Scenario – Step 3

To restrict the query so that it retrieves only the proposals you want, use query filters. The order of the filters does not matter, as long as all of them are specified. The filters all involve objects from the **Pennera Proposal** folder

➤ **Proposal Resp Org Code:** ? →

- Drag **Proposal Resp Org Code (PROP)** to the **Query Filters** area.
- Select “Equal to” from the operators, and then type “4528” in the empty field for PA-Laboratory Medicine.

WHY? → This selects only proposals for which your ORG is responsible.

➤ **Proposal Status:** ? →

- Drag **Proposal Status (PROP)** to the **Query Filters** area.
- Select “In list” from the operators, and then select “Value(s) from list”.
- Select the following from the dialog box that opens:

WHY? → We need this filter to retrieve only the proposals whose final funding decision is outstanding.

CASE SENSITIVE

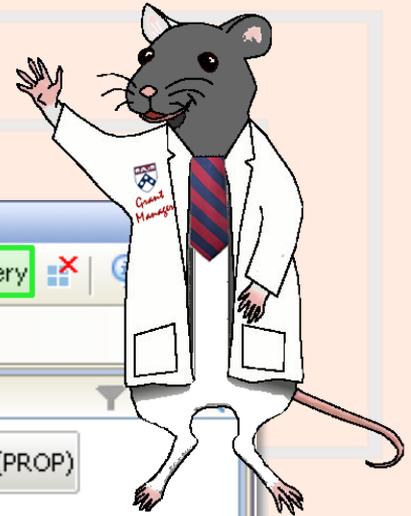
1. *Advance Account*
2. *In Process*
3. *Negotiation*
4. *Negotiation Complete*
5. *Pending*
6. *Revised Budget Requested*
7. *Under Review*

Use these values lists as often as you can to avoid typos or mistakes in formatting which will cause in inaccurate report results!



Regulatory Approvals Scenario – Step 4

Your **Edit Query Panel** should now look like this. Click **Run Query** to advance to the next slide.



Regulatory Approvals Scenario - 2

Edit Query Edit Report Run Query

Add Query SQL

Data Proper..

Result Objects

- Institution No (PROP)
- Pi Name (PROP)
- Sponsor Description (PROP)
- Project Title (PROP)
- Requested Project Start (PROP)
- Requested Project End
- Proposal Status (PROP)
- Submitted Date (PROP)
- Regulatory Type (APPR)
- Approval Status (APPR)
- Reference No (APPR)
- Approval Date (APPR)
- Approved From (APPR)
- Approved To (APPR)
- Review Category (APPR)
- Protocol Attached (APPR)
- Prot No (APPR)

Query Filters

And

- Proposal Resp Org Code (PROP) Equal to 4528
- Proposal Status (PROP) In list Complete;Pending;Revised Budget Requested;Under Review

Query 1

Regulatory Approvals Scenario – Step 5



Your **Edit Report Panel** should now look like this after some formatting changes.
 Note: If a proposal has a submitted date, and its status is **In Process** or **Under Review**, then the submitted date, the status, or both definitely need to be corrected. For more information on proposal status values, see http://www.upenn.edu/computing/da/dw/research/proposals/pennera_proposal.e.html#proposal_status.

