RED
Research Education Development

Research Administration Management Portal (RAMP) Reference Guide: Clinical Trial Agreements for the Research Administration Community

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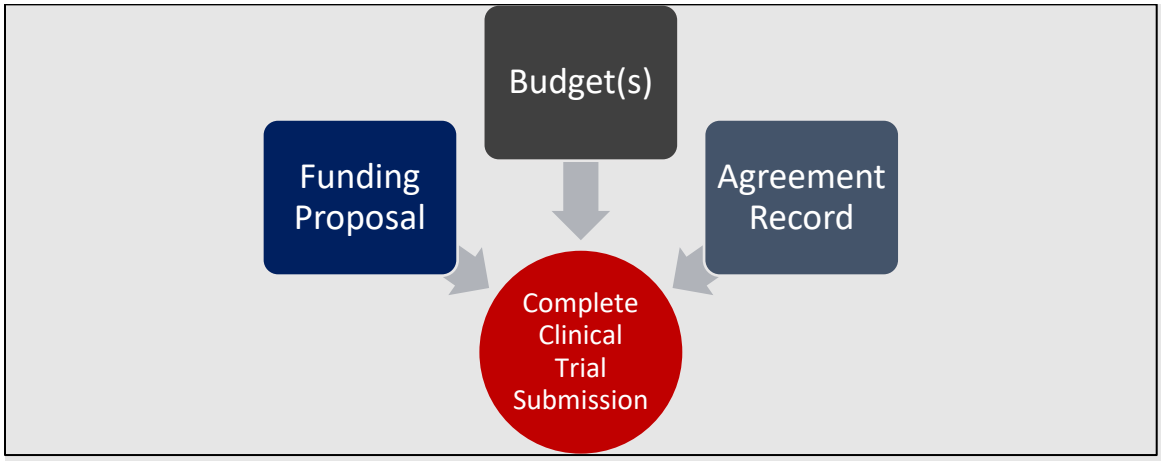
1 Introduction

This guide describes how members of the University of Wisconsin – Madison (UW-Madison) Research Administration Community create and submit Clinical Trial Agreements and their associated Funding Proposals for review in the Research Administration Management Portal (RAMP) Grants and Agreements modules.

Complete CTA (Clinical Trial Agreement) submissions consist of:

1. A funding proposal record.
2. At least one budget record. Additional budgets may be completed as necessary to reflect cost share, subawards, etc.
3. A related agreement record.



2 Create Funding Proposal and Agreements Records

Step-by-step instructions on how to complete a funding proposal record and proposal budget(s) record are contained in the Funding Proposal Guide. Step-by-step instructions on how to complete and link an Agreements record are contained in the Agreements Guide.

2.1 Create a Proposal Record

Complete the Funding Proposal SmartForm to create a proposal record as instructed in the Funding Proposal Guide. The subsections below walk you through any specific details needed for Clinical Trials. Select **Continue** at the bottom of

each page to navigate through the SmartForm pages (the final page has a Finish button instead of a Continue button).

2.1.1 General Proposal Information

6. Instrument Type: Select **Contract**.

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

7a. Type of Research: Select **Clinical**.

9. Submission Information: Indicate that this is a clinical trial, and the agreement will be routed to the contracts team. If you expect to request an advance account, also note that here.

10. Is this a limited submission? Select **No**.

11. Is this a pre-proposal, white paper, or letter of intent to submit? Select **No**.

2.1.2 Personnel

1. Program director / Principal investigator: Select the PI's name here. Fellow, biosketch, or other support documents are not required.

3. Project personnel:

3a. Add any known UW-Madison personnel here.

2.1.3 Submission Information

3. Add any general submission documents: Add any necessary documents here, including draft protocols and budgets, outside IRB (Institutional Review Board) documents, and/or other related items.

