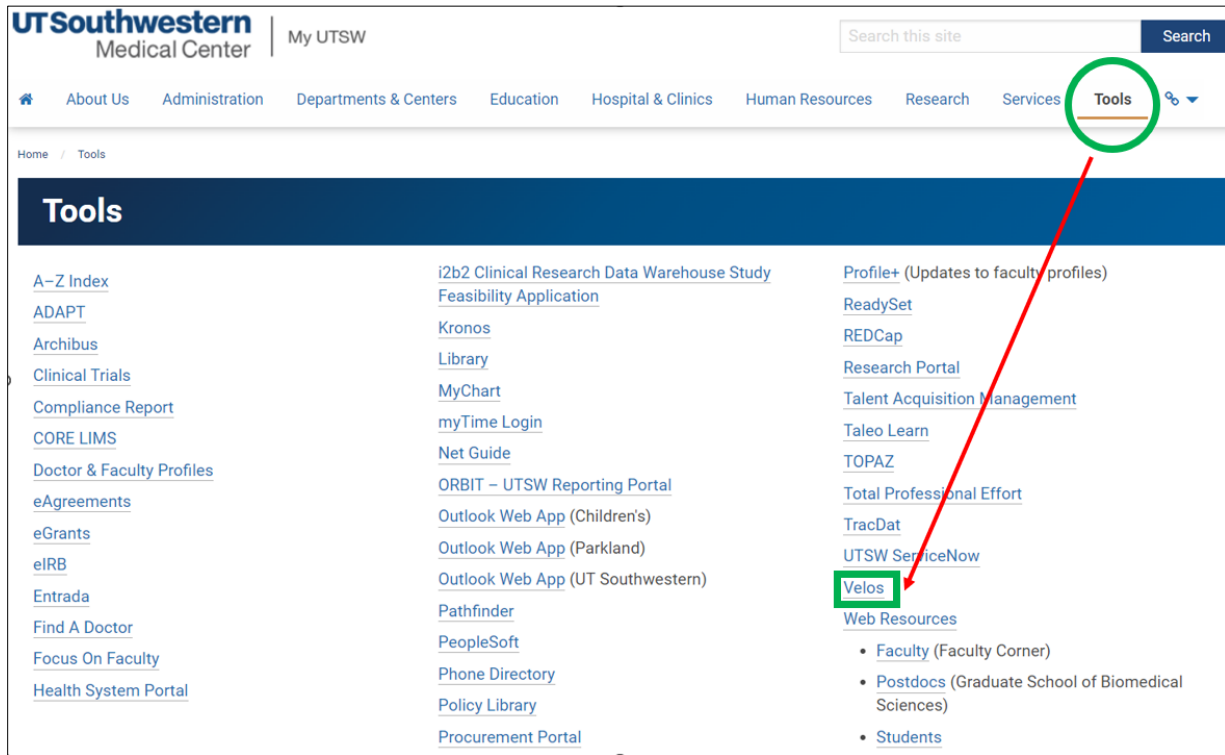
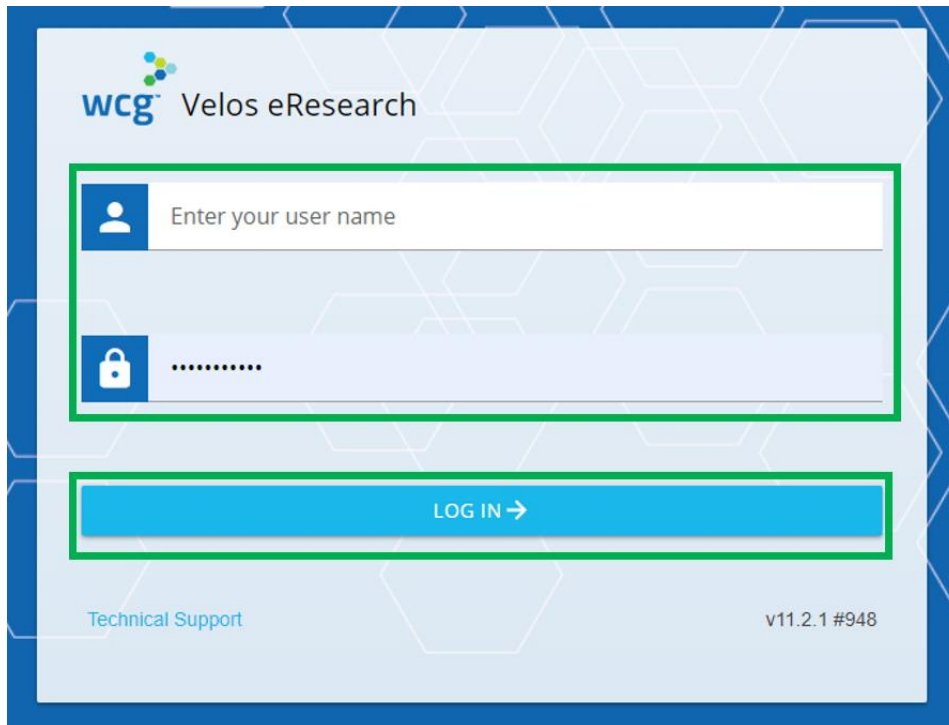


