OnCore – Updating IRB Reviews

Purpose: OnCore is a Clinical Trial Management System (CTMS) from Advarra and gives research teams a single, comprehensive system for managing a trial throughout its life cycle. University of Arizona Health Sciences (UAHS) uses OnCore for a variety of purposes, including managing all clinical trials conducted within UAHS, housing current and approved study documents, housing study calendars and documenting when patient visits have occurred, housing electronic case report forms (eCRF's) for investigator initiated trials (IIT's), creating and running reports, reporting data directly to the National Cancer Institute (NCI), and tracking staff effort on trials.

Due to the scope of staff who access and view study documents in OnCore, it is important that information is kept up-to-date and accurate. The purpose of this work practice is to describe the process for entering IRB-approved study documents (protocols, ICF's, etc.) into OnCore.

Scope: This applies to regulatory staff.

Tools

- Learning Portal: https://oncore-docs.advarra.com/index.php
  In addition, you can log into OnCore and from your profile drop down, select Help → Learning Portal

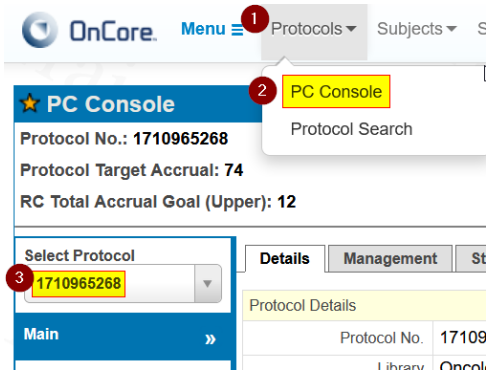
Initial Study Start-up:

1. Update OnCore with the minimum following documents upon IRB approval:
   a. If the study uses an external IRB: UA IRB deferral review
      i. UA IRB deferral approval
   b. All studies: Initial review by IRB of record
      i. Protocol (either sponsor protocol or IRB protocol, as applicable)
      ii. IRB Approval Letter
      iii. IRB-approved ICFs and assents
      iv. Associated approved/clean documents (patient material, IB, etc.) may be uploaded if desired
2. The following documents should **not** be uploaded into OnCore:
   a. IRB rosters

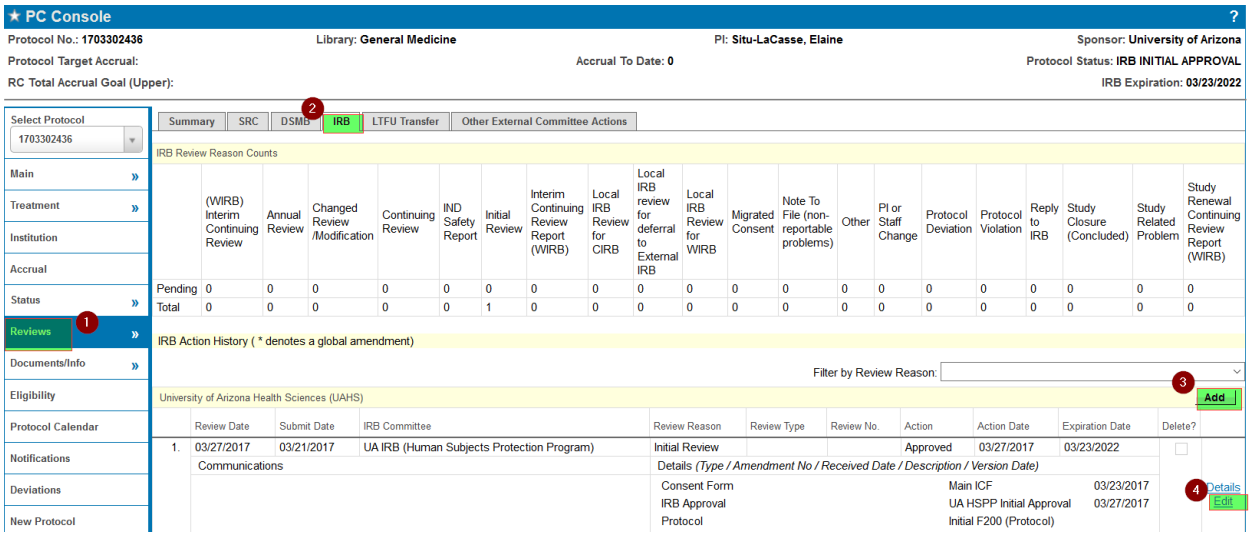
b. Tracked versions of documents (tracked protocol, IB, ICF, etc.) – example redline documents

Process / Steps:

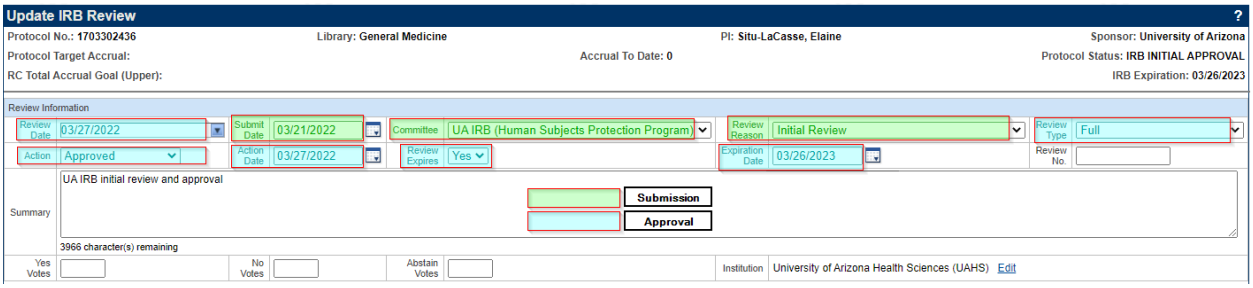
1. Log into OnCore: https://login.advarracloud.com/
2. Go to "Protocols" → "PC Console," and search for the appropriate protocol.



3. Go to "Reviews" → "IRB Reviews." To add a new entry, click "Add." To edit or add data to a previous entry, click "Edit."



4. One entry in OnCore will include submission and approval information associated with a single IRB review. Create a different entry for each IRB review. Examples: Local IRB Deferral, Initial Review, Continuing Review, Changed Review/Modification, etc.
   a. In practice, create a new entry ("Add") for every IRB submission.
   b. Once IRB approval is received, click "Edit" to update the associated submission with IRB approval information and documents.



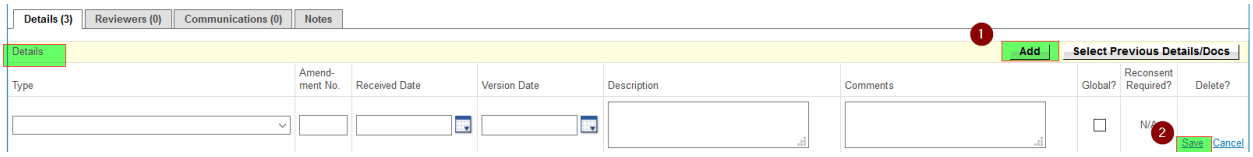
5. Complete the Review Information as described below:

Review Date	• Enter the date the IRB reviewed the submission. • Unless specified, this is usually the same as the Action Date. • Leave this section blank until the IRB has reviewed the submission. Update this section when IRB review is complete.
Submit Date	• Enter the date of IRB submission. • If IRB submission date is unknown, use the Review Date.
Committee	• Choose the IRB who reviewed the submission from the drop-down list.
Review Reason	Choose from the drop-down the reason for submission: • **Changed Review/Modification**: Amendments to the protocol or ICF must be entered; amendments to other materials may be entered if desired • **Continuing Review**: Renewals/continuing reviews • **IND Safety Report**: IND safety reports that were reported to and reviewed by the IRB. • **Initial Review**: Initial review by the IRB of Record. This is the first time the IRB of record reviews the protocol for the site. • **Local IRB Review for Deferral to External IRB**: Review of the UA IRB for any deferred study. • **Other**: Reviews that do not fall into any other category. • **PI or Staff Change**: Reviews for PI or other staff changes. • **Study Closure (Concluded)**: IRB review for study conclusion. This is the final IRB submission at the end of the study. • **Study Related Problem**: IRB review for a protocol deviation, or other major violation that occurred during the course of the study.
Review Type	Choose from the drop-down to match the review level specified by the IRB: • **Exempted** • **Expedited**: IRB reviews that do not go to the full IRB committee, and

	are reviewed by the Chair. • **Full**: IRB reviews that go to full IRB committee. Do not leave blank; if the IRB does not specify, select an option to the best of your knowledge
Action	Choose from the drop-down: • **Approved**: IRB approvals – most reviews Other options include: • **Abandoned**: Study abandoned before IRB reviewed the submission • **Acknowledged**: IRB acknowledgements • **Closed**: IRB determined to close the study. Note, if the IRB approves a closure submission, use the "Approved" action instead. • **Concluded**: IRB determined to conclude the study. Note, if the IRB approves a conclusion submission, use the "Approved" action instead. • **Correction Needed:** IRB determined a correction is needed before giving final approval. • **Deferred**: IRB deferred the review. Note, if the IRB approves a deferral submission, use the "Approved" action instead. • **Disapproved**: IRB disapproved the submission. • **Exempted**: IRB determined the submission was exempt from review. Note, if the IRB acknowledges an exempt submission, use the "Acknowledged" action instead. • **Other**: IRB reviews the submission with an outcome does not fall in any other category. • **Reviewed**: IRB reviewed the study, but did not have any other action (no approval, acknowledgement, etc.). • **Suspended**: IRB determined to suspend the study. • **Terminated**: IRB determined to terminate the study.
Action Date	• Select the date of the IRB action. • For approvals, this is the IRB approval date.
Review Expires	• Choose from the drop-down: • **Yes:** A new expiration date was given with this review. This should only be used for initial review by the IRB of record or continuing review, if an expiration date was indicated in the approval letter. • **No:** No new expiration date was given with this review. This includes initial or continuing review if no expiration date was indicated and all other types of reviews. • If the protocol previously had an expiration date but this requirement was removed in a later Continuing Review, selecting "No" will supersede the old expiration date and "N/A" will now be displayed