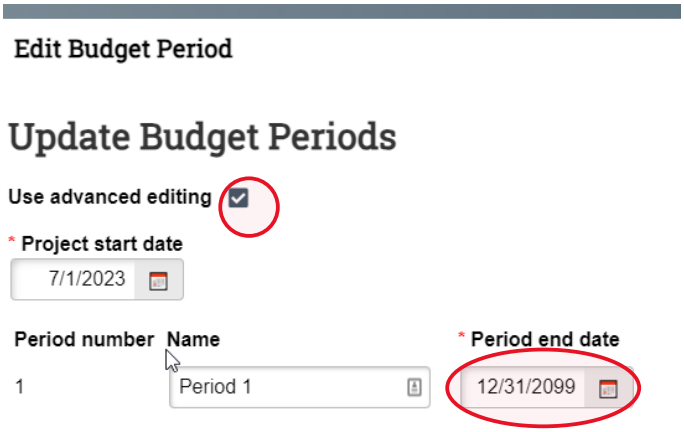
2.1.4 Budget Periods and Key Dates

1. Application submission deadline: If there is a hard deadline, enter it here. If there is not a hard deadline, enter the expected start date of the clinical trial.

6. Modular budget? Select **No**.

7. Budget Period Information

- Select **Remove Period** four times until there is only one period.
- Select **Update Periods**. A slide-in window will appear.
- Select the **Advanced Editing** checkbox.
- Change the **Period end date** to 12/31/2099



2.1.5 Compliance Review

Complete all required questions and have the PI (Principal Investigator) update protocols in ARROW to include the Funding Proposal number (FPxxxxxxxx). ARROW will send this information to RAMP on a daily basis. This information will only need to be added once; the AWDxxxxxxx number will be added automatically to ARROW if the Funding Proposal has been added and then it is funded.

Note: If the use of Human Blood is covered under the IRB protocol, you do not need to also select "Yes" to the Biohazards or Recombinant DNA questions about blood. If the use of Human Blood is not covered under the IRB protocol, do select "Yes" to the appropriate questions and have the PI link the appropriate protocol in ARROW.

2.1.6 Additional Proposal Information

Answer questions as appropriate. Press Continue and then Finish to return to the Funding Proposal Workspace.

2.2 Create a Budget

The next step in the proposal submission process is to access the Budget Workspace and complete the Budget SmartForm as instructed in the Funding Proposal Guide. The subsections below walk through specific details needed for Clinical Trials. Select **Continue** at the bottom of each page to navigate through the SmartForm pages (the final page has a Finish button instead of a Continue button). Clinical Trial budgets are typically $0 as the budget is recorded as payments are made, not as a cost reimbursable budget. **Enter a $0 budget.**

2.2.1 General Budget Information Page

3. Does this budget use the standard F&A cost base and rates? – Select **Yes** if this budget has a federal sponsor or prime sponsor. Select **No** if the budget has a non-federal sponsor and will use the Clinical Trial Rate of 30%.

If **No**, a second **Non-standard F&A cost base and rates** table displays. Select **TDC** as the F&A cost base and enter **30%** as the rate.

