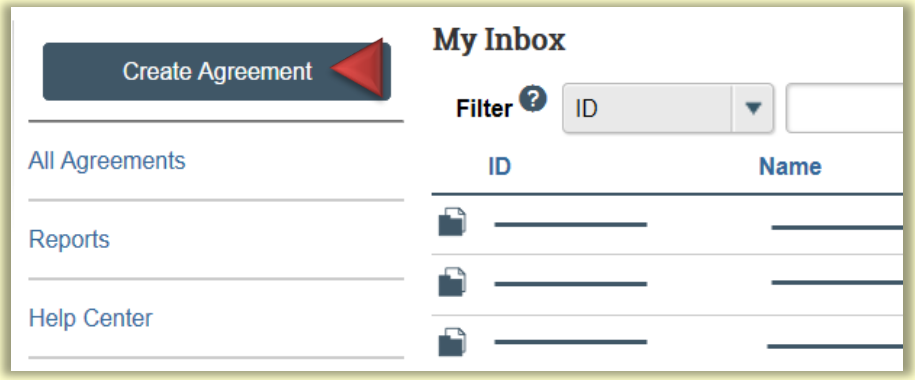
UT Southwestern
Medical Center

eAgreements
Clinical Trial Agreement (CTA) Submission Guide

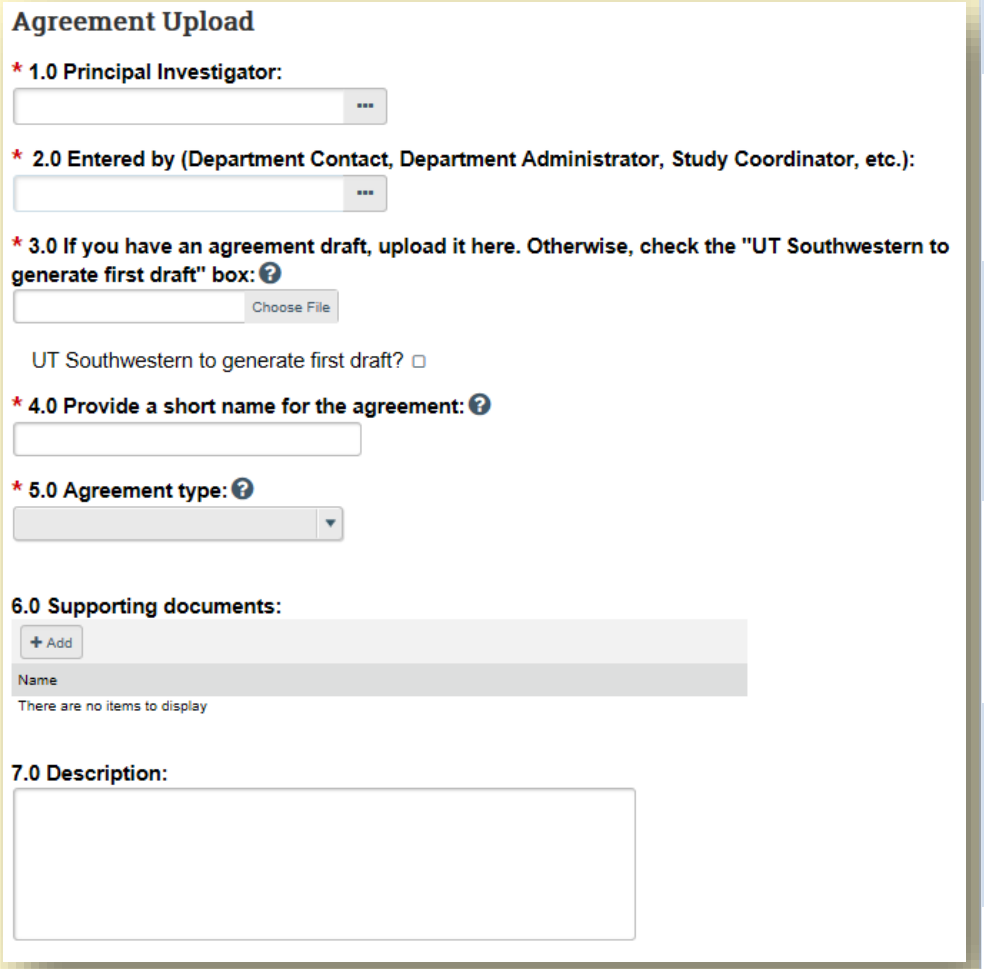
Create the Agreement

From My Inbox, click the **Create Agreement** button.



