MN-GEMS

MN Grants Electronic Management System

MN-GEMS Reference Guide:

Industry Funded Clinical Trial Grants & Agreements Guide for the Research Administration Community

Last Updated April 2024

Version 1

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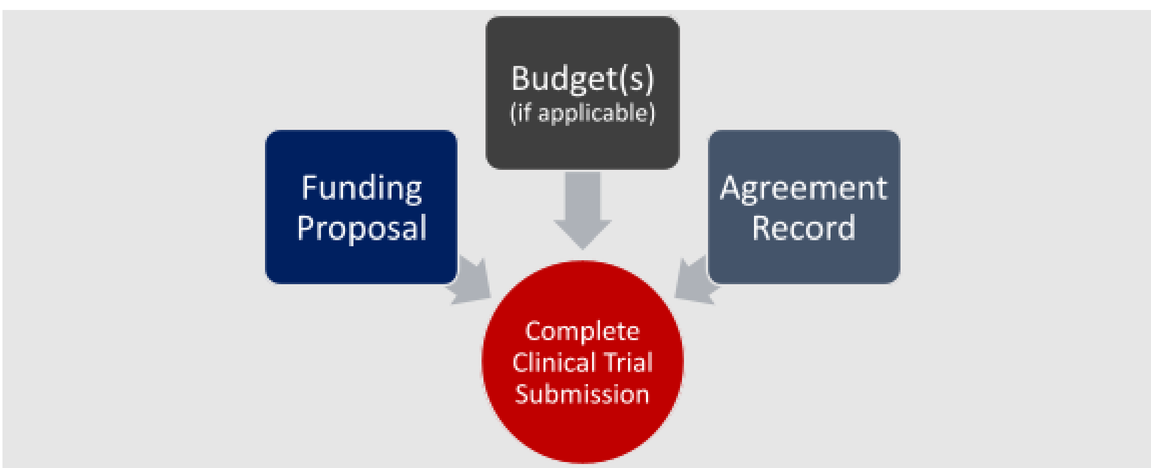
1 Introduction

This guide describes how members of the UMN Research Administration Community create and submit Industry funded Clinical Trial Agreements and their associated Funding Proposals for review in the UMN Grants and Electronic Management System (MN-GEMS) Grants and Agreements modules.

Complete CTA submissions consist of:

1. A funding proposal record.
2. At least one budget record (if a budget exists and is final). If the budget is to be negotiated, the budget will not be entered into the Funding Proposal (this would be an expedited Funding Proposal). Once final, the budget will be added in the Award module (See Section 4, Completing the Budget for this process). If applicable, additional budgets may be completed 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 - Funded B&I.

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

As you are entering your funding proposal in the Grants module, make sure to mark the following questions as demonstrated:

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

7. Primary purpose of this project: Select **Clinical Trial**.

10. Clinical trial is: Select Sponsor Initiated or PI Initiated

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 UMN personnel here.

2.1.3 Submission Information

3. Add any general submission documents: Add any necessary documents here, including draft protocols, and budgets (budget to be included if submission is not an Expedited Funding Proposal), outside IRB documents, and/or other related items. It is not necessary to add the draft agreement here, as that will be done in the Agreements module.

4. Are you submitting electronically, other than to Grants.gov: Choose "Yes" then enter the sponsor contact email address in 4a. In 4b, specify the action you would like your SPA GCO to take (i.e. begin agreement negotiations, submit certain documents to sponsor, etc.).

