

To adhere to UT Southwestern's Clinical Trials Billing compliance policy, a coverage analysis is required for any clinical trial where clinical services will be performed. The analysis is referred to as a **Clinical Trials Coverage Analysis (CTCA)**. The CTCA process is managed in the Velos system.

This tip sheet will guide the Study Team through the process of requesting and approving a CTCA. Please follow the steps outlined in this tip sheet in the order they are presented.

## Step 1: Log into Velos

1. Type this link in your web browser: **https://velos.swmed.edu**

2. Type your login ID in the **Username** field and password in the **Password** field.
3. Click **Login**.
4. To logout, click the **Logout** button.

### Important Info & Tips

- You must enter your Username in all lowercase letters, but your password as you would normally enter it.
- Your username and password will be the same that you use for logging into your email.
- The Velos default e-Signature is **1234**.
- You should allow for pop-ups from the Velos system in your internet browser.

## Step 2: Search for a Study

1. Enter the Velos Study Number in the **Search a Study** field.
2. Click **Search**.

Quick Access	Study Number	Study Title	Study Status
	26068	A study to determine dose of GHI-005 whe...	Coverage Analysis - Submitted

For assistance, contact the IR Service Desk at **214-648-7600**, or [SERVICEDESK@utsouthwestern.edu](mailto:SERVICEDESK@utsouthwestern.edu).

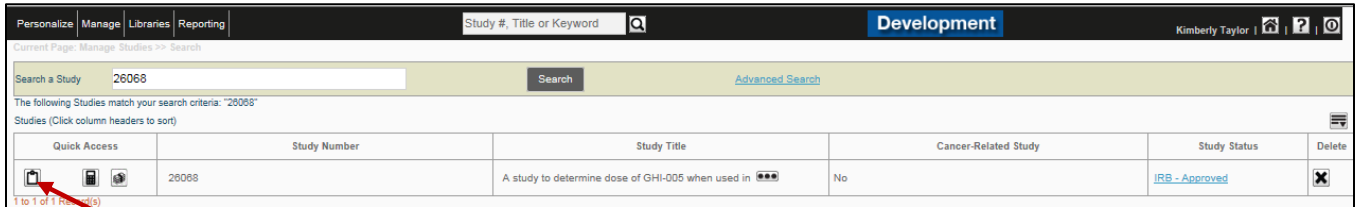
eLearning: <http://www.utsouthwestern.edu/about-us/administrative-offices/information-resources/academic-information-systems/systems/velos.html>

9/3/2014



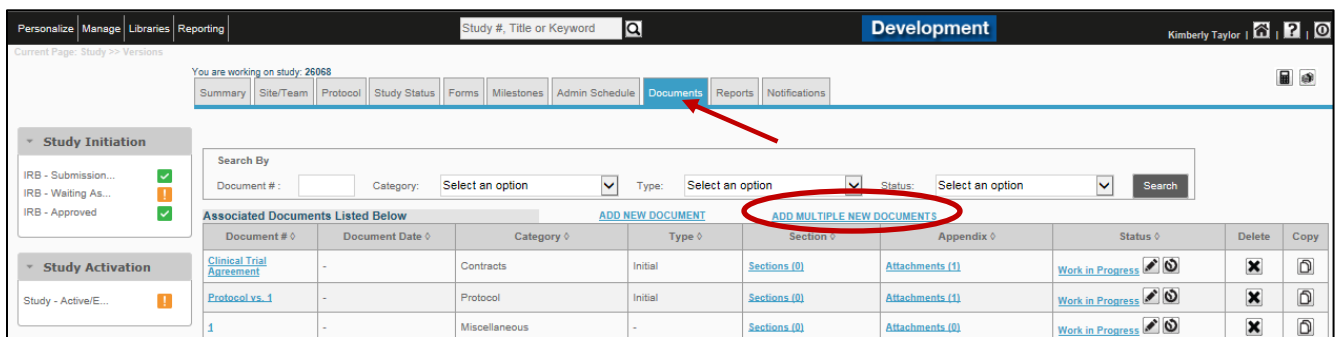
Academy for  
Career Enrichment  
UT SOUTHWESTERN