Q3. How do I request a coverage analysis modification?

To request modifications, login to **Velos** from the **Tools** page on the UTSW website.



Enter your UTSW username and password to login to **Velos**.



In the **Search a Study** field, enter the study number, then click **Search**. Next, click the **Study Administration** icon to pull up the study summary.

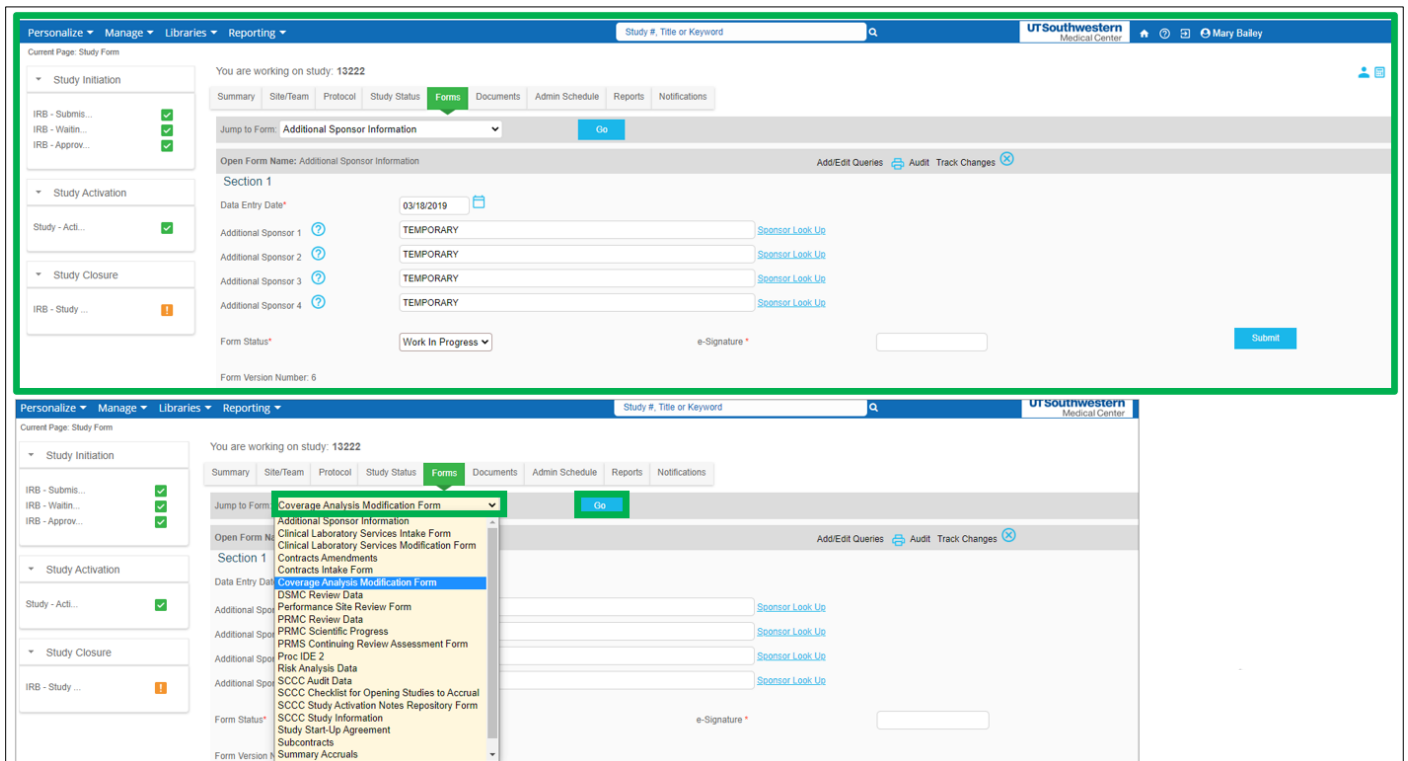
The top screenshot shows the search interface with '13222' entered in the 'Search a Study' field and the 'Search' button highlighted. The bottom screenshot shows the search results for study 13222, with the 'Study Administration' link highlighted in the 'Quick Access' section.

