

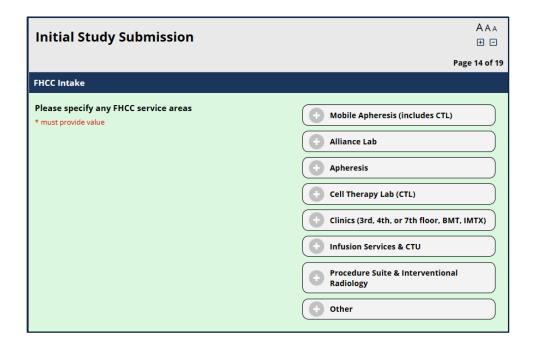
# NOTABLE CHANGES TO THE REDCAP STUDY INTAKE FORM – V. 5/5/2025

A new version of the UW/Fred Hutch Study Intake Form was implemented on 5/5/2025 to streamline study intake submissions and improve overall performance. For example, the previous Study Intake Form had amendment submissions built out individually (A-J), which increased the form size and impacted the ability to pipe data between amendment submissions. The new version has a repeatable amendment form with unlimited submissions. For each new amendment the form starts over fresh, but previous data remains in the system.

The purpose and function of the Study Intake Form is not changing, and most questions remain unchanged from the previous form. However, the structure and the formatting of certain sections/questions were changed to accommodate the functionality of the new repeatable forms. This guide provides an overview of changes you'll find in the new version of the UW/Fred Hutch Study Intake Form.

# FHCC (SCCA) INTAKE FORM

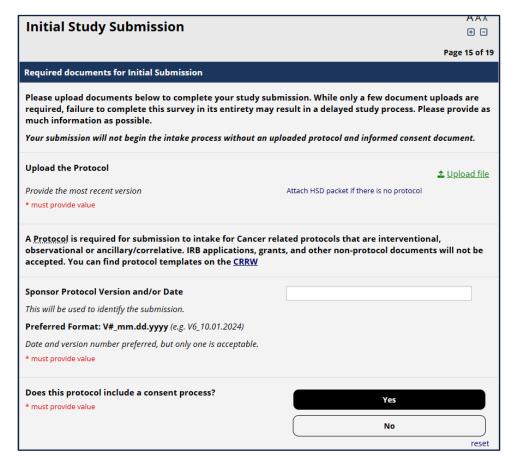
The old SCCA Intake form has been absorbed into the Initial and Amendment Submission forms. As you complete your main submission you will be prompted for the usual questions, but without having to click into another form. These questions will still only appear for relevant studies.





#### **DOCUMENT UPLOAD**

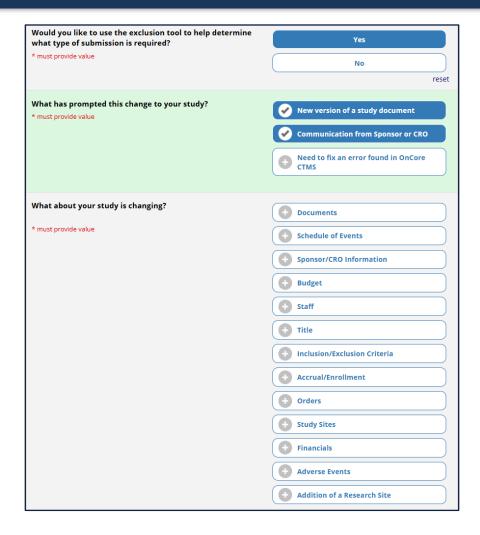
The attachments form has also been absorbed into the main submission form. At the end of the Initial Submission or any Amendment Submission you will be prompted to attach all relevant study documentation. It is important that you upload all documents at this time. The ability to go back into the attachments page after submission is no longer available.



### **AMENDMENT DETERMINATION TOOL**

An *optional* tool has been built into REDCap to help study teams determine if an amendment submission is required. This tool is functionally the same as the current amendment exclusion list but is interactive and will give you a determination upon completion. If the tool determines an amendment submission is required, it may remove choices as no further information is required, and you can continue to submit the amendment. The tool can help tell you if your changes to the study qualify for an amendment or if they can be just sent directly to CTMS without a full submission or uploaded via the Document Upload or Non-Amendment Submission Form. The Non-Amendment Submission form is a much-slimmed down form for Orders Only, Calendar Corrections, or addition of FHCC Procedure suite.





# **AMENDMENT SUMMARY QUESTIONS**

We have heard lots of feedback that many questions on the survey are repeated over and over unnecessarily, although questions may seem repetitive, they are vital to the current form functioning.

