

UFA PILOT—January 2012

Medical School non-federal Clinical Trials to test using the:

- ⇒ **Non-disclosure agreement** (NDA) template
- ⇒ **Clinical Trial Routing Form** (CTRF)

Pilot goals are to facilitate NDA review and contract negotiation using eResearch Proposal Management

Need Help?

ITS Service Center: Technical support (e.g., navigation)

Phone: (734) 764-4957

Hours: Monday—Friday 7 AM—6 PM

DRDA Project Representatives

<http://drda.umich.edu/contacts/drda/staff.html>

Phone: (734) 764-5500

What is an Unfunded Agreement?

An “unfunded agreement” (**UFA**) is a non-financial agreement with a sponsor. Examples of UFA types include:

- Confidentiality (non-disclosure) agreements
- Material transfers (incoming/outgoing)
- Research collaboration agreements

What is a Clinical Trial Routing Form?

The **Clinical Trial Routing Form (CTRF)** is a PAF with a limited set of questions.

A completed CTRF is used to notify DRDA to begin proposal negotiations while the Project Team completes the full PAF.

You can enter a CTRF if:

- The proposal is for a Non-Federal Clinical Trial **and**,
- Your UFA has an **Active State**, a paper UFA already exists, or no UFA is required.

Entering a Non-Disclosure Agreement in eRPM

Create New UFA

1. From your Home Workspace, click **Create New UFA**.

Create New UFA (Pilot Use Only)

2. Complete the **Introduction** page.
 - Select **Non-Disclosure Agreement** from the Agreement Category field.
 - Indicate if you are part of the Medical School **Clinical Trial Demonstration Project** pilot.

To verify pilot participation, email:
ummsresearch@umich.edu.

Already have an existing NDA for a Clinical Trial?

Click **Create New CTRF** to begin the PAF process using the Clinical Trial Routing Form.

Create New CTRF (Pilot Use Only)

Enter Personnel

Enter the **Participant** and the **Primary Administrative Contact** to identify the **Project Team** for the UFA. You must have at least one of each on the UFA to save!

1. Click **Add**.
2. Enter unique name or last name. Use % as wildcard.
3. Click **Select**.
4. Select **Role**.
5. Select **Edit UFA** to grant edit rights to the UFA form.
6. Click **OK**.
7. Click **Add Appointment** for the Participant(s).
8. Enter Appointment options:
 - From HR System: click **Add to UFA**.
 - For future appointments: enter **Title** and **Department ID**, then click **Add to UFA**.
9. Click **OK**.

Role Information:

New term: **“Participant”** is usually the PI; however UFAs don't require PI eligibility.

The person entering the UFA is automatically assigned as the **Administrative Contact**.

If more than one person has the same role, click the radio button next to the name to identify the **Contact Participant**.

Add Appointment

Enter Non-Disclosure Agreement Information



Complete the **Non-Disclosure Agreement** (NDA) page.

Pilot users:

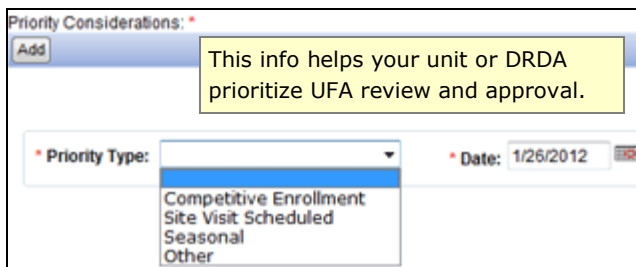
- Always select "Yes."
- Specify the type of trial and the trial phase.

"Yes" to Clinical Trial = use the CTRF to begin PAF process upon UFA approval

Enter Sponsor Information

Enter the **Sponsor Information**. Required fields are:

1. **Project Administrative Home** - defaults from the Contact Participant's appointment.
2. **Priority Considerations** - click **Add** to select the Priority Type and Date. Then click **OK**.



3. **Target Agreement Execution Date** - enter the deadline on which the UFA terms should be finalized.

This date will appear in the lists on the UFAs workspace under **Deadline**.