3. Click  (Study Administration) to pull up study summary.

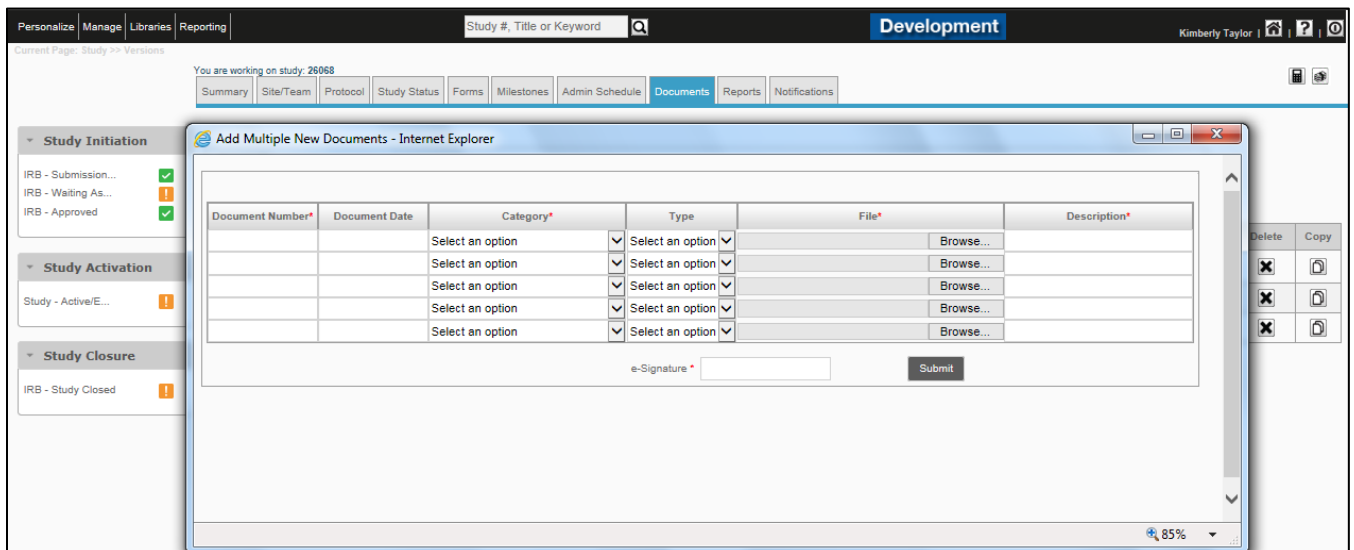


## Step 3: Upload Research Related Documents

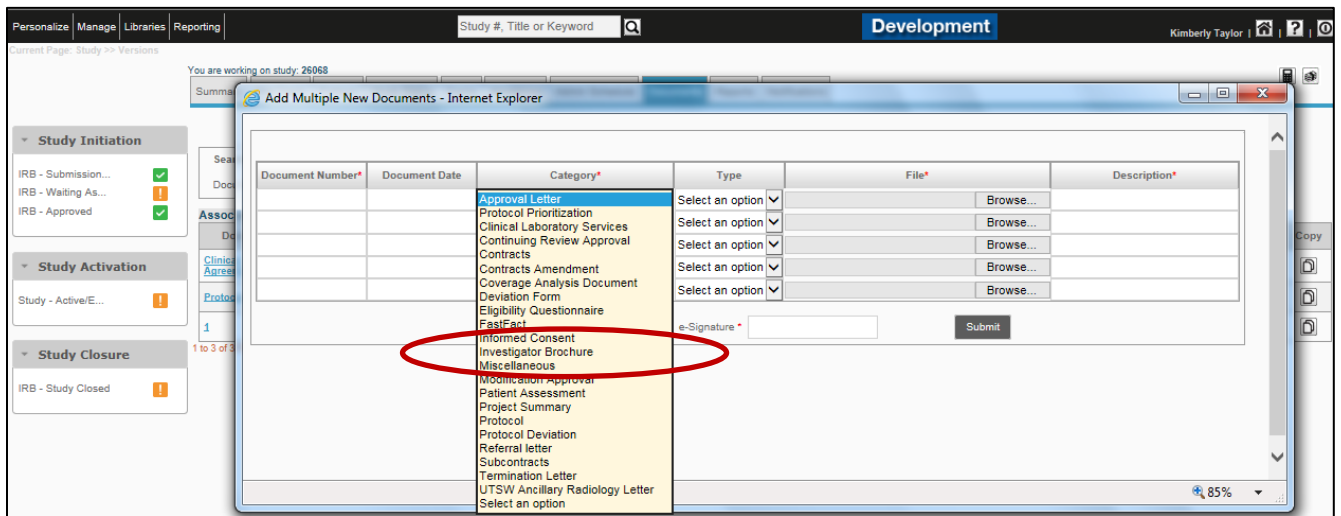
1. Click Documents.
2. Click Add Multiple Documents.
  - Documents to upload: Draft Contracts, Draft Budget, Protocol, UTSW Draft Informed Consent, Regulatory Documents (FDA IND letter, IDE letter, etc.)