You will now be on the **Study Summary** page. Click the **Forms** tab.

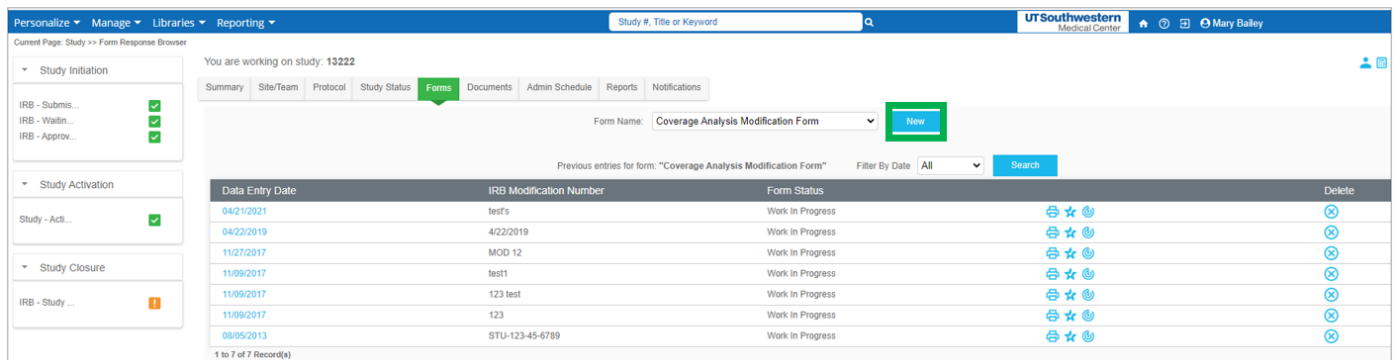
The screenshot shows the Study Summary page for study 13222. The 'Forms' tab is highlighted in the navigation bar. The page displays study information, including the study entered by, principal investigator, and primary research coordinator. A table of IND/IDE information is also visible.