Agreement Upload

Complete the **Agreement Upload** page and click **Continue.**



1.0 Type or select the Principal Investigator name.

2.0 Automatically populates with the logged on user. This user can submit the agreement on behalf of the PI.

3.0 If the sponsor provided a draft agreement, upload it here. Otherwise, select the checkbox.

Select the question mark icon for specific help text.

4.0 Provide a name for the agreement.

Select the question mark icon for specific help text.

5.0 Select the **Clinical Trial Agreement** option.

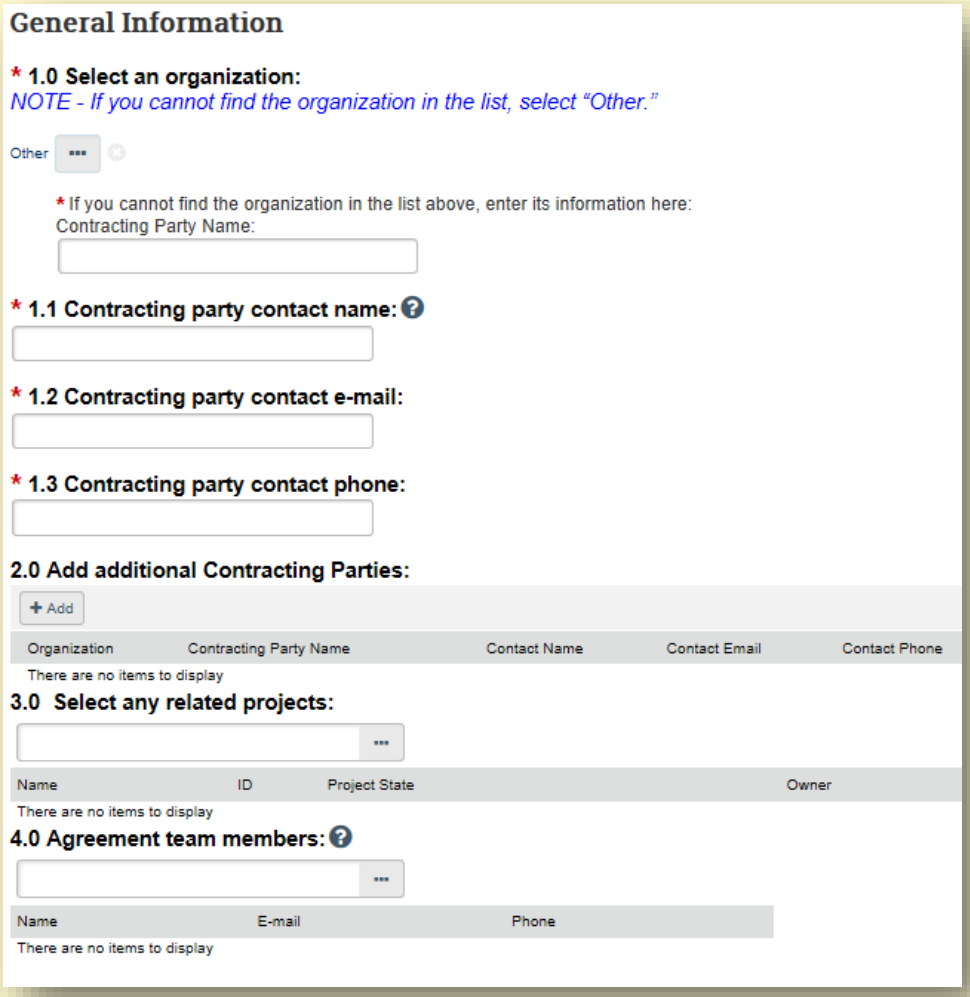
Select the question mark icon for specific help text.