3. Add New Document window displays.

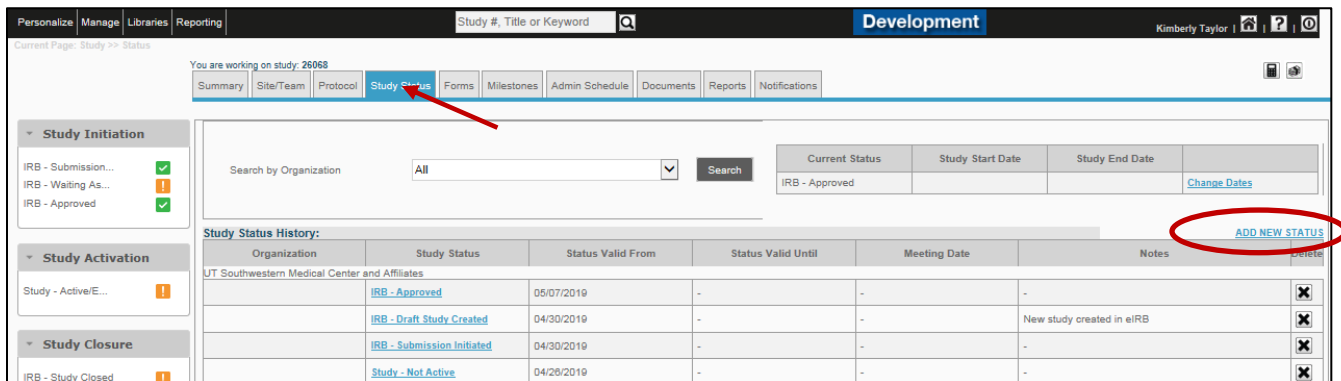


4. Enter the following document information
  - **Document Number**- enter the document name (e.g. Department Budget)
    - Document name is entered in this field because it is visible on documents page
  - **Document Date**- enter the date document is uploaded to Velos
  - **Category**- select Miscellaneous from drop down list
  - **Type**- select either Initial/Final from drop down list
  - **File**- click **Browse** button to search and choose file to upload
  - **Description**- enter the document name (e.g. Department Budget)
5. Enter **e-Signature**.
6. Click **Submit**.



## Step 4: Add a New Study Status

1. Click **Study Status**.
2. Click **Add New Status**.



3. Add a new Coverage Analysis Study Status
  - a) **Organization-** select UT Southwestern Medical Center and Affiliates
  - b) **Status Type-** select Coverage Analysis from drop-down list
  - c) **Study Status-** select Coverage Analysis - Submitted from drop-down list
  - d) **Documented By-** this field will auto populate
  - e) **Status Valid From-** enter the current date

**NOTE:** This status will trigger a Velos notification to the [clinicaltrials@utsouthwestern.edu](mailto:clinicaltrials@utsouthwestern.edu) mailbox.

4. Enter **e-Signature**.
5. Click **Submit**.

The screenshot shows the 'Study Status' form in the Velos system. The form is titled 'Study #, Title or Keyword' and is in 'Development' mode. The sidebar on the left shows 'Study Initiation', 'Study Activation', and 'Study Closure' sections. The main form area is highlighted with a red box and contains the following fields:

- Study Start Date :
- Study End Date :
- Please enter status details:
- Organization ? (Dropdown: UT Southwestern Medical Center and Affiliates)
- Status Type ? (Dropdown: Coverage Analysis)
- Study Status ? (Dropdown: Coverage Analysis - Submitted)
- Documented By \* (Text: Kimberly Taylor, Select User)
- Assigned To (Text: , Select User)
- Status Valid From \* (Text: 05/13/2019)
- Status Valid Until (Text: )
- Meeting Date (Text: )
- Notes (Text area)
- This is study's Current Status
- Organization specific current reportable status
- e-Signature \* (Text: )
- Submit (Button)

## Step 5: PI Review and Approval of CTCA

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1. The Coverage Analyst will complete the CTCA and forward PDFs of the **Coverage Analysis Billing Grid** and **Coverage Analysis Form** to the Primary Research Coordinator and PI through DocuSign for approval.
2. If the PI identifies any changes that need to be made, they will be communicated to the Coverage Analyst via email.
3. The PI will approve the CTCA through DocuSign.
4. The Coverage Analyst will add the Study Status of “**Coverage Analysis – PI Approved**” to the study, and will update the **Coverage Analysis Form**.