	for the expiration date in the study header.
Expiration Date	• Enter the expiration date of the protocol, listed on the approval letter. • Enter the expiration date at Initial Review and at each Continuing Review, if applicable. • For reviews other than Initial and Continuing Review, or if no expiration date is given for those reviews, be sure to select "No" for Review Expires, as described above, and the expiration date field will be greyed out. •
Review No.	• Enter the review number if known. (Ex. WIRB often has continuing review numbers associated with each renewal.) • Leave blank if unknown.
Summary	• Enter a brief description of the submission. (Ex. "WIRB initial review submission and approval.") • For cooperative group studies, specify when the information was posted to CTSU. (Ex. Sent to team on 4/18/2019. Posted to CTSU on 4/10/2019.)
Yes/No/Abstain Votes	• Leave section blank, unless known.
Institution	• Automatically populated. Do not change.

6. Under "Details," click "Add" to add documents.



Complete the Details information as described below:

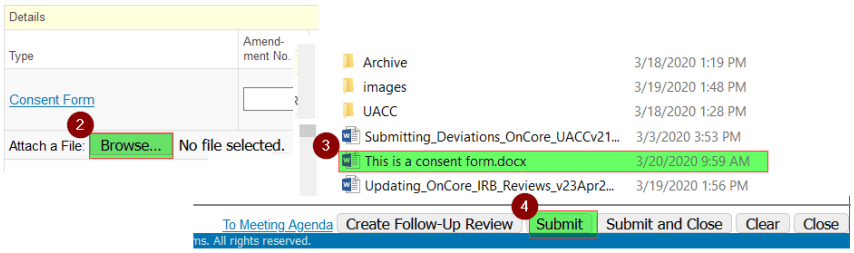
Type	Choose from the drop-down the appropriate document type: • **Action Letter**: Any sponsor, cooperative group, or IRB action letter • **Assent Form**: A child's consent/assent form • **Assent Form (Translated)**: A child's translated consent/assent form • **Consent Form**: Informed Consent Form • **Consent Form (Translated)**: Translated Informed Consent Form • **Disease Team Flowsheet**: Disease team flowsheet – usually uploaded under ePRMS (SRC), not under IRB reviews. • **HIPAA Form**: Standalone HIPAA document for cooperative group studies. • **HIPAA Form (Translated)**: Translated standalone HIPAA document for

	cooperative group studies or for use with short forms. • **IND Safety Report Note to File**: Note to file for IND safety report reviews for billing purposes – usually uploaded under Documents, not under IRB reviews. • **Investigator's Brochure**: Investigator's Brochure • **IRB Acknowledgement**: IRB acknowledgement document • **IRB Approval**: IRB approval document • **IRB Submission Form**: IRB submission form/document • **IRB Submission Receipt**: IRB submission receipt as proof of submission. This could be an email with a time stamp, or a cover letter with a time stamp. • **Lab Manual**: Laboratory manual – usually uploaded under Documents, not under IRB reviews. • **Miscellaneous**: Any document that does not fall under the listed document types. • **Note to File**: Any note to file or memo to file. • **Patient Materials**: Any patient materials such as diaries, questionnaires, brochures, etc. • **Patient Materials (Translated)**: Any translated patient materials such as diaries, questionnaires, brochures, etc. • **Pharmacy Manual**: Pharmacy manual – usually uploaded under Documents, not under IRB reviews. • **Protocol**: Study protocol or protocol admin/clarifications • **Team Resource Review Worksheet Approval**: Approved TRRW – usually uploaded under ePRMS (SRC), not under IRB reviews.
Amendment No.	• Leave blank in most cases. • If relevant, can specify the amendment number. Ex. Protocol Amendment 3.
Received Date	• If documents were received significantly later than their version date, can specify the date the documents were received.
Version Date	• For ICF's, enter the version date. • For protocols, IB's, memos, etc., enter the date of the document version. (Ex. Protocol Amendment 3, dated 3/2/2019, was IRB approved on 4/18/2019. The protocol version date is the date of the protocol document, 3/2/2019). • For IRB submissions and submission receipts, enter the date of IRB submission. • For IRB approvals, acknowledgements, etc., enter the date of IRB approval. • For dates where only the year is known, enter 01/01/YYYY. For dates

