## Q2. How do I request a coverage analysis?

The process begins by determining whether your study requires a coverage analysis by the SPA Clinical Research Services team. UT Southwestern utilizes <u>Velos</u>, a CTMS (Clinical Trial Management System), to manage the coverage analysis process. To request a coverage analysis review, please adhere to the following steps. These tasks may be completed in parallel when appropriate.

- Manage all updates and results on <u>clinicaltrials.gov</u>. Refer to tip sheet under Resources for more information.
- Request access to Velos and eIRB by completing the <u>eResearch Access Request Form</u>.
- Register your study in <u>Velos</u>. Refer to tip sheet under Resources for more information.
- Register your study with <u>IRB</u>. Refer to tip sheet under Resources for more information.
- Request a Coverage Analysis from SPA's Coverage Analysis Team. You can submit your Coverage Analysis (CA) documents through the <u>Velos</u> system once your IRB application is complete or in draft. Refer to tip sheet under Resources for more information.

To request a coverage analysis, login to **Velos** from the **Tools** page on the UTSW website.

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Enter your UTSW username and password to login.

wcg <sup>®</sup> Velos eResearch
2 Enter your user name

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.

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	Velos Glossa	iry of Terms		Velos Glossary of Terms (Updated 1/1/2023)
	Velos Standa	ard Reports Glossary		Description and sample of Velos Reports (Updated October 2020)
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From the **Study Summary** page, click the **Documents** tab.

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After clicking the **Documents** tab, a new screen appears. Select **Add Multiple New Documents**.

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This will direct you to a second screen where you will upload all required documents (see **Documents to Upload** under **items 1 through 8** below):

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## **Documents to upload:**

- 1. Protocol
- 2. Consent draft
- 3. Budget draft, if available
- 4. Investigational New Drug (IND) letter, if applicable
- 5. Investigational Device Exemption IDE letter, if applicable
- 6. Centers for Medicare & Medicaid Services (CMS) IDE approval letter, if billing to Medicare will be done on a research device
- 7. <u>ClinicalTrials.gov</u> Registration Number (NCT) number
- 8. IRB application draft

In the remaining columns in the screenshot above, enter the following document information for each document:

- 9. Document Number
- 10. Document Date
- 11. Category
- 12. Type
- 13. File
- 14. Description

Enter e-Signature, then click Submit.

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

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Next, enter these status details (see screenshot below):

- Organization: choose UT Southwestern Medical Center & Affiliates
- For Status Type and Study Status- Select Coverage Analysis
- Documented By- this field will auto-populate

- Status Valid From- *enter the current date*. Please note that this status will trigger a notification to the Coverage Analysis team.
- Enter e-Signature
- Then click Submit.

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The SPA Coverage Analysis Team will complete the draft coverage analysis and forward the Excel version via email to the PI/Study Team for review and to facilitate sponsor negotiations. You may also access the draft coverage analysis once it is completed by clicking the study's **Documents** Tab. The next steps are as follows:

- Negotiate your final budget with sponsor. Refer to SPA Website: <u>SPA Negotiates Terms</u> for more information.
- A copy of the final coverage analysis will be sent as a PDF and includes the Coverage Analysis Billing Grid and Coverage Analysis Form to the PI/Study Team via DocuSign for final approval (upon final sponsor budget/grant).
- PI will approve Coverage Analysis in DocuSign.
- The SPA Coverage Analyst will add the study status of "Coverage Analysis- PI Approved" to the study in <u>Velos</u> and will update the Coverage Analysis Form.
- Review approved Coverage Analysis and request changes if applicable. Refer to the Velos Coverage Analysis Modification tip sheet under **Resources** for more information.

## Resources

<u>ClinicalTrials.gov</u>	Coverage Analysis Submission Tip Sheet
Clinical Trials.gov Tip Sheets	Velos Coverage Analysis Modification Tip Sheet
Clinical Trials.gov Submission Guidance	SPA Website: SPA Negotiates Terms
Velos/IRB Study Registration Tip Sheet	SPA Website: Review Study