4. **Sponsors** - click **Add** to enter the Name and Role (Direct or Prime) of the sponsor. Then click **OK**.
5. **Sponsor Contact Confirmation** - click **Add** to enter the contact information for the sponsor. Then click **OK**.
6. **DRDA Project Representative**
7. **Routing and Processing Instructions** - provide information for your unit or DRDA.
8. **Supporting Documents** - browse for, then click **Attach** to upload the applicable NDA documentation.

End of UFA Worksheet

Review this page to identify your next steps.

Click **Hide/Show Errors** to verify if any corrections need to be made.

[Hide/Show Errors](#)

Click **Finish** to go to the UFA's summary (Main) page.

[Finish](#)

Project Team: Routing UFAs

From your Home Workspace, click the **UFAs tab** to display your list of UFAs and view an UFA's State.

[UFAs](#)

1. Select the applicable UFA.
2. The **Contact Participant** selects the **Sign UFA** Activity to:
 - Complete the Conflict of Interest Statement
 - Upload COI documentation, if applicable
 - Sign the UFA
 - Click **OK**
2. Click the "Send NDA" option to route the UFA for review.
 - Enter Comments, if applicable
 - Click **OK**

[Activities](#)

[Project Team Send NDA for Unit Processing](#)



If you specified a COI, the "send" Activity changes to "Project Team Send NDA to DRDA."

Your unit can only review and process UFAs meeting the following conditions:

- UFA form signed
- Conflict of Interest = "No"
- Sponsor will accept the NDA template containing standard legal terms

Entering a Clinical Trial Routing Form (CTRF) in eRPM

UFA Workspace

1. From your Home Workspace, click the **UFAs** tab. 
2. Select the applicable UFA from the **Active UFAs** list to open it.
3. Select the **Create Clinical Trial Routing Form** Activity. 

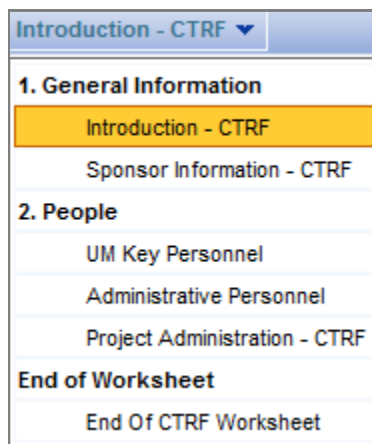
- If you use the **Activity**, the system copies UFA information into the CTRF.
- If you use the **Create New CTRF** button on your Home or UFA Workspace, you will need to complete all fields.

4. Enter the **PAF title**.
5. Click **OK**.

Clinical Trial Routing Form (CTRF)

Enter the CTRF. Some of the required fields are:

- Project title
- Non-Federal Clinical Trial verification
- Sponsor deadline
- Clinical Trial information
- Notes for DRDA
- Supporting Documents (e.g., draft contract, research plan)



Introduction - CTRF ▾

- 1. General Information
 - Introduction - CTRF
 - Sponsor Information - CTRF
- 2. People
 - UM Key Personnel
 - Administrative Personnel
 - Project Administration - CTRF
- End of Worksheet
 - End Of CTRF Worksheet

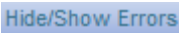
1.2.1 Is this PAF being requested for a Non-Federal Clinical Trial? * Required to Save


Yes No

Information that defaults from the UFA (e.g., sponsor information, personnel) can be edited **except** for question 1.2.1.

End of CTRF Worksheet

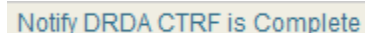
Review this page to identify your next steps.

Click **Hide/Show Errors** to verify if any corrections need to be made. 

Click **Finish** to go to the CTRF's summary (Main) page. 

Project Team: Notify DRDA Activity

1. Click **Notify DRDA CTRF is Complete** to alert DRDA to begin contract negotiation.



2. Enter **Comments**, if applicable.
3. Click **OK**.

Completing this activity opens the full PAF. The PAF **State** changes from CTRF Preparation to Proposal Preparation.

Finish the PAF, as applicable, to route the proposal for unit review.