6.0 (Optional) Attach any supporting documents.

7.0 (Optional) Add descriptive information, as needed.

General Information

Complete the **General Information** page and click **Continue.**



1.0 Type or select the name of the contracting party. Select "Other" if the organization is not listed and type its name. The wildcard symbol (%) can be used when typing the name or searching the list.

1.1 – 1.3 Provide the contracting party's contact name, email, and phone number.

Select the question mark icon for specific help text.

2.0 (Optional) Add any additional contracting parties.

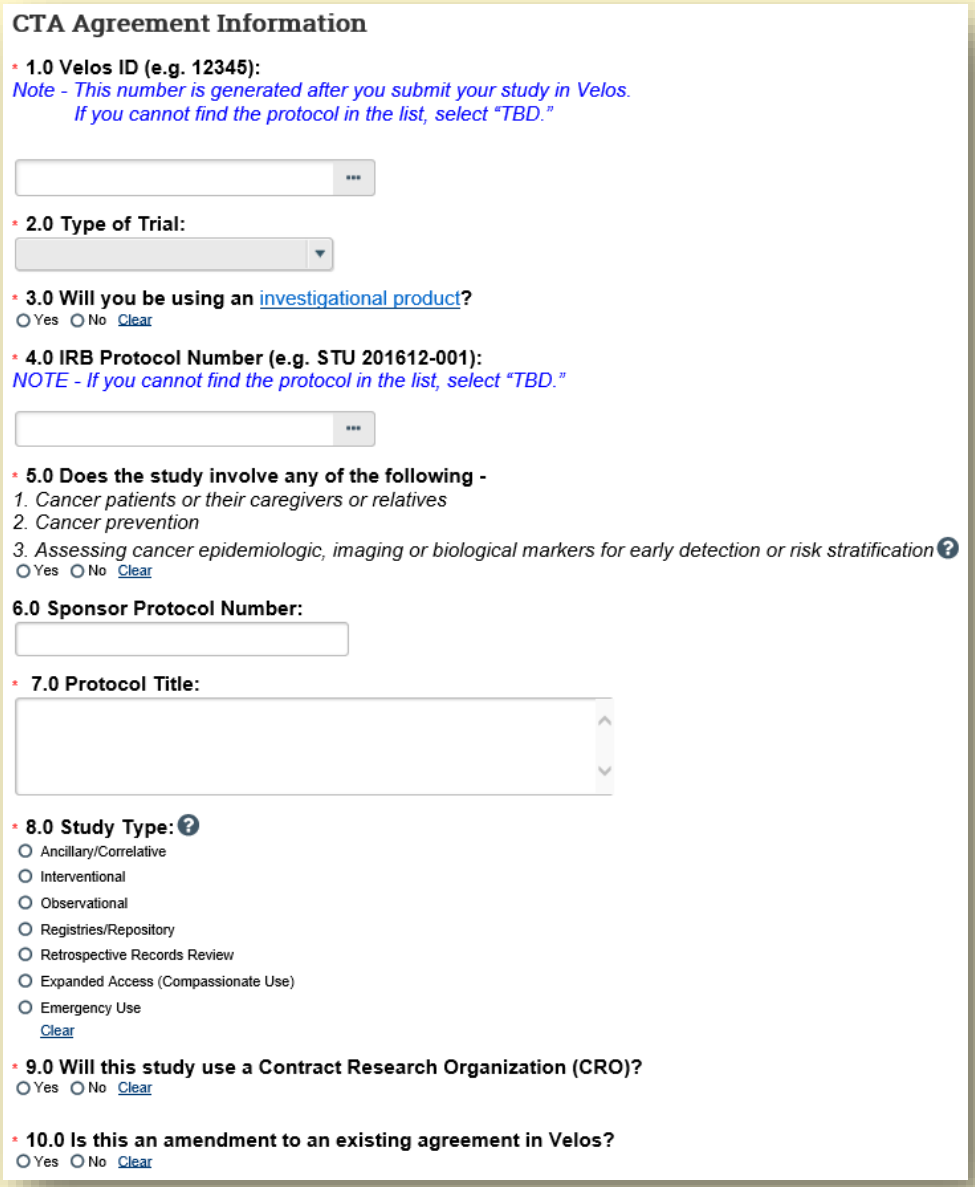
3.0 (Optional) Select any related agreements that are in the system.