IND/IDE Types	IND/IDE Number	IND/IDE Grantor	IND/IDE Holder Type	NIH Institution, NCI Division/Program Code (If applicable)	Expanded Access?
IND Exempt	rusty test1	N/A	Organization	Select	<input checked="" type="checkbox"/>
IND	Shibys drug h	N/A	N/A	Select	<input type="checkbox"/>
IDE	Shibys device h	N/A	Investigator	Select	<input type="checkbox"/>
IDE Exempt	Shibys drug g	N/A	Investigator	Select	<input type="checkbox"/>
IND/IDE	Shibys device c	N/A	N/A	Select	<input type="checkbox"/>
IDE	Shibys device g	N/A	N/A	Select	<input type="checkbox"/>
IND	Shibys drug f 11111	N/A	N/A	Select	<input type="checkbox"/>
IDE	Shibys device d	N/A	N/A	Select	<input type="checkbox"/>
IND	Shibys drug e	N/A	N/A	Select	<input type="checkbox"/>

After clicking the **Forms** tab, a new window appears. From the drop down menu, select the option for **Coverage Analysis Modification Form**, then click **Go**.



On the next screen, click **New**.



The study team should complete **Section 1** of the form. Leave form status as **“Work in Progress.”** Next, enter your **e-signature** then click **Submit**.

You are working on study: 13222

Summary Site/Team Protocol Study Status **Forms** Documents Admin Schedule Reports Notifications

Jump to Form: Coverage Analysis Modification Form

Open Form Name: Coverage Analysis Modification Form

Section 1 (To be filled out by the study team)

Data Entry Date*

Velos Number*

IRB Modification Number*

Has Modification Gone to IRB? * Yes No

Does this affect the Budget and/or items and services? * Yes No

What is the change to the budget and/or items and services?

Section 2 (To be filled in by the CCAG)

CTCA Modification Not Required

Coverage Analysis Analyst

CTCA Modification Request Received

CTCA Modification Draft Completed

CTCA Modification QA Complete/Ready for PI Review

CTCA Modification On Hold

CTCA Modification Hold Removed

CTCA Modification PI Approved

CTCA Complexity

Study Calendar Name

Coverage Analyst Comments

Form Status*

e-Signature*

On the next screen, select **Study Status**, then **Add New Status**.

Personalize Manage Libraries Reporting UTSouthwestern Medical Center Mary Bailey

Current Page: Study >> Status

You are working on study: 13222

Summary Site/Team Protocol **Study Status** Forms Documents Admin Schedule Reports Notifications

Search by Organization: All

Current Status: Study - Study Calendar Received in UTSW EMR Study Start Date: 06/19/2019 Study End Date:

Study Status History:

Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes	Delete
UT Southwestern Medical Center and Affiliates	Study - Study Calendar Received in UTSW EMR	01/09/2023	-	-	Sent 13222-GRID_JJ - Calendar Successfully To UTSW EPIC.	<input type="button" value="X"/>

Next, enter these **status details**:

- Organization: choose UT Southwestern Medical Center & Affiliates
- Status Type: Select Coverage Analysis from drop-down list
- Study Status- Select Coverage Analysis- Modification Submitted from drop down list
- Documented By- this field will auto-populate with your name
- Status Valid From- **enter the current date**.
- Enter e-Signature
- Click Submit.

The screenshot shows the 'Study Status' form for study 13222. The form is titled 'Please enter status details:' and includes the following fields:

- Organization: UT Southwestern Medical Center and Affiliates (dropdown menu)
- Status Type: Coverage Analysis (dropdown menu)
- Study Status: Coverage Analysis - Modification Submitted (dropdown menu)
- Documented By: (Will auto-populate) (text field)
- Assigned To: (text field)
- Status Valid From: 02/06/2023 (text field)
- Status Valid Until: (text field)
- Meeting Date: (text field)
- Notes: (text area)

Red arrows point to the Organization, Status Type, Study Status, and Status Valid From fields. A green box highlights the Organization, Status Type, Study Status, and Status Valid From fields. The e-Signature and Submit buttons are also highlighted with green boxes.

The SPA Coverage Analysis Team will complete the coverage analysis modification and submit approval request to PI/Study Coordinator via DocuSign. They will also revise your final budget if appropriate.

The SPA Coverage Analyst will add the study status of "Coverage Analysis Modification- PI Approved" to the study in [Velos](#).