

## PI – Submitting a Completed Application

Only the PI can submit a completed study application. Before submitting, all required fields on the application must be complete, all applicable members of the study team must accept their role, and the application must be moved to ready-to-submit. It is also recommended that you run the **Error Check** and **Application Checklist** activities before submitting the application. For more information, see the [Preparing an Application for Submission](#) step-by-step procedure.

### Study Workspace

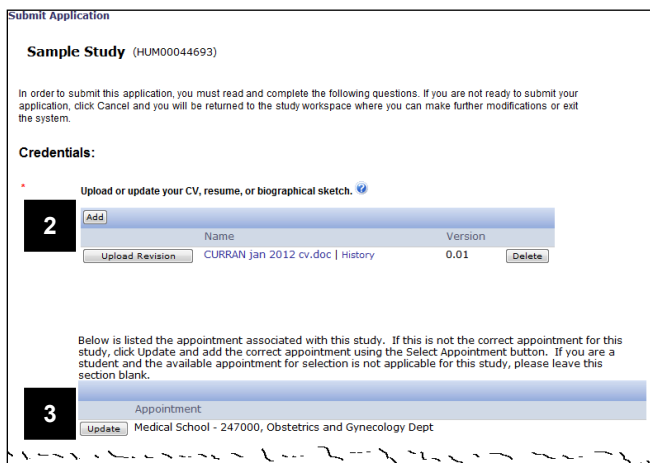


1. After clicking the name of the study from the **Ready to Submit** section of your **Inbox**, click the **Submit Application** activity in the Study Workspace.

#### Notes:

- You can also click **Submit Application** from section **45. End of Application** of the Study Application (not shown).
- After clicking **Submit Application**, the system will automatically run an error check. You must address all errors before proceeding.

### Submit Application Window



2. (Optional) Click **Upload Revision** to update any documents listed in the **Credentials** section, or click **Add** to upload any new documents to the section.
3. (Optional) Click **Update** if you wish update the appointment associated with the study.

Submit Application Window (Cont.)

**4**

Conflict of Interest:

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

What is an outside interest? To view your current disclosure information detail in M-Inform or to make changes to your disclosure information in M-Inform, [click here to go to M-Inform](#) and follow the instructions.

**D1\*** Do you, your spouse, domestic partner, or dependents have an outside interest or relationship with a non-UMH entity that relates to this research in one of the following ways:

**5**

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g., device, compound, drug, software, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

Yes  No Clear

**D2** If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

**6**

4. Note your **Current Disclosure Status in M-Inform**.

5. Read COI question **D1** and respond by clicking the applicable Yes/No radio button. If your answer to D1 is "Yes," complete question **D2**.

**Note:** Depending on a combination of your current disclosure status and your response to the COI question, you may be required to update your disclosure in M-Inform before submitting. See below for more details.

6. (Optional) Click **View Management Plan in M-Inform** to verify that one exists, or in order to update your current disclosure in M-Inform.

Disclosure Status / COI Question Response Scenarios

- In ALL cases where you answer "no," you can submit the application.
- If you answer "yes" and have not disclosed, you will have to disclose in M-Inform before you can submit.
- If you answer "yes" and have disclosed but have no outside interests, you will have to update your disclosure in M-Inform before you can submit.
- If you answer "yes" and have disclosed and have outside interests, you will be able to submit the application but will see a pop-up warning that says if necessary, update your disclosure information.

Submit Application Window (Cont.)

Investigator Assurances:

I certify that the information provided in this application represents an accurate description of the intended study. I agree to comply with University policies and procedures, sponsor and grant contracts, as well as by federal, State, and local laws and regulations concerning the protection of human subjects in research, the use and management of funds and, where applicable, the appropriate billing of healthcare services. These requirements include, but are not limited to:

- Conducting the research as described in the IRB-approved application.
- Implementing no changes in the approved study, including the informed consent document, without prior approval of the IRB.
- Submitting Scheduled Continuing Review Applications, including project termination, in a timely manner.
- Notifying the IRB of any unanticipated problems, adverse events (AEs), or other reportable information or occurrences (ORIOs) in a timely manner in accordance with the terms of the IRB's approval and published IRB guidelines.
- Submitting an accurate billing calendar, if a calendar is required, and maintaining the ability to provide the necessary documentation to support the billing calendar.
- Your certification in eResearch indicates that you have personally reviewed the most current drafts of the study protocol, informed consent document, sponsor contract and budget (if applicable) and that the billing calendar classifications of routine care, monitoring for complications, study paid items, and "not applicable" are complete and accurate. You will upload final documents within eResearch. In certain instances, the total number of times an item or service will occur over the course of an entire study is a reasonable estimate based upon your clinical knowledge and experience. You are required to provide supporting documentation for any item or service designated on the billing calendar as "routine". Necessary documentation may include clinical protocols, compendia and governmental or professional societal guidelines. In the absence of formal protocols and guidelines, you should be prepared to provide an auditor with information sufficient to support your professional clinical determination that the designation of services as "routine" meets the applicable standard of care. This may include a sampling of patient documentation with similar diagnoses that are not on study. The documentation must be readily available in the event of an internal audit conducted by your department, the UMHS Compliance Department, health plans or government programs such as Medicare or Medicaid.

I understand that as Principal Investigator, I assume full responsibility for the conduct of the study, and for the protection of the rights and welfare of human subjects involved in this research.

I agree to abide by the above assurance statement:  **7**

Click OK to submit this application for review. Do not further edit this application unless instructed to do so by a review committee. You will be notified by email as review committee approvals are granted or denied.

\*Required

**8**

7. Check the box to indicate that you agree to abide by the **Investigator Assurance** statement.

8. Click **OK** to submit the application for review by the appropriate committee(s).