4.0 Add individuals at UT Southwestern who require access to the agreement. The logged on user will automatically be added to this list.

Select the question mark icon for specific help text.

CTA Agreement Information

Complete the **CTA Agreement Information** page and click **Continue.**



1.0 Select the Velos ID for the clinical trial**.**

2.0 Select the type of trial.

For trial types other than "Device," study phase is required.

3.0 Indicate whether an investigational product will be used. If "Yes," an additional question will appear.

4.0 The IRB Protocol Number automatically populates upon selection of the Velos ID.

5.0 Indicate whether the study is cancer-related.

Select the question mark icon for specific help text.

6.0 The Sponsor Protocol Number automatically populates upon selection of the Velos ID.

7.0 The Protocol Title automatically populates upon selection of the Velos ID.

8.0 The Study Type automatically populates upon selection of the Velos ID.

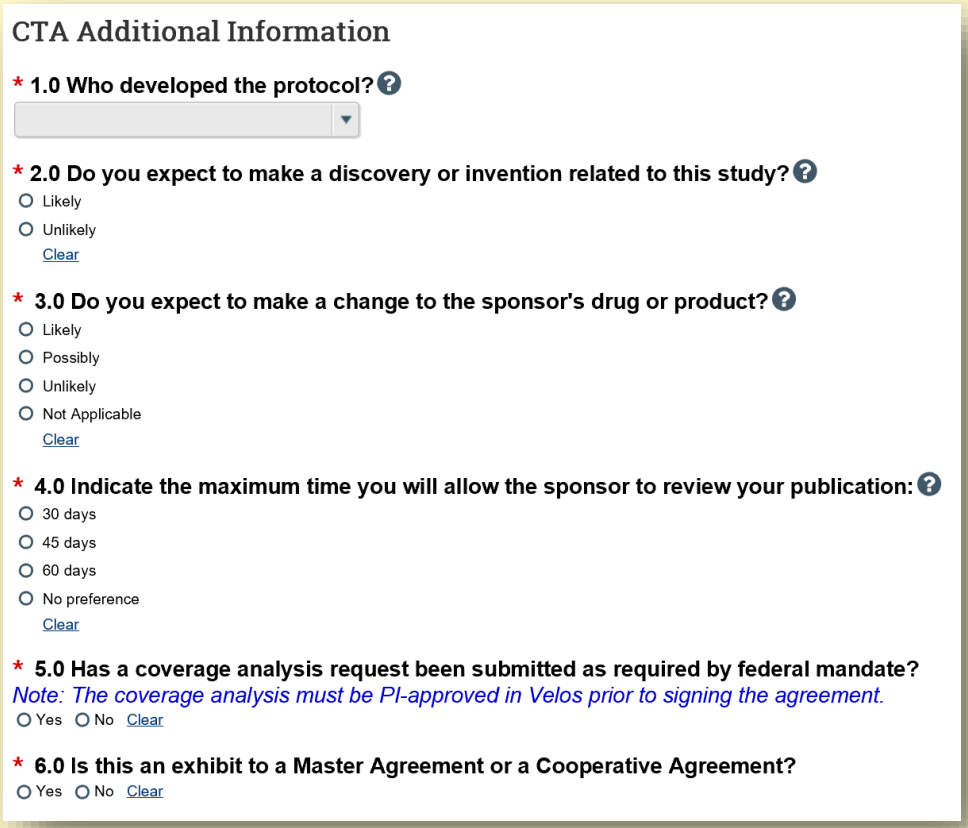
9.0 Indicate whether a contract research organization will be utilized.