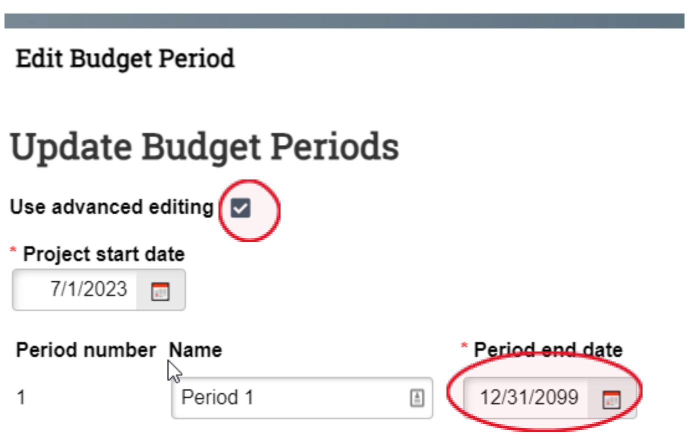
2.1.4 Budget Periods and Key Dates

1. Application submission deadline: If there is a hard deadline, enter it here (**note**, this would only be applicable for true proposal submissions, not files that are ready to begin contract negotiations). If there isn't a hard deadline, enter the expected start date of the clinical trial.

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

7. Budget Period Information

- Select **Remove Period** 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 the anticipated end date of the clinical trial



9. Sponsor due date is: Most industry clinical trials will be **Target Date** (because there is no true proposal to submit to the sponsor and the parties are ready to begin contract negotiations). Receipt Date is only to be used when a **proposal** needs to be submitted to the sponsor for their review and consideration.

2.1.5 Compliance Review

Complete all required questions and have the PI update protocols in ETHOS and eProtocol to include the Funding Proposal number (FPxxxxxxxx). ETHOS and eProtocol will send this information to MN-GEMS on a daily basis. This information will only need to be added once; the AWDxxxxxxx number will be added automatically to ETHOS and eProtocol 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

Industry clinical trial Funding Proposals will be **zero dollar Funding Proposals**. (However, if the clinical trial budget is complete at the time of Funding Proposal creation, follow the budget instructions in the Funding Proposal Guide) Access the Budget Workspace by clicking on the hyperlink under the **Budgets tab**. The subsections below walk through specific details needed for Clinical Trials. These are the only items that need to be completed for the Budget at this time.

General Budget Information Page

3. Does this budget use an approved sponsor F&A cost base and rates? – Select **No** for an industry sponsor and enter the correct cost base and F&A percentage. Business and Industry sponsored trials can utilize the Business and Industry Clinical Trial Rate of 30% Total Direct Costs.

7. Is an F&A Waiver needed for this project? Choose Yes or No

These are the only steps to be completed at this phase for the budget on an industry clinical trial. Hit **save** and **exit**.

2.3 Attaching an Advance Account Request to your Funding Proposal

If an Advance Account Request is needed, click **Add Attachments** via the hyperlink on the left hand side of the Funding Proposal workspace. Upload your fully completed and signed Advance Account Request sheet and click **OK**.

2.4 Create a Linked Agreement

Click on the Create Agreement hyperlink then choose **Funded Agreement: Business and Industry** and hit **OK**. Navigate to the Agreement record by clicking the hyperlink under Related Projects.

Note: If an agreement record already exists for the Clinical Trial, link the Funding Proposal with the Agreement record in MN-GEMS by using the Manage Relationships activity on the Funding Proposal Workspace. Instructions for Managing Relationships can be found on the Manage Relationships in the Funded B&I Agreements Guide.

Choose **Edit Agreement** and fill in the information as fully and accurately as possible. **SPA will use this information to aid in its contract negotiations and will assume its accuracy.** For step-by-step information on how to complete the Clinical Trial Agreement record, consult the Agreements Guide - Funded B&I.

3 Route Records for Review and Approval

Navigate back to the Funding Proposal record and 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.

Note: You will only need the PI to "Certify" and primary College Research Dean approve via "Department Review" for $0 expedited Funding Proposals.

Step-by-step instructions on how to complete and link an Agreements record are contained in the Agreements Guide - Funded B&I.

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 (as required by the department). 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 Quick Guide.

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 MN-GEMS terminology, the department is the division/dean's office level of review. This will make the record view only.

4. If needed to contact the SPA GCO assigned to the agreement, use the **Contact Owner** function on the Agreement record as instructed in Section 8 of the Funded B&I Agreement Reference Guide.

4 Completing the Budget and Approvals on Expedited Funding Proposals

Once budget negotiations are complete, approvals and budget entry into the Award Record is required. The administering department needs to route ancillary approvals to the entire routing chain and will allocate the budget per the total estimated contract amount at the time of the initial agreement setup. The department administrator will need to add the budget differently depending on if the award has an advanced account or not.

