


How to Access IRB Protocols

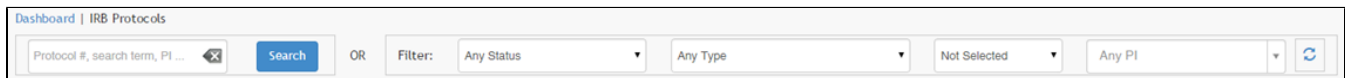
Document Links:

- IRB Protocols Search
 - Velos Filter
 - Filters and Progress Report Details
- Analyst Functions
 - Contact List
 - How do I update Study Personnel - POC?
 - Update Institutional Status
 - eResearch (VELOS) Details
 - eResearch Statuses
 - Unassociate and Sync eResearch Links

IRB Protocols Search

IRB Protocol listings are now available through ORCA. .

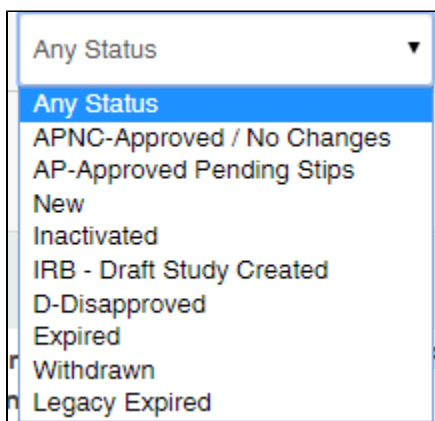
- Log onto ORCA <https://vpr.uthscsa.edu/orca/>
 - Sign in with your email address and domain password (use the Google Chrome web browser)
- Once logged on:
 - Click on the header option, **Protocols**.
 - Click **IRB Protocols** from the drop down.
 - Use the search fields to locate a protocol.
- Locate the IRB Protocol you want to view and click  from the first column, Actions.



Dashboard | IRB Protocols

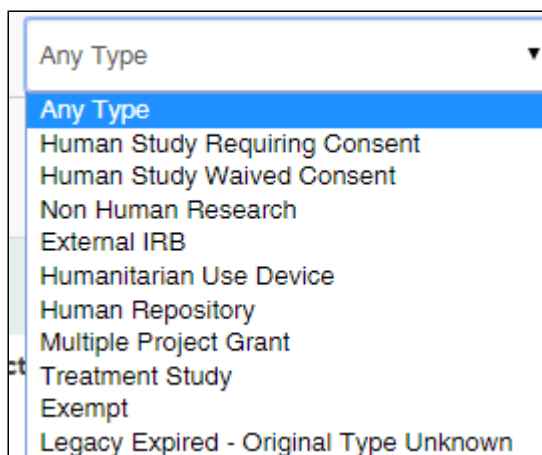
Protocol #, search term, PI ... OR Filter: Any Status Any Type Not Selected Any PI

Expanded drop downs for Filter: Any Status; Any Type and Not Selected fields above.



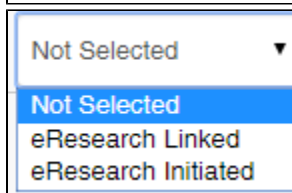
Any Status

- Any Status
- APNC-Approved / No Changes
- AP-Approved Pending Stips
- New
- Inactivated
- IRB - Draft Study Created
- D-Disapproved
- Expired
- Withdrawn
- Legacy Expired



Any Type

- Any Type
- Human Study Requiring Consent
- Human Study Waived Consent
- Non Human Research
- External IRB
- Humanitarian Use Device
- Human Repository
- Multiple Project Grant
- Treatment Study
- Exempt
- Legacy Expired - Original Type Unknown