Regulatory Approvals for PA-Laboratory Medicine Proposals

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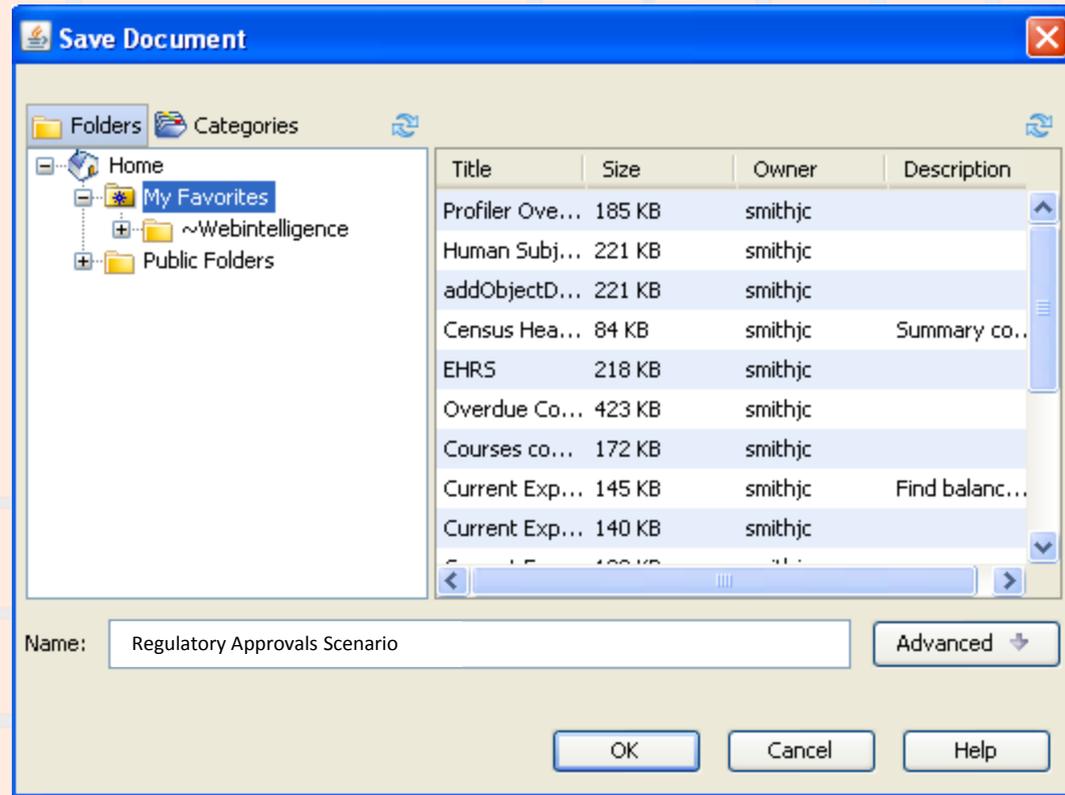
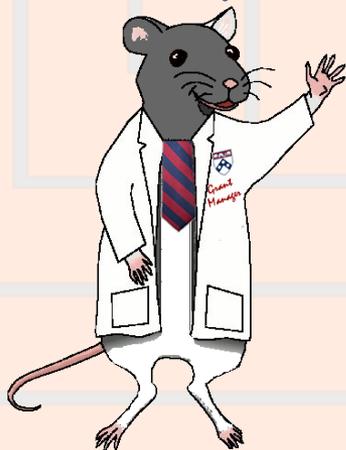
Institution No (PROP)	Sponsor Description (PROP)	Project Title (PROP)	Requested Project Start (PROP)	Requested Project End	Proposal Status (PROP)	Submitted Date (PROP)	Regulatory Type (APPR)	Approval Status (APPR)	Reference No (APPR)	Approval Date (APPR)
10003264	PHILIP MORRIS EXTERNAL RESEARCH PROGRAM	ROLE OF NEUTROPHIL DEFENSINS IN LUNG INJURY	6/1/05	5/31/08	Pending	8/25/04	Human Subjects	Closed	803109	
10003264	PHILIP MORRIS EXTERNAL RESEARCH PROGRAM	ROLE OF NEUTROPHIL DEFENSINS IN LUNG INJURY	6/1/05	5/31/08	Pending	8/25/04	Lab Animals	Terminated	800996	
10003264	PHILIP MORRIS EXTERNAL RESEARCH PROGRAM	ROLE OF NEUTROPHIL DEFENSINS IN LUNG INJURY	6/1/05	5/31/08	Pending	8/25/04	Lab Animals	Terminated	801383	
10003264	PHILIP MORRIS EXTERNAL RESEARCH PROGRAM	ROLE OF NEUTROPHIL DEFENSINS IN LUNG INJURY	6/1/05	5/31/08	Pending	8/25/04	Radiation Safety		R125	
	NATIONAL	Human neutrophil								

Regulatory Approvals Scenario – Step 6

Once you have run your query, you can save it. *If you do further formatting or query edits, continue to save often so you don't lose your work to an untimely "timeout"!*

- Click the **Save** icon and the following **Save Document** dialog box will appear
- Select the **My Favorites** folder on the **Folders** tab
- Type in a distinctive title for your report in the **Name:** textbox
- Click **OK**.

You can only save queries/reports to your own **My Favorites** folder or any subfolders that you have created within it to help organize your cache of reports.



Regulatory Approvals Scenario – Wrap Up

What is the status of the regulatory approvals for my outstanding proposals?