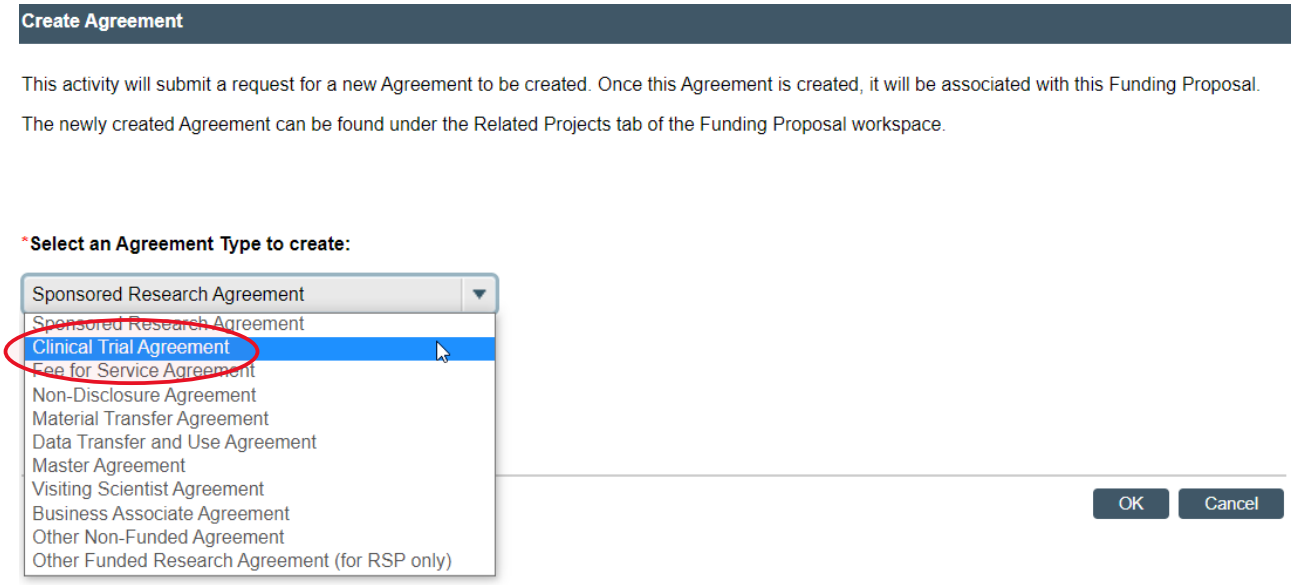
4. Will you require detailed budget tables for this budget submission? Select **No** for both **Travel** and **Participant Support Costs**.

Save and exit the budget when the **General Information** page is complete. Nothing else needs to be completed for a Clinical Trial budget.

Note: We do not need to enter the maximum amount of the award as that is recorded in the Agreement (*CTA Agreement Information Q7. What is the estimated budget of the trial?*).

2.3 Create a Linked Agreement

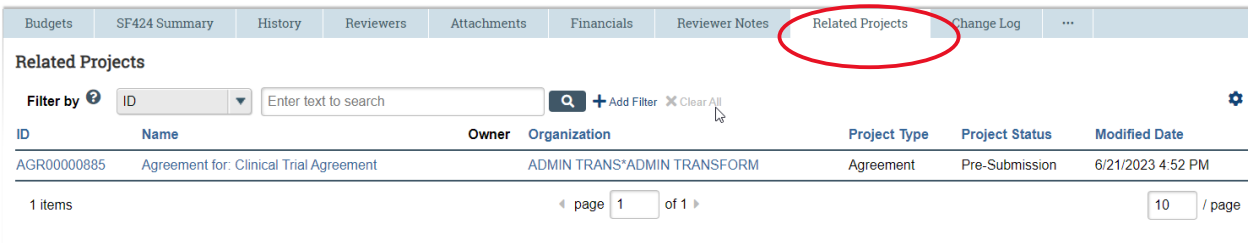
From the Funding Proposal Workspace, press the **Create Agreement** activity. A slide-in window will appear.



Note: If an agreement record already exists for the Clinical Trial, link the Funding Proposal with the Agreement record in RAMP by using the Manage Relationships activity on the Funding Proposal Workspace. Instructions for Managing Relationships can be found on the Manage Relationships Job Aid.

Select **Clinical Trial Agreement** from the dropdown menu and press **OK**.

Navigate to the Related Projects tab to find the link to the Agreement.



Press on the **ID** or **Name** to go to the Agreement workspace.

Press on the **Edit Agreement** button and fill in the information as fully as applicable. Only fields with red asterisks are required, however filling the information in completely will reduce the back-and-forth discussions with the RSP (Research and Sponsored Programs) Contracts Team.

For step-by-step information on how to complete the Clinical Trial Agreement record, consult the Agreements Guide.