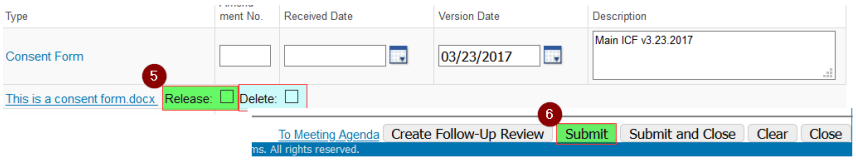
	where the month and year are known, enter MM/01/YYYY. • For documents that do not have a version date on the document itself, enter the IRB approval date.
Description	• Add a brief description of the document. If the document name is clear, the description can be the same as the document name. • Helpful to include a study identifier and dates in the description. (Ex. "INCB 50465-112 Main ICF UAHSv18Apr2019 approved 22Apr2019.")
Comments	• This field is visible only to regulatory coordinators. • Add any additional/helpful comments, as needed. (Ex. add a brief summary of changes next to the ICF and/or protocol.) • If re-consent is required, indicate in the comments who needs to re-consent. (Ex. "Re-consent required for all patients receiving study drug.")
Global?	• Leave blank in most cases. • An amendment may be marked as 'Global' if each participating institution's IRB must approve the amendment as approved by the Research Center's IRB. Checking this box will cause the record to appear as a 'Pending Amendment' on the PC Console > Institution tab. • Only used for multi-center IIT studies that utilize OnCore.
Reconsent Required?	• For consent and HIPAA documents, this check box can be used to indicate if re-consent is required. • Options to indicate re-consent for patients consented, eligible, on study, on treatment, on follow-up, or all. • Use this check box as determined by the IRB.

7. After entering all the appropriate information for the individual document, click "Save."

8. Attach the appropriate study documents from the electronic study folder and click submit.

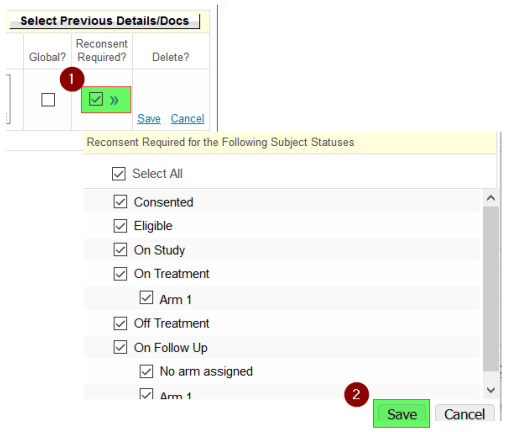


9. IMPORTANT: All documents must be released by checking the box Release and then clicking Submit.

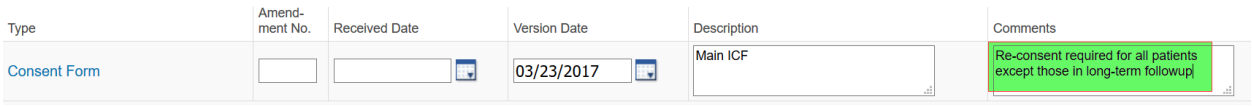


10. If a file was uploaded incorrectly, delete individual files by pressing “delete” next to the document and click Submit. To delete the entire entry, press “delete” next to the entry. Note, deleting the entry will also delete any associated attachments.

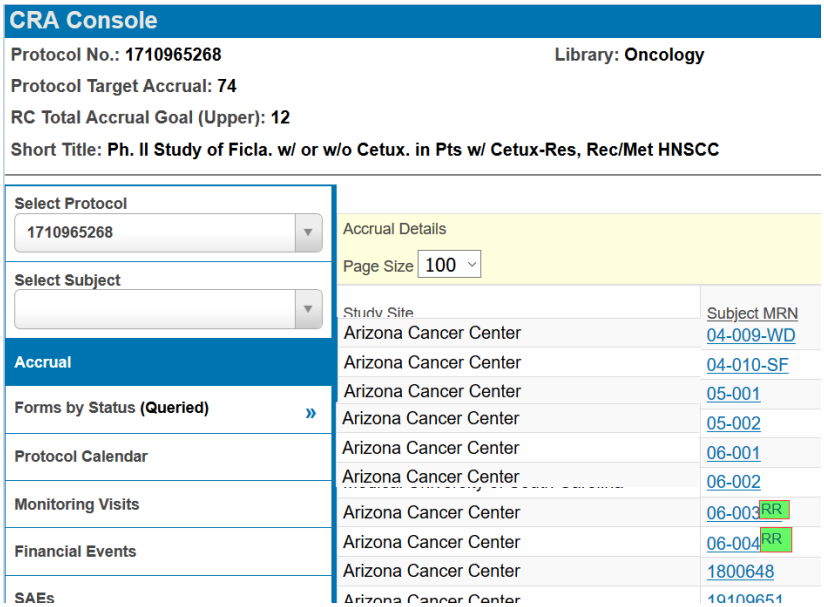
11. OnCore provides an option to indicate when re-consent is required. This populates as a checkbox in OnCore as “Re-consent Required” (“RR”). When “RR” has been checked, applicable patients will have an “RR” flag next to their name.



a. Re-consent required can be flagged for patients consented, eligible, on study, on treatment, on follow-up, or all. There can be an option to flag RR for a specific study arm.
b. Helpful to include which patients need to re-consent in the comments section of the ICF.