If "Yes," additional questions will appear.

10.0 Indicate whether the current submission is an amendment to an existing agreement in Velos.

CTA Additional Information (continued on Page 7)

Complete the **CTA Additional Information** page and click **Finish.**



1.0 Indicate who developed the protocol, the investigator or sponsor.

Select the question mark icon for question-specific help text.

2.0 Indicate whether a discovery or invention is likely.

Select the question mark icon for question-specific help text.

3.0 Indicate whether a change such as drug reformulation will be made to the product.

Select the question mark icon for question-specific help text.

4.0 Indicate the maximum time that the sponsor should have to review the publication.

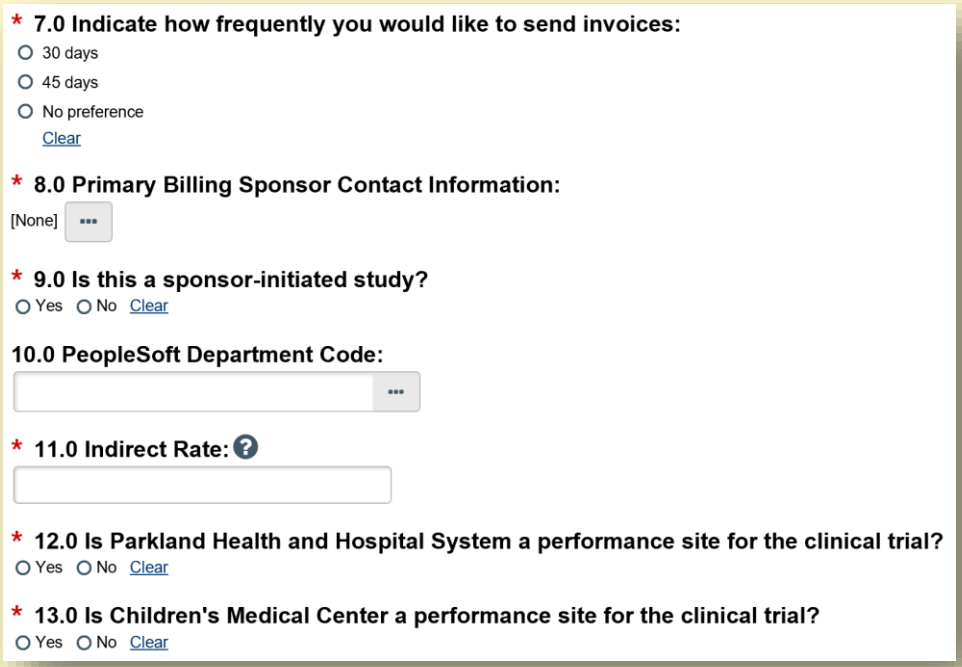
Select the question mark icon for question-specific help text.

5.0 Indicate whether the coverage analysis request has been submitted.

6.0 Indicate whether the agreement is an exhibit to a Master or Cooperative Agreement.

CTA Additional Information (continued from Page 6)

Complete the **CTA Additional Information** page and click **Finish.**



7.0 Indicate the desired frequency of invoicing.

8.0 Provide the name and contact information for the primary billing sponsor contact.

9.0 Indicate whether the clinical trial is sponsor-initiated.

If "Yes," additional questions will appear.

10.0 (Optional) Select the PeopleSoft Department code.

11.0 Provide the indirect rate and include the percent (%) sign.

Select the question mark icon for specific help text.

12.0 Indicate whether Parkland will be a performance site for the clinical trial.

13.0 Indicate whether Children's Medical Center will be a performance site for the clinical trial.

After clicking **Finish**, the Agreement Workspace will appear.

Submit the Agreement

From the Agreement Workspace, click the **Submit** button on the left side of the screen.