4.1 Award Records with an Advanced Account

4.1.1 Ancillary Reviews of Finalized Budget

Because the expedited Funding Proposal was initially routed without a budget, the budget will need to be approved by the entire approval routing chain from the Award Record. Please include the budget and any other pertinent information or attachments the approvers would need for the approval process. Please see the following guide for more information: Initiate, Manage, and Complete an Ancillary Review.

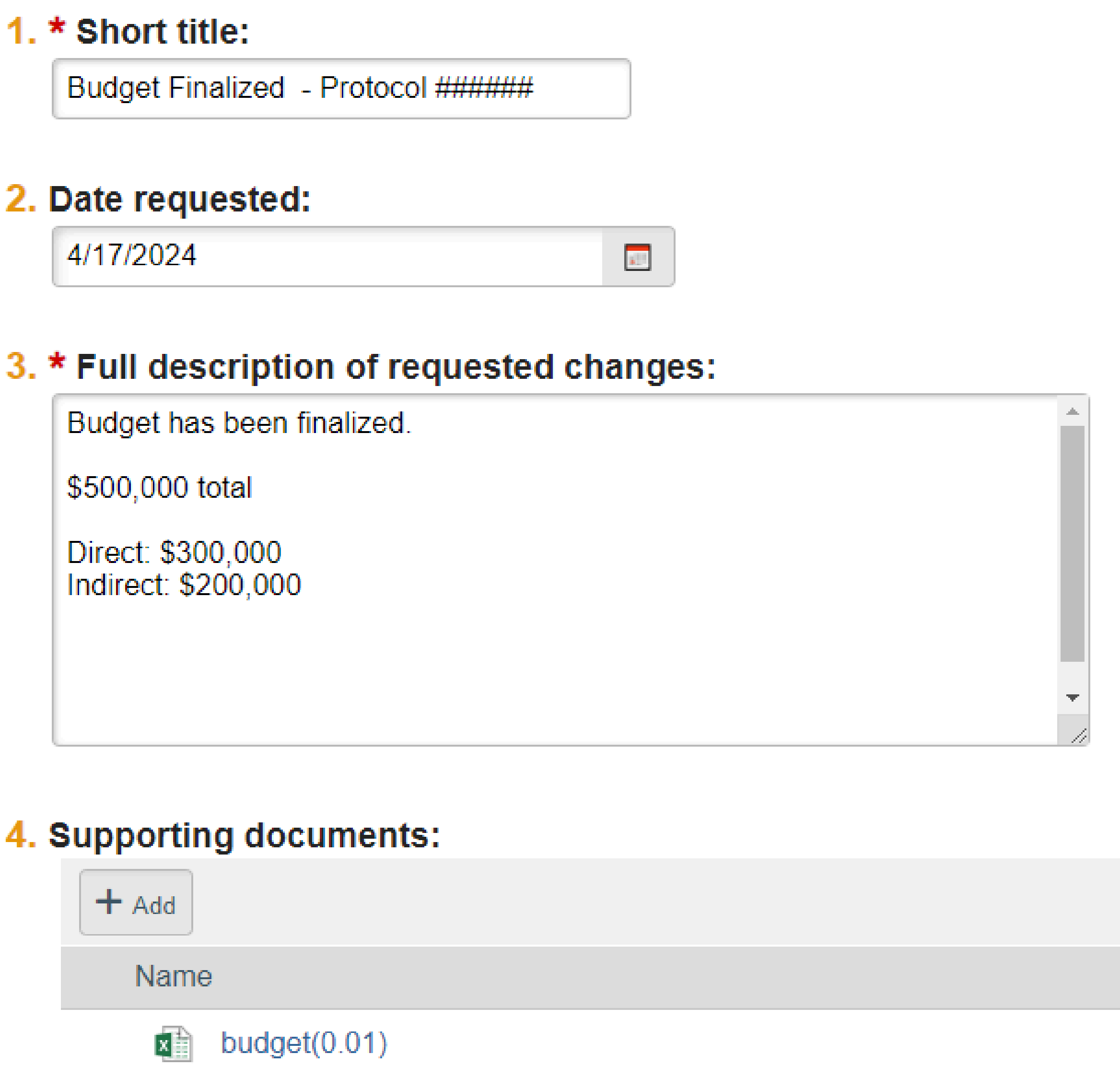
4.1.2 Request Award Modification

If the project has an Advanced Account status, the department administrator will need to navigate to the Award Record and select **Request Award Modification** from the left hand navigation bar.