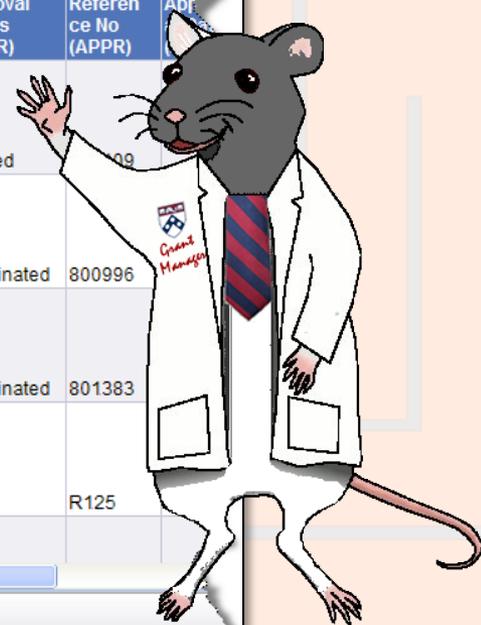
This report lists outstanding proposals by PI and provides enough information that you can meet with the PI and review details of regulatory requirements and approvals.



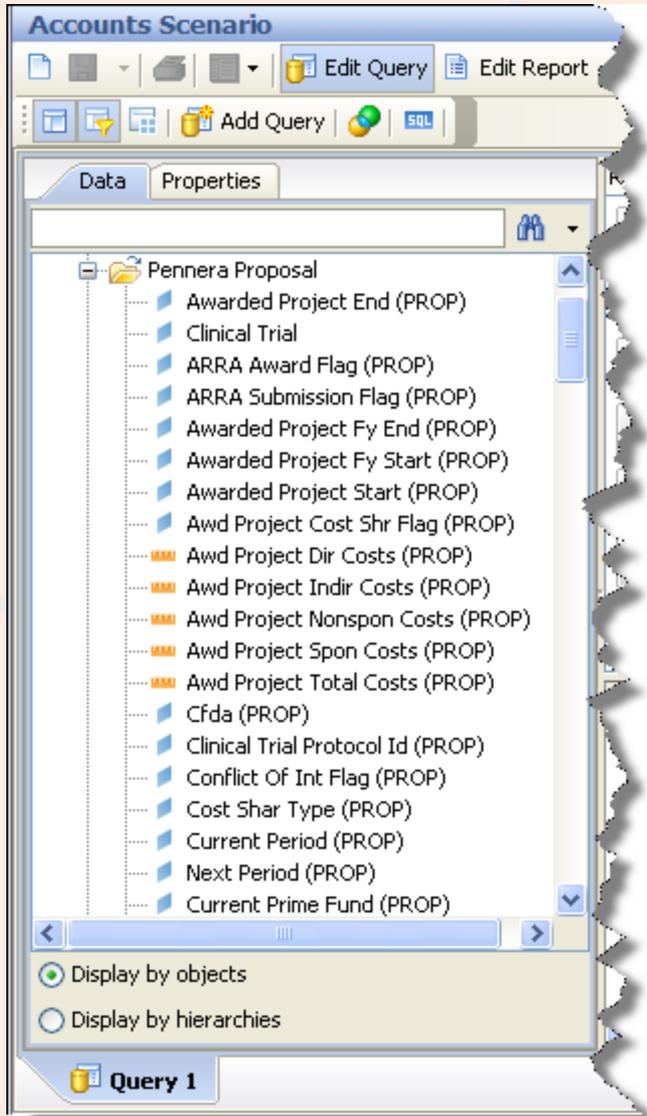
Regulatory Approvals for PA-Laboratory M

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Institution No (PROP)	Sponsor Description (PROP)	Project Title (PROP)	Requested Project Start (PROP)	Requested Project End	Proposal Status (PROP)	Submitted Date (PROP)	Regulatory Type (APPR)	Approval Status (APPR)	Reference No (APPR)	Appr
10003264	PHILIP MORRIS EXTERNAL RESEARCH PROGRAM	ROLE OF NEUTROPHIL DEFENSINS IN LUNG INJURY	6/1/05	5/31/08	Pending	8/25/04	Human Subje	Closed	09	
10003264	PHILIP MORRIS EXTERNAL RESEARCH PROGRAM	ROLE OF NEUTROPHIL DEFENSINS IN LUNG INJURY	6/1/05	5/31/08	Pending	8/25/04	Lab Animals	Terminated	800996	
10003264	PHILIP MORRIS EXTERNAL RESEARCH PROGRAM	ROLE OF NEUTROPHIL DEFENSINS IN LUNG INJURY	6/1/05	5/31/08	Pending	8/25/04	Lab Animals	Terminated	801383	
10003264	PHILIP MORRIS EXTERNAL RESEARCH PROGRAM	ROLE OF NEUTROPHIL DEFENSINS IN LUNG INJURY	6/1/05	5/31/08	Pending	8/25/04	Radiation Saf		R125	
	NATIONAL	Human neutrophil								



Why choose objects from the Pennera Proposal table?

