Title:	Instructions for Users of the CTRC Study Startup Dashboard	Origination Date:	12.1.24
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CLINICAL AND TRANSLATIONAL RESEARCH CENTER (CTRC)

ADULT CTRC STUDY STARTUP DASHBOARD: USER MANUAL

CONTENTS

QUICK TIPS TO KEEP IN MIND WHEN UTILIZING THE STUDY STARTUP DASHBOARD

1. All studies are to be managed through the CTRC Study Startup Dashboard. Please review and utilize this letter for any studies with Startup prior to the Dashboard inception.
2. The study PI or CRC can add additional members to the dashboard as needed at any time.
3. You must click "submit and notify" with any status change to trigger notifications.
4. Selecting "Refresh" on each page will display the most recent changes.
5. A question mark in the right-hand corner will be directed to the INFORM ticketing system in the event of a system error, or generic questions.
6. All visit names must match both OnCore and Scheduler template names.
7. All orders must be built on the most recent version of the MD Orders Template (automatically loaded in each folder).
8. **Do not use "Open in Desktop" to work on MD Orders, the orders will not save back to the Dashboard and any changes made will not be reflected in the dashboard.**
9. For Industry studies requiring CTRC Core Lab, a lab manual must be uploaded.
10. If changes or a Core Lab build are required to only an Industry Lab manual, please email the Core Lab directly to update.
11. Status updates are only required by the study team in their respective drop-down list.
12. Only the lead CRC(s) assigned to the study will receive all study notifications and status changes via email.
13. When orders are submitted, a PI meeting request will trigger the CCTSI administrator to schedule. Once scheduled, the date will be displayed in the PI meeting box on the MD Orders page.
14. **Orders will not be accepted for any changes/amendments without track changes or highlighting within the Word Document.**
15. MD orders will be locked once submitted to Pharmacy to review, no edits can be made after this step.
16. You must go to null or "-"status if you need to trigger notification while keeping the status the same. This will send the email notification. For example, "orders submitted' then 'null' and back to 'order submitted' so that a new notification is sent out when re-submitting the orders. Without changing to null will not notify the needed team and hence this step is important.
17. For changes to the study PI submit an INFORM ticket to have the study folder updated.
18. It is advised that you check history regularly to ensure the notifications as well as if any comments have been added by any of the members.
19. Comments in history feature do not create notifications only the status changes do.