Not Selected

- Not Selected
- eResearch Linked
- eResearch Initiated

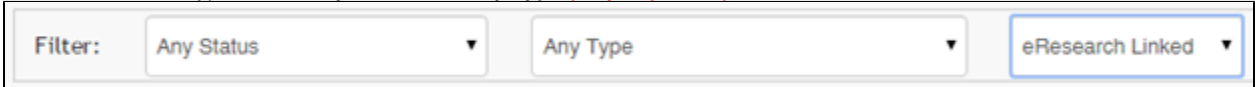
Velos Filter

When accessing IRB Protocols, there is a filter option specific to Velos eResearch:

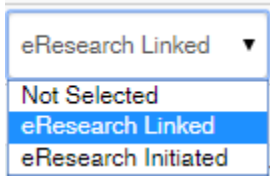
- eResearch Linked
- eResearch initiated

Keep in mind, there are over 5,000 records to filter through, so when sorting, the sort feature will take some time:
From the filter bar, click the new drop down

1. Set the Status and Type filter to **Any Status** and **Any Type (very important)**




2. From the filter bar, click an option from the drop down:



3. Click the refresh table icon to set the filter.
4. You will now see your list of results.

Filters and Progress Report Details

All header options: **Actions**; **Protocol Number**; **Protocol Details**; **VELOS eResearch**; **Expiration and PI** can be used to filter. One click and items will sort.

Column	Details
Action	<ul style="list-style-type: none">• IRB Progress Report details - will include a count down to to when the Progress Report is due (PR Due: X days) and when the progress report is received into the office (PR Rcvd: YEAR-Month-Date)• *PR Rcvd is coming from PIMS' field DateRptRecd.  <ul style="list-style-type: none">• To view and edit IRB Protocol details, click the folder icon. You will be directed to the Analyst Functions page for that specific protocol.

will show details to the eResearch ID's **CTMS number** and **Enrollment Status** and **Created** for those studies created in Velos eResearch. If there is no created date, this indicates the protocol was not initiated in Velos eResearch.

VELOS eResearch

eResearch ID: CTMS 15-2056
 Enroll. Status: ---
 Created: 2015-07-02

Velos eResearch Study Status History

In Velos eResearch the **Study Status** is tied to the Protocol's Status that can be found in O.R.C.A. The date reflects when the Status changed.

Study Status History:

Organization	Study Status	Status Valid From
UTHSCSA	<u>HSC - Active</u>	
	<u>PRE-ACTIVATION/UT</u>	07/09/2015
	<u>IRB - Approved/UT</u>	09/04/2014

Actions	Protocol Number	Protocol Details	VELOS eResearch	Expiration	PI
<p>PR Due: 2 day(s) PR Revd: 2015-04-09</p>	15-2056	<p>Trial of Standard of Care for the Treatment of Stage I/II Cervical Cancer</p> <p>Phase: Human Study, Requiring Consent</p> <p>IRB Status: Active</p>		2015-05-06	
<p>PR Due: 2 day(s) PR Revd: 2015-03-24</p>	15-2056	<p>Trial of Standard of Care for the Treatment of Stage I/II Cervical Cancer</p> <p>Phase: Human Study, Requiring Consent</p> <p>IRB Status: Active</p>		2015-05-06	