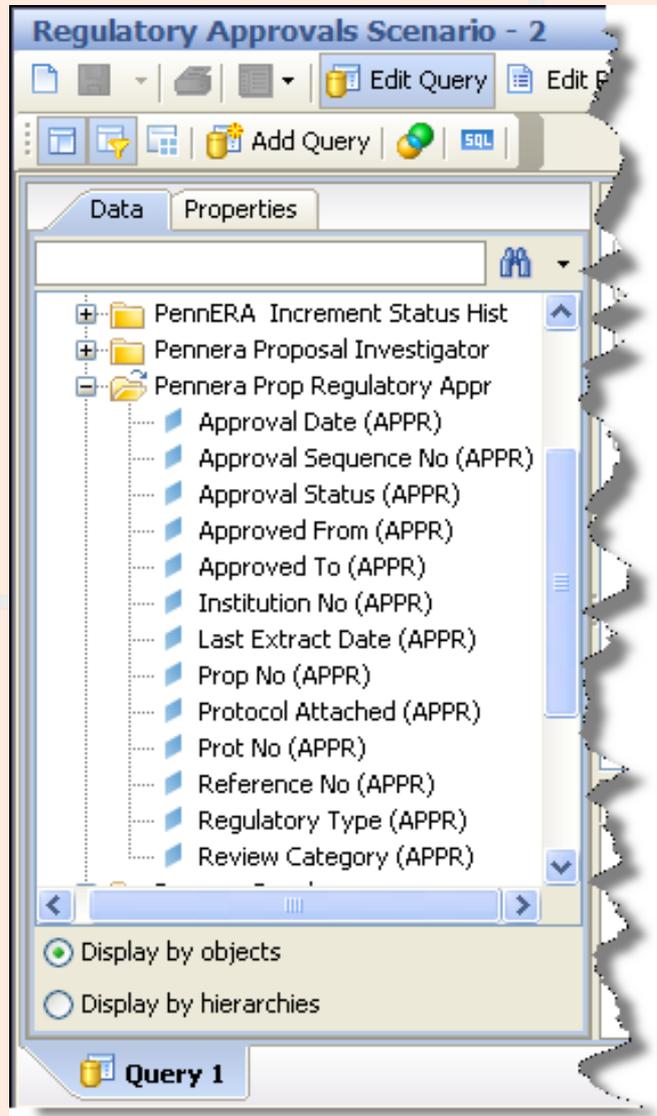


Use the Pennera Proposals table when you want the latest information on the proposal as a whole. Some common uses of the table are:

- **Finding proposals submitted to a particular sponsor.** ("Which proposals were sent to sponsor 09470, the National Institutes of Health?")
- **Comparing what was requested for a funding cycle to what was awarded.**
- **Looking up information on a proposal when its current (or previous) prime fund is known. If awarded funding for a proposal is tracked using more than one fund, the prime fund is the one used to track most of the money.** ("What is the project title for the proposal whose current prime fund is 512345?")
- **Reporting on proposals with particular attributes.** ("What proposals are for Federal Demonstration Projects (FDP Flag = 'Y')?")
- **Looking up information on a project that spans funding cycles.** ("What do we have on record for my project, which is now being funded for the 20th year? The 'First Institution No.' for the project is 12345678.")

You should not use the Pennera Proposals table when you want summarized information for one or more of the proposal's periods, or when you want detailed information on the proposal's requests or increments.

Why choose objects from the Pennera Prop Regulatory Appr table?



Use the Pennera Prop Regulatory Appr table when you want the information on the aspects of a proposal that are subject to regulatory oversight. If a proposal does not require any regulatory approvals, there are no records for that proposal in the Pennera Prop Regulatory Appr table.

Besides approvals for protocols involving human subjects or laboratory animals, the table tracks approvals for

- biosafety
- carcinogens, teratogens, or mutagens
- clinical trials
- hazardous materials
- in vitro formation of recombinant DNA
- infectious agents
- radiation safety
- select agents (biological agents or toxins deemed by the federal government to be a threat to the public, animal or plant health, or to animal or plant products)

Some common uses of the table are:

- Listing proposals that require a particular kind of regulatory approval. ("How many of Dr. Doe's proposals require radiation safety approval?")
- Finding the proposals that have been linked to a human subjects or lab animal protocol, based on the regulatory type and the protocol's ID number (reference number).

← Return to previous