SECTION 1: HOW TO NAVIGATE THE DASHBOARD

1.1: Accessing the Dashboard

If you receive a notification when opening the Dashboard that an updated version of the application has been released, please be sure to select the refresh button at the upper right corner. This will always notify you when you are using an older version.
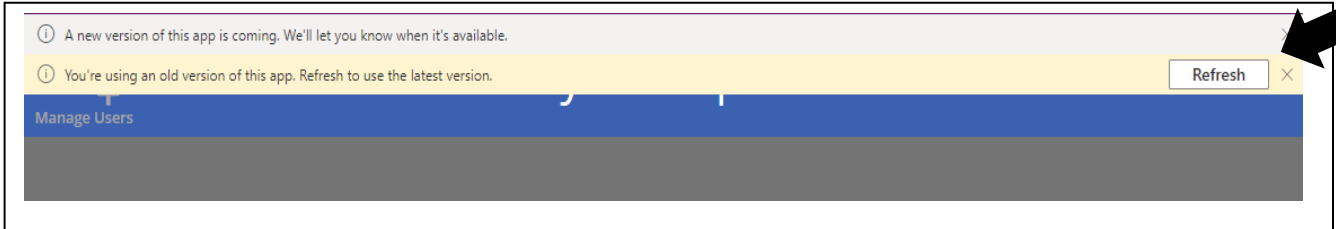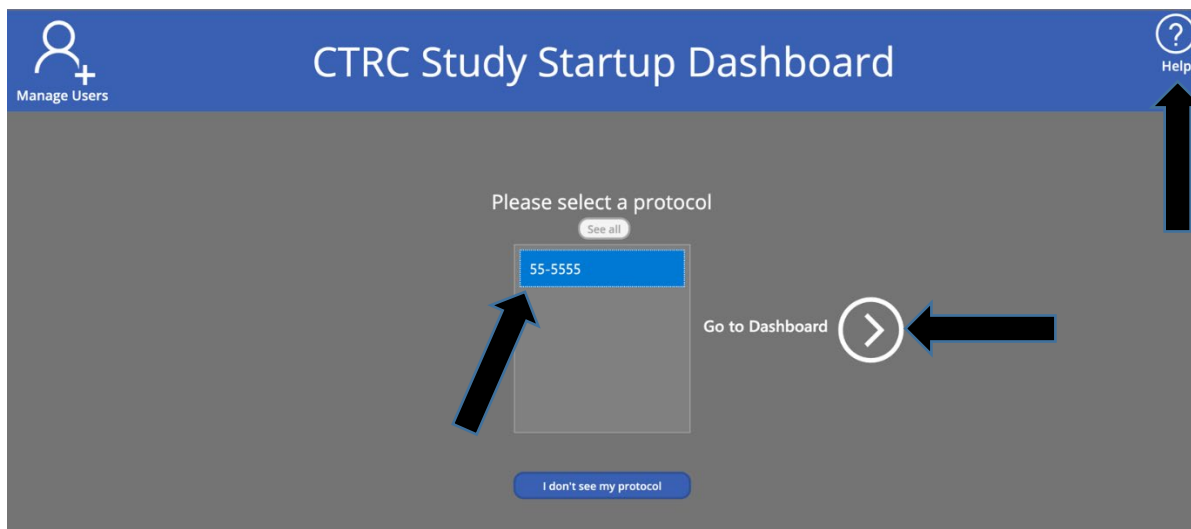

Additionally, you will need to "allow access" if ever requested within the dashboard.
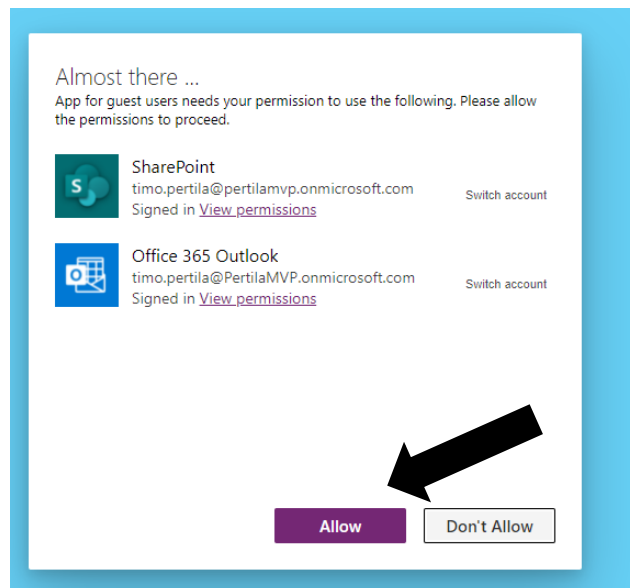
1.2: CTRC Study Startup Dashboard Home Screen

1.2.1: The home screen page displays access to all user-associated studies, user management, global view, and INFORM ticketing. These will all be described in detail in the following sections.

1.3: Opening study folder: select the COMIRB number and select the "Go to Dashboard" arrow (above)

1.3.1 If your study is not listed, select the "I don't see my protocol" button. If your study does not populate, notify your study team to add you as a member or submit an INFORM ticket

1.4: CTRC Study Startup Dashboard will open and display the global view. The global view provides status updates for each CTRC core during study-startup

1.4.1 Status updates within global view will correspond with each core review and approval. The study will be open for scheduling when all relevant cores show 'core startup complete' and scheduler status displays as "Ready- Open in scheduler". Drop downs status updates will including feasibility review and status updates.