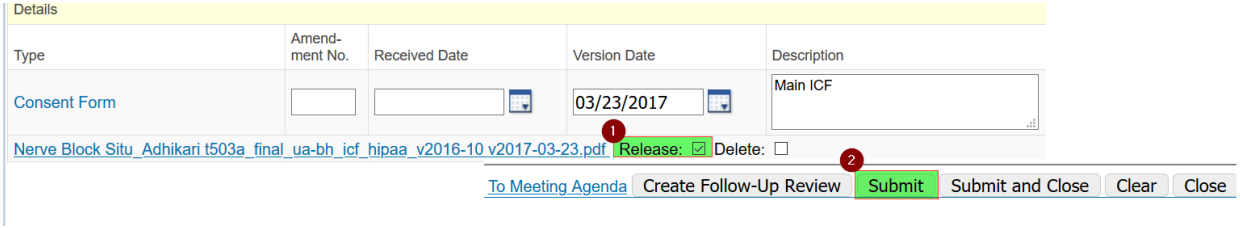
c. To see which patients have been flagged, go to "PC Console" → "Accrual" → "Subject → "CRA Console." Patients who don't need re-consent or who have already been re-consented will not be flagged. Note, this may populate incorrectly, depending on the



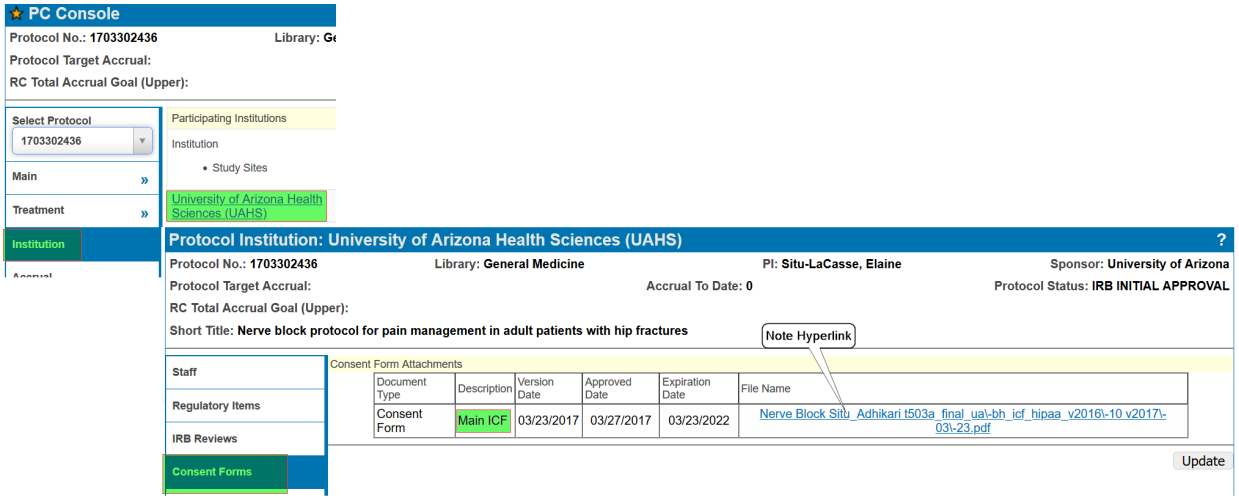
IRB's actual requirements.

12. Once IRB approval is received, press "Release" on all documents associated with the approval. If the ICF was updated, ensure that only the current ICF is released by un-releasing previous versions.
    a. "Releasing" a document creates a hyperlink that allows other staff to download the document to view.
    b. "Un-releasing" a document will remove the hyperlink, so staff cannot download the document. The document will still be uploaded in OnCore, but will not be available for other staff to view.
    c. Only the most current ICF should be available to download, so ensure that the previous ICF has been "un-released." To do this, navigate to previous IRB reviews, click "Edit,"

and un-release the previous ICF's.

