

ResearchUVA Powered By Huron allows for two alternative routes to submit a Clinical Trial Agreement (CSA) for OSP review:

Submit Funding Proposal with Approvals; Create Agreement

1 Create a Funding Proposal from the Grants module, making sure to select the following answers on the General Proposal Information Page of the Smart Form:

6. **Instrument type:**

Grant

Contract

Cooperative Agreement

Subaward

[Clear](#)

7. **Primary purpose of this project:**

Research On-Grounds

Research Off-Grounds

Instruction On-Grounds

Instruction Off-Grounds

Other Sponsored Activity On-Grounds

Other Sponsored Activity Off-Grounds

Industry-Funded Clinical Trial

DHHS Institutional Training Grants

[Clear](#)

Answer remaining Smart Form Pages as appropriate for the project.

2 Be sure to answer Question 1 on the Compliance Review Page of the Smart Form as follows:

1. **Human subjects involved in this project:**

Yes No [Clear](#)

a. **Is this a clinical trial?**

Yes No [Clear](#)

Answer remaining Smart Form Pages as appropriate for the project.

3 Follow the Completion Instructions Page on the Smart Form and then click [Finish](#) to exit the Smart Form.

4 Select the Working Budget from the Budgets Tab in the lower middle of the Funding Proposal Workspace:

Budgets	SF424 Summary	History	Reviewers	Attachments	Financials	Reviewers Notes	Related Projects	Change Log
Working Budgets								
Name	SmartForm	Date Modified	State	Funding Source	Total	In Financials?		
[Sponsor] Budget	Smart	7/15/2022 3:20 PM	Draft	Industry/Fair Profit	\$0	yes		

5 Select [Edit Budget](#) on the left side of the Budget Workspace

6 Be sure to answer “No” to Question 3 on the General Budget Information Smart Form, select “TDC” from the drop-down list under “Non-standard F&A cost base and rates,” and then enter 30 for all budget periods for industry-sponsored clinical trials:

3. **Does this budget use the standard F&A cost base and rates?**

Yes No [Clear](#)

Standard F&A cost base and rates

Period	Start	End	Rate
F&A Cost Base	8/1/2022	7/31/2023	30%
MTDC	8/1/2022	7/31/2023	30%

Non-standard F&A cost base and rates

Period	Start	End	Rate
F&A Cost Base	8/1/2022	7/31/2023	30%
TDC	8/1/2022	7/31/2023	30%

Under the Personnel Cost Definition Tab, add all relevant personnel. For each Staff Member, click on [Update](#) and then change the number in Question 4 to \$0. Answer Question 6 as applicable for each Staff Member.

Under the Personnel Costs Tab, click on [Show Effort](#), enter the applicable effort and salary percentage for each Person.

Important: No further budget information is needed at this time for an industry-sponsored clinical trial agreement.

7 Return to the Funding Proposal Workspace by following the navigation breadcrumbs at the top of the page:

Dashboard	Agreements	Grants
Funding Proposal	Complex Projects	Awards
	Reports	Help Center

Grants > [CSA Submission Process Guide](#) > [Sponsor] Budget

8 Execute the [Create Agreement](#) Action on the left side of the Funding Proposal Workspace. Ensure that [Clinical Trial Agreement](#) is selected from the drop-down list in the pop-up window that appears and then click 'OK.'

9 Submit the Funding Proposal for Approvals and Review following the processes outlined in the [Job Aid: Routing and Approvals - SOM](#).

10 Navigate to the Agreement that you created in Step 8 by opening the Related Projects Tab and then selecting the CSA record:

Budgets	SF424 Summary	History	Reviewers	Attachments	Financials	Reviewers Notes	Related Projects	Change Log
Related Projects								
Filter by <input type="text"/> Enter text to search <input type="button" value="Add Filter"/> <input type="button" value="Clear All"/>								
ID	Name	Owner	Organization	Project Type	Project Status	Modified Date		
CSA00000028	Agreement for: CSA Submission Process Guide		MD-RADL Rad Research	Agreement	Pre-Submission	7/15/2022 3:35 PM		

11 Follow the processes described in the [Reference Guide: Agreements Guide for the Research Community](#) to prepare the Agreement Smart Form. Once the Smart Form is complete, send an email to SOMOGC@hscmail.mcc.virginia.edu with the CSA and FP #s for review.

Important: Because PI, Department, and School approval will be documented in the Funding Proposal, there is no need to create Ancillary Reviews to document these approvals on the CSA. SOMOGC and OSPNOA will assign the CSA record for review and negotiation as soon as the FP is complete.

Submit CSA Request with Ancillary Reviews; Submit Funding Proposal After Budget Negotiations Are Complete

1 Execute the [Create Agreement](#) Action on the Agreements module, making sure to select Clinical Trial Agreement from the drop-down list under Question 5 on the Agreement Upload page of the Agreement Smart Form. Otherwise, complete the Agreement Smart Form as appropriate for the project.

2 Once the Smart Form is complete, collect Ancillary Reviews by following the processes outlined in [SOM NFA Submission – Quick Guide for PIs] as well as the [Job Aid: Submitting an Agreement to OSP](#).

3 After all Ancillary Reviews are approved, email SOMOGC@hscmail.mcc.virginia.edu with the CSA # for review. This will allow the CSA record to be reviewed as needed at SOMOGC and OSP and then assigned to the appropriate OSP Contract Negotiator for review and negotiation.

4 At any time prior to contract execution, follow Steps 1 – 7 on the left side of this guide to prepare the required Funding Proposal.

Important: even after the terms and conditions of the contract have been fully negotiated, UVA will not execute a funded agreement such as a CSA until a funding proposal has been submitted.

5 Execute the [Manage Relationships](#) Action on the left side of the Funding Proposal Workspace and add the CSA record that you created in Step 1 above.

6 Because the required approvals were documented via Ancillary Review in Step 2 above, there is no need to collect approvals on the Funding Proposal as well.

Therefore, you can execute the [Submit For Department Review](#) Action on the left side of the Funding Proposal Workspace, and then immediately [Certify](#) and [Approve](#) the FP to route it for Specialist Review.

Important: In the pop-up window that appears when you execute the [Approve](#) Action, be sure to include a comment that the PI and Department Chair approvals have been documented in the related CSA record. This comment will help ensure that SOMOGC Specialist to whom your FP is assigned can refer to the correct CSA record and approve the FP accordingly.