

# 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.

The screenshot displays the 'Initial Study Submission' form. At the top right, there are accessibility icons (AAA) and a page indicator 'Page 14 of 19'. Below the title bar is a dark blue header for 'FHCC Intake'. The main content area has a light green background and contains the text 'Please specify any FHCC service areas' followed by a red asterisk and the note '\* must provide value'. To the right of this text is a vertical list of eight buttons, each with a plus icon and a label: 'Mobile Apheresis (includes CTL)', 'Alliance Lab', 'Apheresis', 'Cell Therapy Lab (CTL)', 'Clinics (3rd, 4th, or 7th floor, BMT, IMTX)', 'Infusion Services & CTU', 'Procedure Suite & Interventional Radiology', and 'Other'.

## 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.*

Initial Study Submission

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Required documents for Initial Submission

Please upload documents below to complete your study submission. While only a few document uploads are required, failure to complete this survey in its entirety may result in a delayed study process. Please provide as much information as possible.  
Your submission will not begin the intake process without an uploaded protocol and informed consent document.

Upload the Protocol

Provide the most recent version

Attach HSD packet if there is no protocol

\* must provide value

A Protocol is required for submission to intake for Cancer related protocols that are interventional, observational or ancillary/correlative. IRB applications, grants, and other non-protocol documents will not be accepted. You can find protocol templates on the [CRRW](#)

Sponsor Protocol Version and/or Date

This will be used to identify the submission.

Preferred Format: V#\_mm.dd.yyyy (e.g. V6\_10.01.2024)

Date and version number preferred, but only one is acceptable.

\* must provide value

Does this protocol include a consent process?

Yes


No

reset

## 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.

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Would you like to use the exclusion tool to help determine what type of submission is required?

\* must provide value

Yes

No

reset

What has prompted this change to your study?

\* must provide value

☒ New version of a study document

☒ Communication from Sponsor or CRO

☐ Need to fix an error found in OnCore CTMS

What about your study is changing?

\* must provide value

+ Documents

+ Schedule of Events

+ Sponsor/CRO Information

+ Budget

+ Staff

+ Title

+ Inclusion/Exclusion Criteria

+ Accrual/Enrollment

+ Orders

+ Study Sites

+ Financials

+ Adverse Events

+ Addition of a Research Site

## 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.

Do you need to make changes to the sites selected for this study?

**Previous selections:**

**Epic Billing Sites:** Fred Hutch Clinic at SLU, Fred Hutch Hospital within UWMC

**Non-Epic Sites:** Translational Research Unit (TRU)

☒ Yes. I need to update my site selections.

☐ No. The selections are correct.

## 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.

Status	Survey Title
✔ Completed	Initial Study Submission
✔ Completed	Changes to My Study – #1 <a href="#">+ Take this survey again</a>
<a href="#">Begin survey</a>	Tru Intake
✔ Completed	Radiology Application – #1 <a href="#">+ Take this survey again</a>
✔ Completed	Ids Pricing Request – #1 <a href="#">+ Take this survey again</a>

## 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.

Submission Information	
Current Amendment Letter	<input type="text" value="B"/>
Is the below submitter information still correct?	<input checked="" type="radio"/> Yes. All submitter information is up to date <input type="radio"/> No. I need to update the submitter information. <a href="#">reset</a>
<b>Previous submitter information:</b> <b>Study Submission Contact:</b> Chase Cameron cacamero@fredhutch.org  <b>Additional Contacts:</b>  <small>* must provide value</small>	
Type of Submission	<input type="text" value="Orders Only"/> <a href="#">reset</a> <small>* must provide value</small>
Does this submission require IRB approval?	<input type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a> <small>* must provide value</small>
Please describe the changes for your Orders Only submission:	<input type="text"/> <small>* must provide value</small> <a href="#">Expand</a>
If orders changes are needed that are not driven by sponsor document changes do not submit a REDCap Amendment, please submit a ticket to CIS via <a href="#">Clinical Applications New Issue/Request Intake Form</a>	
Upload Documents related to your Orders Only submission	<a href="#">Upload file</a> <small>More fields will appear as you upload</small>

## 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.

- ❖ 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 [CTMS@fredhutch.org](mailto:CTMS@fredhutch.org).