Quick Reference Card for PI/Project Team: Unfunded Agreements (Pilot)

**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.

**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 uniqname 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**.

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)**

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

http://eresearch.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 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.

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 info helps your unit or DRDA prioritize UFA review and approval.

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.

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

Project Team: Routing UFAs

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

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

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)

**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.

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### 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.