- In the Pop-up:
  - Section 1: Please name the modification “Budget Finalized - Protocol Number”.
  - Section 2: Date the request is being made.
  - Section 3: Please state the total estimated award amount (broken down by direct and indirect costs), the total startup amount to be

invoiced (broken down by IRB fee, pharmacy fee, startup fee, etc.) and any other pertinent information.

- Section 4: Please upload the budget spreadsheet.
- Once the request is complete, click **Finish.**


1. * Short title:
Budget Finalized - Protocol #######
2. Date requested:
4/17/2024
3. * Full description of requested changes:
Budget has been finalized.
$500,000 total
Direct: $300,000
Indirect: $200,000
4. Supporting documents:
+ Add
Name
budget(0.01)

4.2 Funding Proposal without an Advanced Account

Once the agreement and budget negotiation is complete (or, in the event that the agreement will not be executed and sponsor has agreed to pay the start-up funds), the department must route the FP for full approvals prior to agreement execution and award setup.

4.2.1 Return Funding Proposal for Changes

Once the GCO has completed the agreement negotiation, the GCO will return the FP for changes by the FP preparer (department administrator or CTFS). If budget negotiation is completed prior to agreement negotiation, the FP preparer may email GCO and the GCO will return the FP for changes by the FP preparer.

4.2.2 Complete FP SmartForm questions

Review the FP SmartForm and complete any missing questions and update changed information.

4.2.3 Complete FP Budget

Follow the directions in the Funding Proposal Reference guide to complete the FP budget to reflect the approved budget.

4.2.4 Ancillary Reviews of Finalized Budget

Because the expedited Funding Proposal was initially routed without a budget, the budget will need to be approved by the entire approval routing chain. Please see the following guide for more information: Initiate, Manage, and Complete an Ancillary Review.

4.2.5 Route Funding Proposal for Department Review

In the comments, be sure to note that this approval is for the final budget on an executed contract. Remember that in MN-GEMS terminology, the department is the division/dean's office level of review. This will make the record view only.

4.2.6 SPA GCO Will Transition FP to Awarded

When Department Review is complete, FP will transition to “Specialist Review.” GCO will review FP, and if approved, GCO will transition FP to “Pending Sponsor Review”. GCO will initiate the Award Setup.

4.3 Budget Reconciliation

- The SPA GCO will allocate the budget per the breakdown provided in the steps above.
- The administering department will need to reconcile the entire anticipated budget amount at the time of the initial agreement setup. The “startup fees” should be put on the “Professional Services” line and the rest of costs in the “SPA Reserve Internal” line or the actual direct and indirect cost lines if known. Please see the Budget Reconciliation Quick Guide.

Note: The IRB record should be updated/connected at this time.

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 - Funded B&I. 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 CON. 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 EFS.** This will allow it to be easily searchable for future amendments.

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 that is linked to this Agreement and list the PeopleSoft/EFS number of the original agreement.

4. Complete PI Ancillary reviews. If a draft amendment is uploaded, signatures are typically necessary, and the amendment will follow the same workflow as an agreement, including obtaining PI approval of the amendment using the Ancillary Review. The GCO will route an Ancillary review to the PI, unless the modification includes a signature line for the PI.

5. Submit the Agreement record. As the PI will have certified the EFS record attached to the award, it is not required here. If you would like to send the record for review to your dean's office, use the Manage Ancillary Reviews activity. Detailed instructions for submitting an agreement for ancillary review can be found in the Initiate, Manage, and Complete an Ancillary Review.