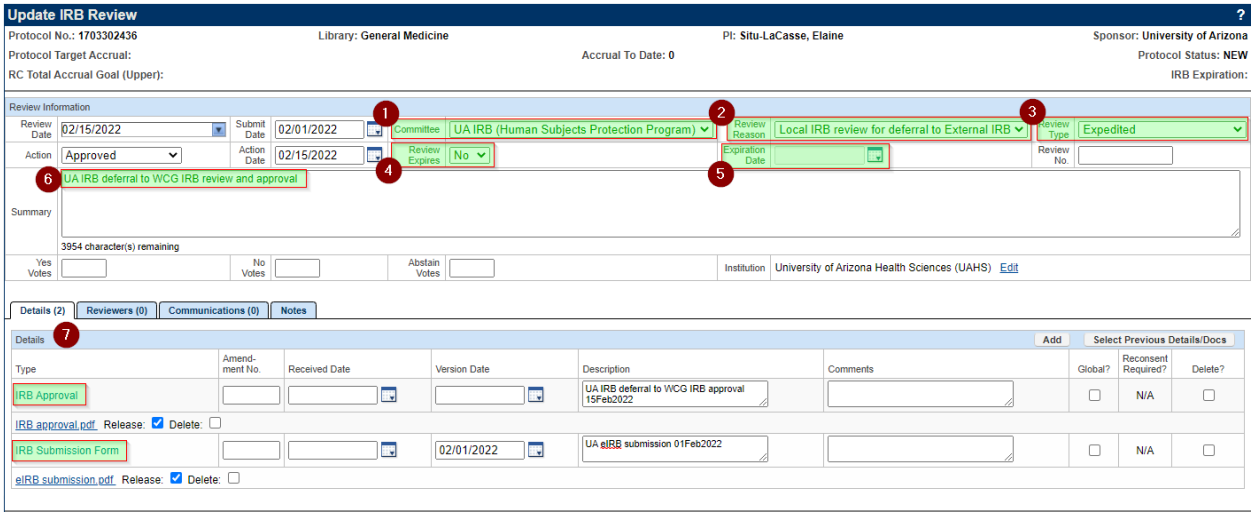


13. To ensure the correct ICF is available in OnCore, go to the study protocol "PC Console" → "Institution" → "University of Arizona Health Sciences (UAHS)" → "Consent Forms." Note that only the current ICF's should be hyperlinked and available to view.



Examples

Example of OnCore entry for IRB deferral:

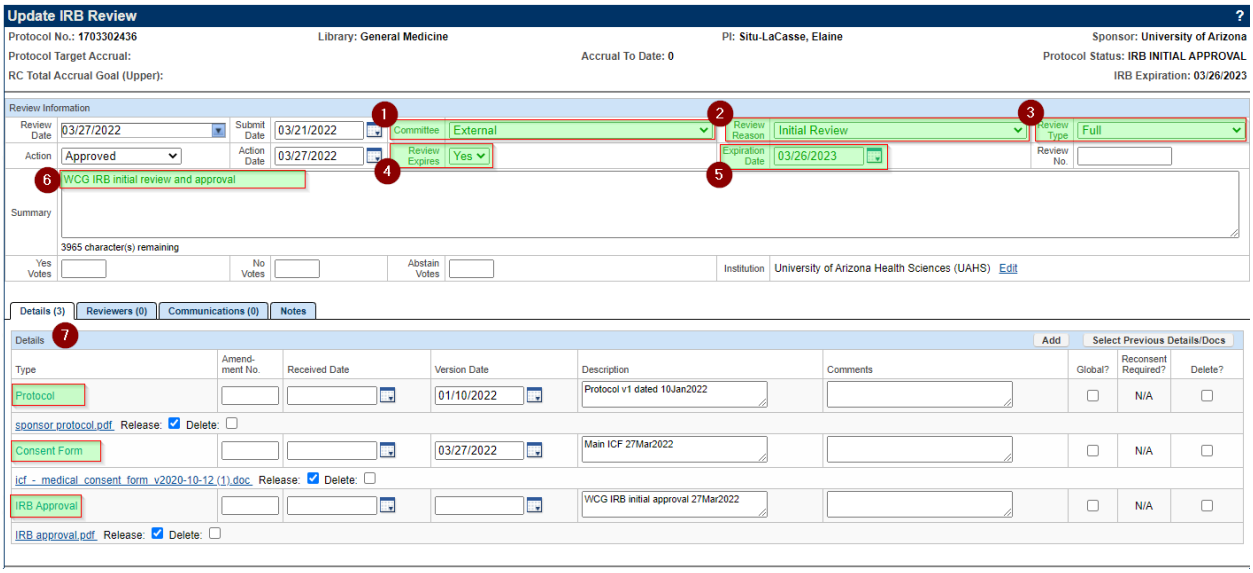


Notes:

1. Committee = UA IRB (Human Subjects Protection Program)
2. Review Reason = Local IRB Review for deferral to External IRB
3. Review Type = Expedited
4. Review Expires = No
5. Expiration Date is greyed out
6. Summary = UA IRB deferral to [External IRB Name] review and approval
7. Details = Upload the IRB Submission Form and the IRB Approval letter. No protocol, IB, ICF, or patient materials uploaded, as this is a deferral, and all protocol documents will be uploaded under the initial IRB review. All documents are released. No IRB rosters and no tracked changes are included.