With the new form we are easily able to reference previous answers. When completing an amendment, you will be prompted with summary questions about different required sections. It will show your most recent answers and ask if anything needs to be updated. If it does not, you are done with that section and can move to the next without needing to re-answer questions we already have answers for.





# **SURVEY QUEUES**

With the new style of repeating forms your survey queues will look a little different. Instead of beginning a new survey each time you are ready to submit another amendment or make an update to IDS or Radiology, you will Take previously completed surveys again. A button will appear saying "Take this survey again." This will not take you back to previously submitted answers but will instead open a brand-new blank version of that survey ready for you to take again.

Your amendments will continue to use the alphabetical naming conventions you are used to. (Amendments A-L). But you will not see those listed in the survey queues, instead you will see numbers. These are just counting the number of times each survey has been taken. They will not always match each other; the form tracks amendments in the backend and will display the correct amendment letter inside the forms and on all your communications. When coming to this page "Changes to My Study" will always be available and it should continue to be where you go when you have a change to your study. After completing the Changes survey, the other required surveys will become available. You should be able to ignore the instance numbers and just take the available surveys.



#### **IDS AND RADIOLOGY CHANGES**

IDS and RadApp forms have also been changed into a repeated format. When submitting your first IDS or Rad app you will see the same questions you are used to seeing, but when it is time to submit an amendment, you will see some changes to the form. Like the main amendment submission, you will see your previous answers and will be asked to only submit changes or new requests.

This submission is an amendment submission. Please only mark items that need to be changed from previous submissions. To assist with this submission, your previous selections are included below.

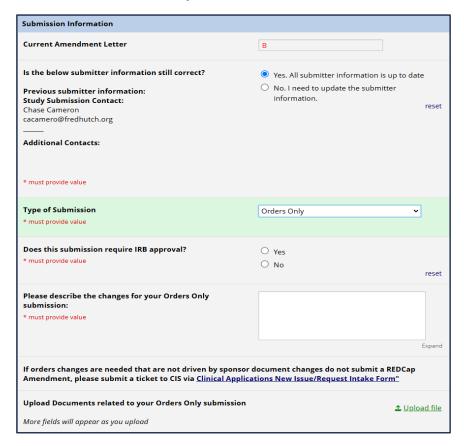
Anticipated # of patients: 6
# of scans per patient (total): 4
Approximate time frame (years): 2
Are measurements of tumors, such as RECIST reads, required? Yes



### **NON-AMENDMENT SUBMISSIONS**

Orders Only submissions, Calendar Corrections, and addition of FHCC Procedure Suite are no longer housed inside the full amendment submission survey. In the previous version of REDCap you were directed to submit an amendment, answer some leading questions that determined you do not need to submit a full amendment, and then a bunch a logic in the form hides the rest of the questions. This process was clunky and added extra steps for submitters.

The new form is noticeably shorter, asking only for the submitter's name, a short description and any relevant documents for an Orders Only submission.



### Document Upload - Changes to Attachments

Oncology, FH Non-Oncology and UW Non-Oncology studies with study activity at FHCC-SLU have a new Non-Amendment Document Upload form in REDCap.

- Study documents that have been assessed by the study team as not having an impact to the Schedule of Events, Billing Grid, or Orders (e.g., Study Manuals) should be uploaded to REDCap via the Document Upload form.
- For Studies Pre OTA: Study teams to upload clean copies and redline versions.





Updated: 5/06/2025 | V 1.0

For Studies Post OTA: Study teams should upload redline versions only via REDCap. Clean copies of documents should be uploaded to OnCore to the IRB tab or Docs/Info as applicable.

This will send the documents to CRT for review, if an amendment is required based on their review the submitter will be notified to submit an amendment (full or orders only). The decision tool will also inform you what to do with other documents if they do not necessitate a full amendment submission, whether that be email directly to CTMS or uploaded into OnCore.

## **QUESTIONS?**

Additional CTMS Online Office Hours are being scheduled from 5/7 - 5/15/2025 for any questions relating to the updated UW/FHCC Study Intake Form. Additional Office Hours will be held between 12-1:00pm PT on the following dates:

Zoom Link: Click to join Office Hours.

- Wednesday, 5/7
- Thursday, 5/8
- Monday, 5/12
- Wednesday, 5/14
- Thursday, 5/15

Help will also be available during usual Online Office Hours, Tuesdays from 10am – 12pm PT and Fridays from 1-3pm PT (please use link above or access via the OnCore landing page). For immediate assistance, please call the CTMS Program Office at 206-667-2868 or email us at <a href="https://creativecommons.org/linearing-center-of-commons.org/linearing-center-of-cent