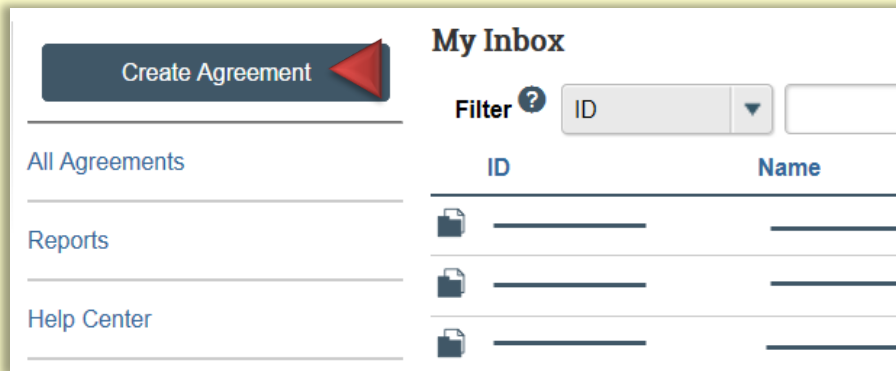




**eAgreements  
Treatment Use Agreement (TUA)  
Submission Guide**

## Create the Agreement

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



The screenshot shows a user interface with a navigation menu on the left and a main content area on the right. The navigation menu includes links for "All Agreements", "Reports", and "Help Center". The main content area is titled "My Inbox" and features a "Filter" dropdown menu currently set to "ID". Below the filter is a table with two columns: "ID" and "Name". The table contains three rows, each with a document icon, a blank "ID" field, and a blank "Name" field.

	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 **Treatment Use Agreement (Compassionate Use)** 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
There are no items to display				

**3.0 Select any related projects:**

Name	ID	Project State	Owner
There are no items to display			

**4.0 Agreement team members: ?**

Name	E-mail	Phone
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.

# Treatment Use (Compassionate Use) Information

Complete the **Treatment Use (Compassionate Use) Information** page and click **Continue**.

## Treatment Use (Compassionate Use) Information

\* **1.0 Type of treatment** ([Click here](#) to visit the FDA website for more information):

- Emergency Use
  - Expanded Access (Compassionate Use)
  - Single Use IND
- [Clear](#)

\* **2.0 Type of Investigational Product:**

**3.0 Where will the Investigational product be delivered?**

+ Add

Name	Address	City	State	Zip Code	Email
There are no items to display					

\* **4.0 Velos ID (e.g. 12345):**

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

\* **5.0 IRB Protocol Number (e.g. STU 201612-001):**

**6.0 Sponsor Protocol Number:**

**7.0 Protocol Title:**

\* **8.0 Will this study use a Contract Research Organization (CRO)?**

- Yes  No [Clear](#)

**1.0** Indicate the type of treatment.

**2.0** Select the type of investigational product.

**3.0** (Optional) Select **Add** to provide the location(s) where the investigational product will be delivered.

**4.0** Select the Velos ID for the treatment use study.

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

**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** Indicate whether a contract research organization will be utilized.

If "Yes," additional questions will appear.

## Treatment Use Additional Information

Complete the **Treatment Use Additional Information** page and click **Finish**.

### Treatment Use Additional Information

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

\* **2.0 Upload all FDA Documentation:**

+ Add

There are no items to display

\* **3.0 Upload patient consent document(s):**

+ Add

There are no items to display

**4.0 Primary Billing Sponsor Contact Information (if applicable):**

[None] ...

**5.0 PeopleSoft Department Code:**

[None] ...

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

**2.0** Select **Add** to attach all FDA documentation.

**3.0** Select **Add** to attach all patient consent document(s).

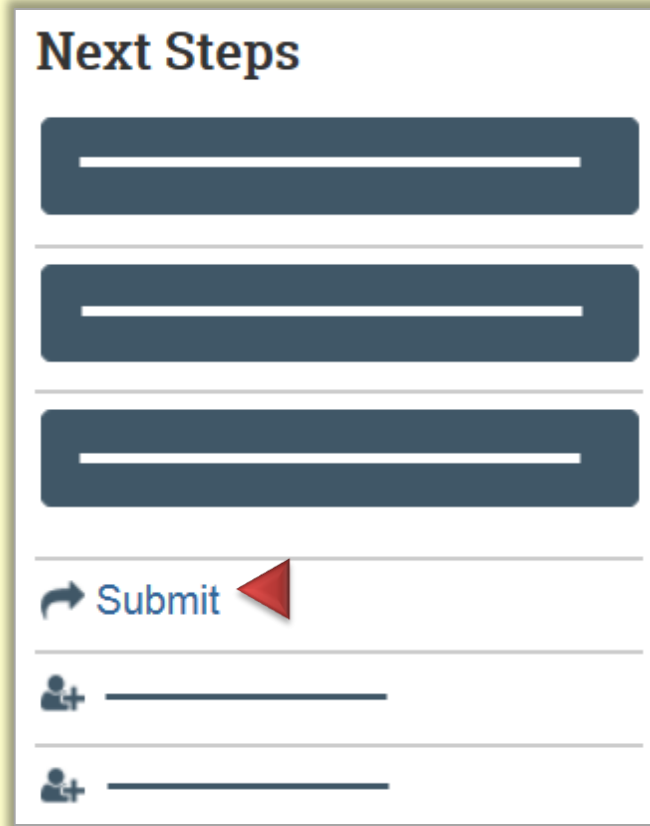
**4.0** (Optional) Provide the sponsor billing contact information.

**5.0** (Optional) Select the PeopleSoft Department Code.

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 Step 1]

[Redacted Step 2]

[Redacted Step 3]

➔ **Submit** 

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