CTRF Changes Mockup

An outline and mockup of the CTRF changes to support the new Proposal Submission Deadline Policy coming with the eResearch Proposal Management (eRPM) 5.4 update on July 22, 2019.

● **Section 1 - General Information**
  ○ Renumber **Introduction** page questions
  ○ Renumber and revise **Sponsor Information** page questions
    ■ Revise and move 1.9 Priority Considerations/Comments and 1.10 Deadlines to Section 2 **Project Administration** page

● **Section 2 - People**
  ○ No changes to **UM Investigators** page
  ○ No changes to Ineligible Job Code Comments, if applicable
  ○ No changes to **Administrative Personnel** page
  ○ Renumber some questions on **Project Administration** page
    ■ 5.18 Project Representative question → 2.10
    ■ 5.19 Notes for ORSP question → 6.2.3 other instructions for ORSP
    ■ **New** 6.1.3 Target Date question
    ■ 6.2 Documents uploader → 6.4

● **End of CTRF Worksheet**
  ○ No changes
1. General Information

Complete all required fields to prepare a new Clinical Trial Routing Form (a shortened version of the PAF).

Once the CTRF forms are completed and ORSP is notified to begin review of the contract and negotiations, the remaining PAF sections will be available for completion. Once the full PAF is complete, it is required to be routed for approvals following the same process as a standard PAF.

NOTE: The CTRF process should only be used if this PAF is being created for a Clinical Trial Site Activity (31200) or other Non-Federal Clinical Trial. If this PAF is not for one of these two cases, please use your browser’s “Back” button to exit this set of forms and create a standard PAF.

Required questions are noted with either:

* Required to Save – Question must be completed before you can save and leave the page.
* Required to Save (cannot edit once saved) – Question must be completed before a proposal can be routed for approval.

Introduction

1.1 Project Title (Displays in eRP M system) * Required to Save

Example CTRF

1.1.2 Long Title (Displays in Reporting and PAN/PACs)

Example CTRF

1.1.3 Is this PAF being requested for a Non-Federal Clinical Trial? * Required to Save (cannot edit once saved)

Yes  No

1.1.4 Is this project considered Clinical Trial Site Activity (Class code: 31200)? * Required to Save (cannot edit once saved)

Yes  No

1.5 If Amendment, enter an Award ID

Upon selection of an Award ID, the related project grant will be displayed:

***

HELP

Change the default Project Title to match the proposal or protocol title.

Limited to 256 characters.

Identifies the proposal or protocol in the system (e.g., listed in PAF Workspace, Home Workspace).

Additional Help

HELP

Please identify whether you are routing a proposal for external funding, a contract/standing agreement that ORSP must negotiate, or both. For additional information, see the ORSP website for definitions of proposals and contracts/agreements.

Additional Help

HELP

U-M follows the 2014 NIH Clinical Trial Definition: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. (See the NIH definition with footnotes.)

Please note that how legal or regulatory requirements apply to your clinical trial may depend upon other definitions. For help with ClinicalTrials.gov requirements, consult the UMMS Office of Regulatory Affairs website. For assistance conducting clinical trials at UMHS, consult the Clinical Trials Support Office website.

HELP

Relates to financial class codes.

Please note that if this CTRF was created from a UFA, this question will be defaulted to “Yes.” If necessary, the class code can be updated when the record becomes a full PAF.

HELP

If this PAF is related to a previously awarded project, enter the Award ID number. If you don't know the Award ID use the PAF Query to find the correct Award ID. After selecting the Award ID, the related project grant number(s) will be displayed.
1.7 Sponsors *

Priority Considerations and Comments and Deadlines questions moved to Project Administration page. Questions have been rearranged and renumbered. Existing questions 1.20 - 1.20.5 remain unchanged.

Type Sponsor name. 
Select Type (Direct or Prime). 
Click Save. 

Direct Sponsor is required to route for approval. 
To add a Prime Sponsor, click Add. 

One direct and one prime sponsor can be entered here. 
If there are more than two sponsors for the PAF, note the additional sponsors in question 5.19. Notes for ORSP.

1.7.3 Sponsor Contact Information: *

There are no items to display.

1.7.4 Sponsor Reference Number

Enter the number/identifier provided by the sponsor, if applicable.
### 2. Project Administration

#### 2.7 Project Administrative Home: *

- [ITS Enterprise App Svcs](#)

**Help**

Defaults to the selected appointment for the UM Principal Investigator.

Can be changed if desired using the Select button.

#### 2.7.1 Contact PI: *

- [Pam Principal](#)

**Help**

Select one administrative contact.

The Primary Administrative Contact is:
- always able to edit the PAF (when it is an editable state)
- route the PAF for approval.

#### 2.8 Primary Administrative Contact: *

- [Ann Admin](#)

**Help**

#### 2.10 Project Representative: *

[Project Representative question moved to 2.10](#)

**Help**

If you do not know your Project Representative, see [staff sponsor assignments](#) or call [ORSP information](#) 734-764-5500.

#### 6.1.2.1 Priority Consideration Type

[Priority Consideration Type question moved to 6.1.2.1](#)

**Help**

Enter which factor is driving a Target Date for execution in 6.1.3, with an explanation of the circumstances. This will assist ORSP with prioritization of the contract execution.
6.1.3 Target Date

A Target Date is optional, considered a preference, and can be provided in conjunction with a Submission Deadline or on its own. If there is no Sponsor Deadline but proposal submission or agreement execution is targeted by a certain date, enter the date here. If there is a Submission Deadline, but an earlier proposal submission is requested, enter the date here.

Explain reason for entering the Target Date and consequences of missing Target Date. ORSP staff will make reasonable efforts to submit proposals and execute agreements by the requested Target Date, but can make no guarantees as circumstances beyond their control may prevent them from doing so (e.g., high proposal volumes, exceptionally long or complex agreements, a sponsor who is not responsive, etc.).

6.1.5 School/College Deadline

Deadline questions appear after Target Date

6.1.6 Dept/Unit Deadline

Refer to your School/College for deadline policy information.

6.2.3 Proposal Submission, Contract/Funding Agreement Review and/or Negotiation, or Other Instructions for ORSP

Enter contract/funding agreement review and/or negotiation and/or other instructions for ORSP:

Notes for ORSP question revised and moved to 6.2.3

If yes, include detailed instructions in 6.2.3. Proposal Submission Details and Additional Instructions for ORSP.

6.4 Documents:

You are required to upload the draft study agreement. Attach any other supporting documentation, if needed.

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<th>Last Upload</th>
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Documents upload renumbered to 6.4