3 Route Records for Review and Approval

Follow your division or dean's office guidelines for approvals. Step-by-step information for routing Funding Proposal (FP) records can be found in the Funding Proposal Guide. Step-by-step instructions on how to complete and link an Agreements record are contained in the Agreements Guide.

3.1 Order of Reviews and Approvals

1. Send FP ancillary reviews as applicable. This may include chair, multi-PI, or additional department review approvals. These can be done on the FP record. For step-by-step instruction, see the Ancillary Review Guide.

2. Ensure the PI has certified the record. If this has not been done when the record is routed for division/dean's office review, the PI will receive an email requesting they certify. For guidance on certification, see the PI Certify Job Aid.

3. Submit the FP record for department review. In the comments, be sure to note that there is a related agreement record. Remember that in RAMP terminology, the department is the division/dean's office level of review. This will make the record view only.

4. Check with your division/dean's office about submitting the Agreement record. Some dean's offices will submit the Agreement record after review of the FP. Others may have the departments send the Agreement record separately.

4 Requesting an Advance Account

RSP Contracts Team will assign themselves specialist/owner on the relevant FP and Agreement records and send the FP to Pending Sponsor Review once it has been certified by the PI and the division/dean's office reviews have been completed. If an Advance Account is necessary, the department or division will be able to send

the request once this action has been taken by RSP. To contact RSP about the state of the FP, use the Contact Owner function on the Agreement as instructed in the How to Contact the Agreement Owner Job Aid.

Instructions for completing an Advance Account request are in the How to Request an Advance Account Job Aid.

5 Clinical Trial Agreement Modifications

Modifications to Clinical Trial Agreements records will be handled differently for converted records and new records.

5.1 Modifications for Converted Agreements Records

This section will indicate only areas that are specific to this clinical trial modification process. Step-by-step instructions for creating an agreement record can be found in the Agreements Guide. Contact your division/dean's office for any specific requirements for attachments or approvals.

1. Find the Award. A converted award will have an ID number starting with MSN. Once the award has been located, press on the Name link to enter the workspace.

2. Complete the Create Agreement activity. This will create a new agreement that will serve as both the Clinical Trial Agreement going forward and to process the modification.

- **Press the Create Agreement activity on the Award Workspace.** Note you may have to Manage Access to have this activity available to you.
    - **Title the Agreement with the original CTA title from WISPER.** This will allow it to be easily searchable for future amendments. We will include notes about the modification in the RSP Information area.

3. Go to the new Agreement and Edit the Agreement. It can be found on the Related Projects tab of the Funding Proposal.

- **Upload the amendment to the Clinical Trial Agreement for Q3: Upload agreement draft.**
- **Upload the original, fully executed CTA for Q7: Supporting documents.**
- **In the Project description text box, indicate this is for an amendment to the original CTA agreement/award linked to this Agreement and list the WISPER number of the original agreement.**

4. Complete PI certification and Ancillary reviews. Please see the How to Obtain PI Certification on Agreement Module Records and How to Obtain Deans Office Division Approval on an Agreement Module Record Job Aids.

5. Submit the Agreement record. As the PI will have certified the WISPER record attached to the award, it is not required here. If you would like to send the record for review to your division/dean's office, use the Manage Ancillary Reviews activity. Detailed instructions for submitting an agreement can be found in the How to Submit an Agreement Job Aid.

5.2 Modifications for New Records

This section will indicate only areas that are specific to this clinical trial modification process. Step-by-step instructions for submitting an amendment to an agreement record can be found in Chapter 12 of the Agreements Guide.

1. Find the Agreement. A new agreement will have an ID number starting with AGR. Once the agreement has been located, press on the Name link to enter the workspace.

2. Complete the Create Amendment activity. This will create a related record to the original agreement record.

3. Complete PI certification and Ancillary reviews. Please see the How to Obtain PI Certification on Agreement Module Records and How to Obtain Deans Office Division Approval on an Agreement Module Record Job Aids.

4. Submit the Agreement record. Detailed instructions for submitting an agreement can be found in the How to Submit an Agreement Job Aid.