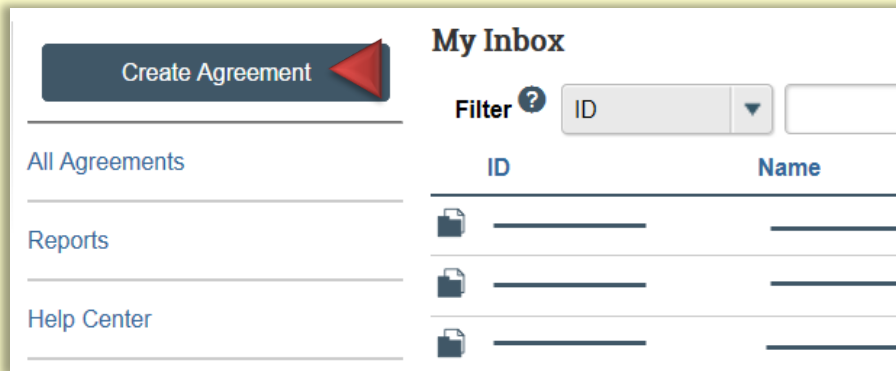





**eAgreements
Clinical Trial Agreement (CTA)
Submission Guide**

Create the Agreement

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



The screenshot shows a user interface for 'My Inbox'. On the left, there is a vertical navigation menu with three items: 'All Agreements', 'Reports', and 'Help Center'. At the top of this menu is a dark button labeled 'Create Agreement' with a red triangle pointing to the right. To the right of the menu is the 'My Inbox' section. It features a 'Filter' dropdown menu currently set to 'ID', followed by an empty search input field. Below this is a table with two columns: 'ID' and 'Name'. The table contains three rows, each starting with a document icon followed by blank lines for the ID and Name.

	ID	Name
	_____	_____
	_____	_____
	_____	_____

Agreement Upload

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

Agreement Upload

* 1.0 Principal Investigator:

* 2.0 Entered by (Department Contact, Department Administrator, Study Coordinator, etc.):

* 3.0 If you have an agreement draft, upload it here. Otherwise, check the "UT Southwestern to generate first draft" box: ?

 Choose File

UT Southwestern to generate first draft?

* 4.0 Provide a short name for the agreement: ?

* 5.0 Agreement type: ?

6.0 Supporting documents:

+ Add

Name

There are no items to display

7.0 Description:

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**.

General Information

*** 1.0 Select an organization:**

NOTE - If you cannot find the organization in the list, select "Other."

Other

* If you cannot find the organization in the list above, enter its information here:

Contracting Party Name:

*** 1.1 Contracting party contact name: ?**

*** 1.2 Contracting party contact e-mail:**

*** 1.3 Contracting party contact phone:**

2.0 Add additional Contracting Parties:

Organization	Contracting Party Name	Contact Name	Contact Email	Contact Phone
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There are no items to display

3.0 Select any related projects:

Name	ID	Project State	Owner
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There are no items to display

4.0 Agreement team members: ?

Name	E-mail	Phone
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There are no items to display

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**.

CTA Agreement Information

1.0 Velos ID (e.g. 12345):

*Note - This number is generated after you submit your study in Velos.
If you cannot find the protocol in the list, select "TBD."*

2.0 Type of Trial:


3.0 Will you be using an [investigational product](#)?

Yes No [Clear](#)

4.0 IRB Protocol Number (e.g. STU 201612-001):


NOTE - If you cannot find the protocol in the list, select "TBD."

5.0 Does the study involve any of the following -

1. Cancer patients or their caregivers or relatives
 2. Cancer prevention
 3. Assessing cancer epidemiologic, imaging or biological markers for early detection or risk stratification 
- Yes No [Clear](#)

6.0 Sponsor Protocol Number:

7.0 Protocol Title:

8.0 Study Type: 

- Ancillary/Correlative
 Interventional
 Observational
 Registries/Repository
 Retrospective Records Review
 Expanded Access (Compassionate Use)
 Emergency Use
[Clear](#)

9.0 Will this study use a Contract Research Organization (CRO)?

Yes No [Clear](#)

10.0 Is this an amendment to an existing agreement in Velos?

Yes No [Clear](#)

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**.

CTA Additional Information

* **1.0 Who developed the protocol?** ?

* **2.0 Do you expect to make a discovery or invention related to this study?** ?

- Likely
 Unlikely
[Clear](#)

* **3.0 Do you expect to make a change to the sponsor's drug or product?** ?

- Likely
 Possibly
 Unlikely
 Not Applicable
[Clear](#)

* **4.0 Indicate the maximum time you will allow the sponsor to review your publication:** ?

- 30 days
 45 days
 60 days
 No preference
[Clear](#)

* **5.0 Has a coverage analysis request been submitted as required by federal mandate?**

Note: The coverage analysis must be PI-approved in Velos prior to signing the agreement.

- Yes No [Clear](#)

* **6.0 Is this an exhibit to a Master Agreement or a Cooperative Agreement?**

- Yes No [Clear](#)

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 how frequently you would like to send invoices:**

- 30 days
 45 days
 No preference
[Clear](#)

*** 8.0 Primary Billing Sponsor Contact Information:**

[None]

*** 9.0 Is this a sponsor-initiated study?**

- Yes No [Clear](#)

10.0 PeopleSoft Department Code:

*** 11.0 Indirect Rate: ?**

*** 12.0 Is Parkland Health and Hospital System a performance site for the clinical trial?**

- Yes No [Clear](#)

*** 13.0 Is Children's Medical Center a performance site for the clinical trial?**

- Yes No [Clear](#)

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.


Next Steps


[Redacted]

[Redacted]

[Redacted]

Submit 

 _____

 _____