1.5: Select the "Orders" stethoscope to open the MD Orders folder (above)

1.5.1: This page displays all status updates for each core related to the "MD Orders". Status updates may include the need for the study team to update the MD order documents, provide lab manuals, or update lab needs, among others. Studies that do not require MD orders do not need to view this 'orders' tab as it will not be relevant to study startup.
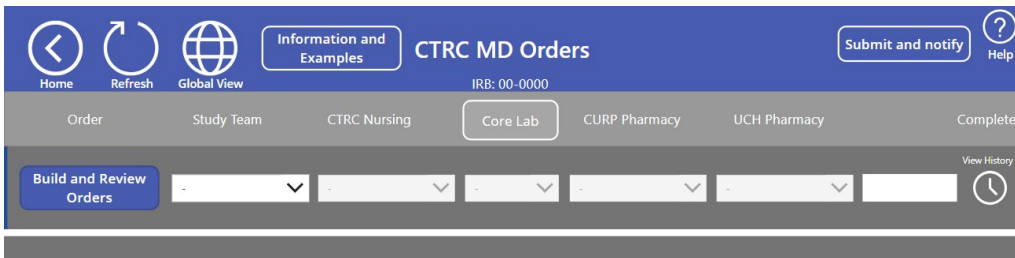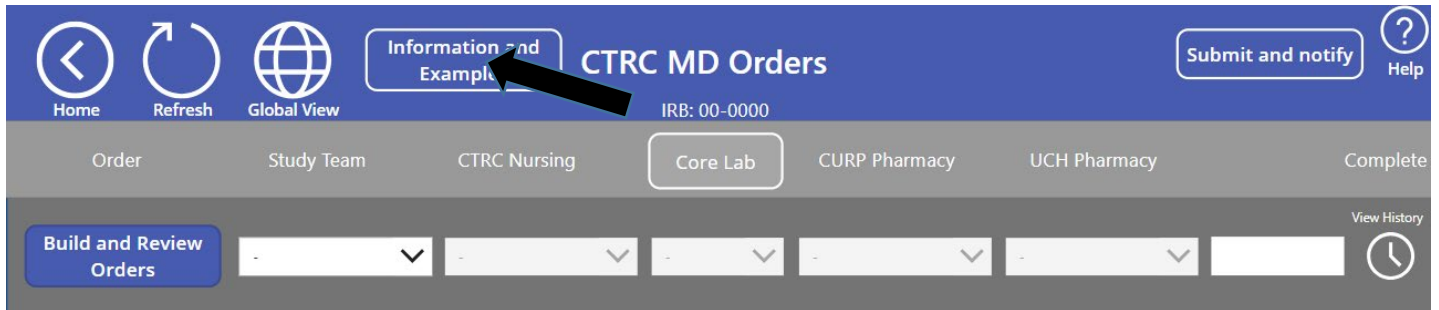
1.6 Viewing History and Comments