Regulatory Work Practice

Example of OnCore entry for initial IRB review, with expiration date

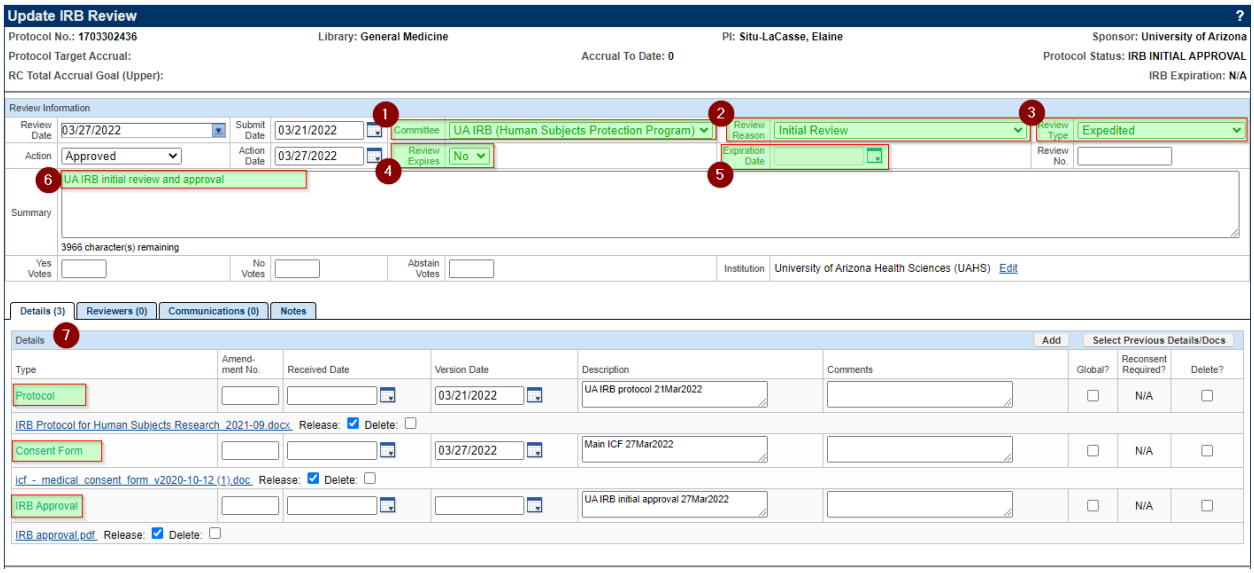


Notes:

1. Committee = External
2. Review Reason = Initial Review
3. Review Type = Full
4. Review Expires = Yes
5. Expiration date is populated
6. Summary = [IRB name] initial review and approval
7. Details = All approved documents (protocol, ICF, IRB approval, etc.) are uploaded and released. No IRB rosters and no tracked changes are included.

Regulatory Work Practice

Example of OnCore entry for initial IRB review, with no expiration date

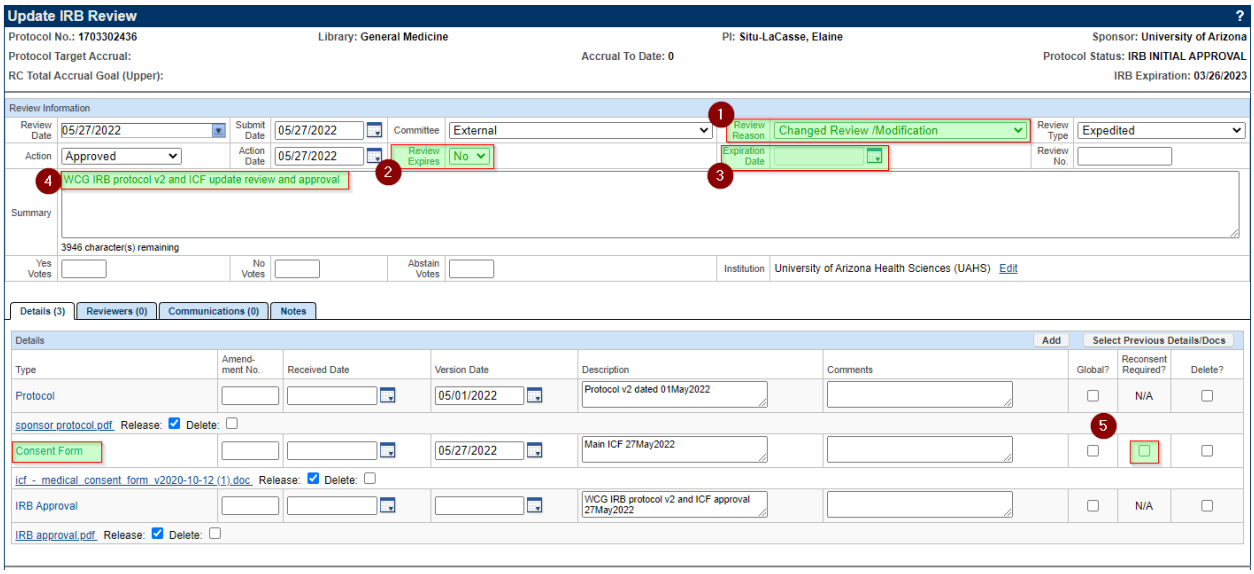


Notes:

1. Committee = UA IRB (Human Subjects Protection Program
2. Review Reason = Initial Review
3. Review Type = Expedited
4. Review Expires = No
5. Expiration Date is greyed out
6. Summary = [IRB name] initial review and approval
7. Details = All approved documents (protocol, ICF, IRB approval, etc.) are uploaded and released. No IRB rosters and no tracked changes are included.