Sort and Filter options are located on the header

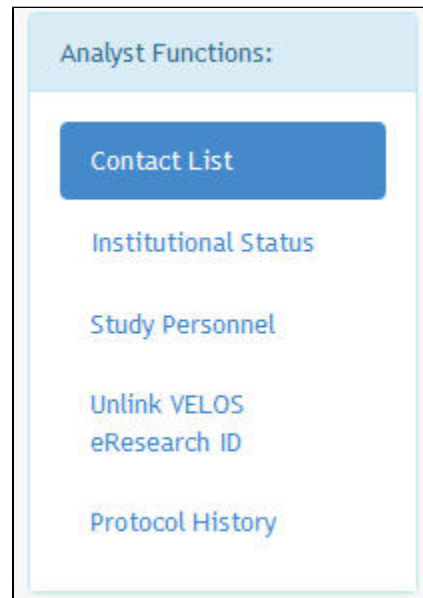
Progress Report Due count down

Actions	Protocol Number	Protocol Details	VELOS eResearch	Expiration	PI
	20150262HU	Title: Randomized Trial of Standard Care versus Mesh Closure of Umbilical Port Site after Laparoscopic Cholecystectomy Type: Human Study Requiring Consent HSC Status: HSC - Active Update HSC Status	CTMS 99-0100 2015-02-18	2016-03-10	
	20150263HU	Title: Randomized Trial of Standard Care versus Mesh Closure of Umbilical Port Site after Laparoscopic Cholecystectomy Type: Human Study Requiring Consent HSC Status: HSC - Active Update HSC Status	CTMS 99-0001 Not Recruiting / UT 2015-02-18	2016-03-10	
	20150293HU	Title: Randomized Trial of Standard Care versus Mesh Closure of Umbilical Port Site after Laparoscopic Cholecystectomy Type: Human Study Requiring Consent HSC Status: HSC - New Update HSC Status	Oral ho CTMS 80-0100 2015-02-24	2016-03-24	
	20140233EX	Title: Randomized Trial of Standard Care versus Mesh Closure of Umbilical Port Site after Laparoscopic Cholecystectomy Type: Human Study Requiring Consent	CTMS 99-0010 2014-09-04	2019-03-21	
	20150486HU	Title: Randomized Trial of Standard Care versus Mesh Closure of Umbilical Port Site after Laparoscopic Cholecystectomy Type: Human Study Requiring Consent	CTMS 99-0002 PRE-ACTIVATION / UT 2015-03-19		

Analyst Functions

Both OCR and CTO roles will have access to this page. Analyst Functions will allow for study Point of Contact to be managed in addition to the management of Institutional Status and removing eResearch link to an IRB Protocol.

Actions completed within each function will be displayed in the Protocol History view.



Contact List

The contact list provides a summary view of the protocol details including the PI, Co-PI, emergency contacts, point of contact, and delegates.

How do I update Study Personnel - POC?

- [IRB Protocols - Analyst Functions#AnalystFunctions-StudyPersonnel](#)

Update Institutional Status

This section should only be modified by an OCR staff member. All IRB protocols will contain the section, *Institutional Status*. This status will be displayed only in O.R.C.A. and will not be found in the PIMS database.

1. Access O.R.C.A., click Protocols > IRB Protocols
2. Search for your protocol
3. From the Actions column, click the blue folder
4. From the Analyst Functions menu, click the link, **Institutional Status**
5. **Select an Institutional Status**
6. **Set the Effective Date** by clicking into the field

7. Click the button, Change Status

Update Institution Status

Select Institution Status:

Set Effective Date:

eResearch (VELOS) Details

eResearch Statuses

The below items are details that are view-only in O.R.C.A., except Current Institution Status. Next to each item will include the data source. If any item below is incorrect, the data source will need to be modified to make the correction.

Field	Source Data
eResearch ID	eResearch / Velos
IRB Status	PIMs database
Enrollment Status	eResearch / Velos
Current Institution Status	O.R.C.A.

Unassociate and Sync eResearch Links

This section should only be modified by a **CTO Manager** and will be available only to those protocols which are currently linked to eResearch.

If section, Wipe eResearch Linking is unavailable, it is due to a link not being present.

eResearch Info

eResearch ID: CTMS 99-0100
IRB Status: IRB - Approved
Enrollment Status: Not Set
Current Institution Status: HSC - Active Effective Date: Not Set

Unassociate eResearch Link

Select Yes to remove eResearch link to ORCA:

Note: this will remove the link in ORCA to eResearch and remove the ORCA ID and Protocol Number from VELOS

Sync eResearch with ORCA

Select Yes to sync eResearch with ORCA:

Note: this will update the protocol number, protocol title, protocol type, irb status and institutional status in eResearch with the values in ORCA

For **technical** assistance contact the IT department of the Vice President of Research
or email vpr-it@uthscsa.edu