Regulatory Work Practice

Example of OnCore entry for amendments:

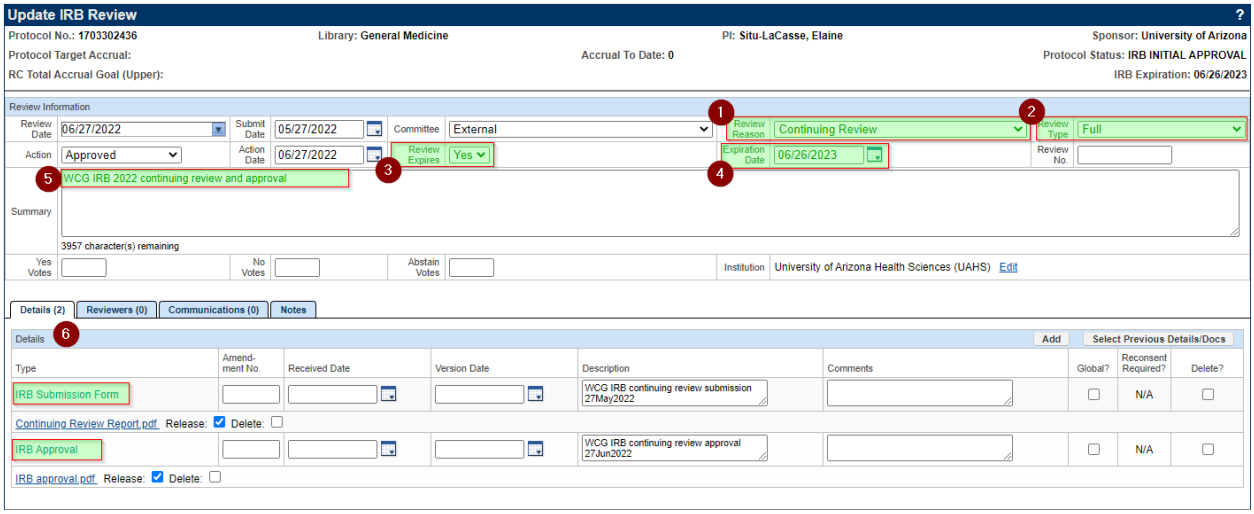


Notes:

1. Review Reason = Changed Review/Modification
2. Review Expires = No
3. Expiration Date is greyed out.
4. Summary = [IRB Name] [Description of amendment] review and approval
5. Details = Re-consent is not required in this instance. All approved documents are released. No IRB rosters and no tracked changes are included.

Regulatory Work Practice

Example of OnCore entry for continuing review, with expiration date:

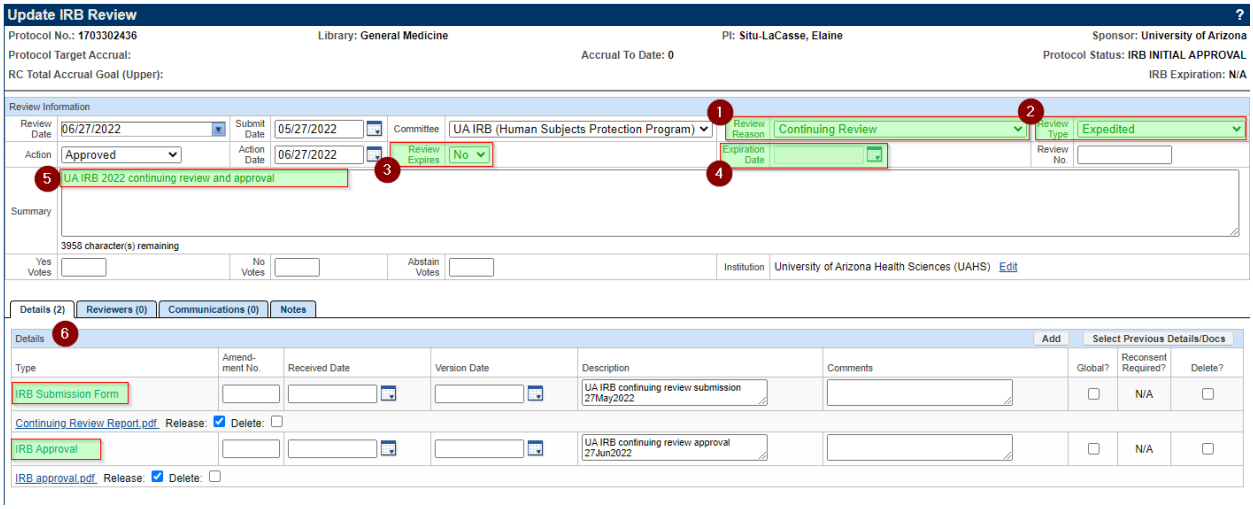


Notes:

1. Review Reason = Continuing Review
2. Review Type = Full
3. Review Expires = Yes
4. Expiration date is populated
5. Summary = [IRB name] continuing review and approval.
6. Details = All documents are uploaded and released. No IRB rosters and no tracked changes are included.

Regulatory Work Practice

Example of OnCore entry for continuing review, with no expiration date:



Notes:

1. Review Reason = Continuing Review
2. Review Type = Expedited
3. Review Expires = No
4. Expiration date is greyed out
5. Summary = [IRB name] continuing review and approval.
6. Details = All documents are uploaded and released. No IRB rosters and no tracked changes are included.