1.6.1 There are two locations to review all study history of status updates, and any comments required for changes to documents.
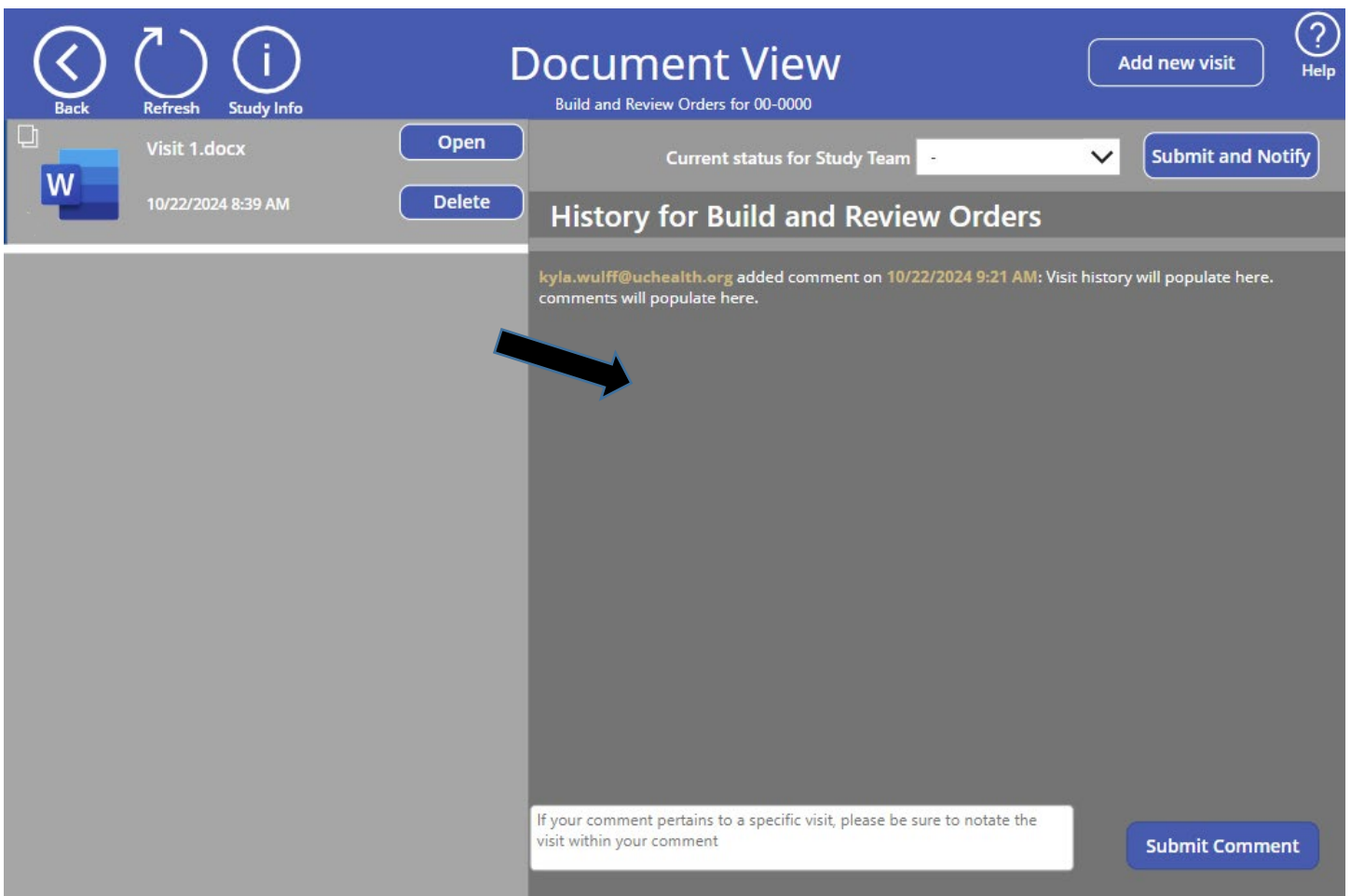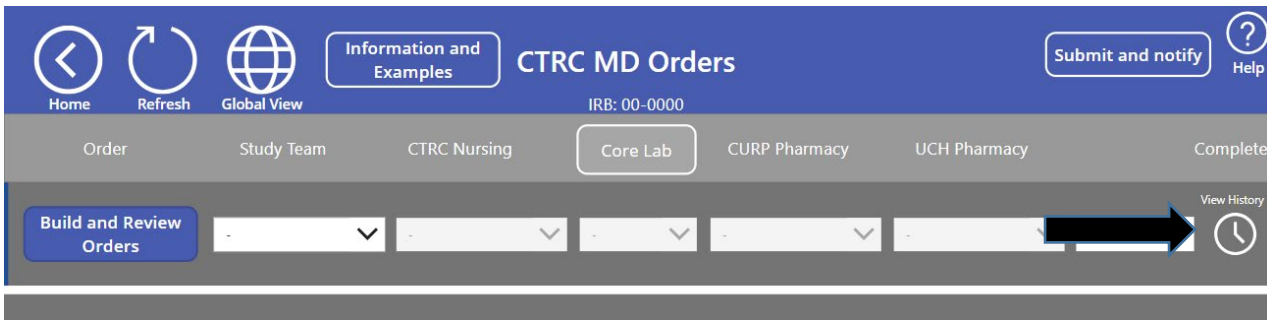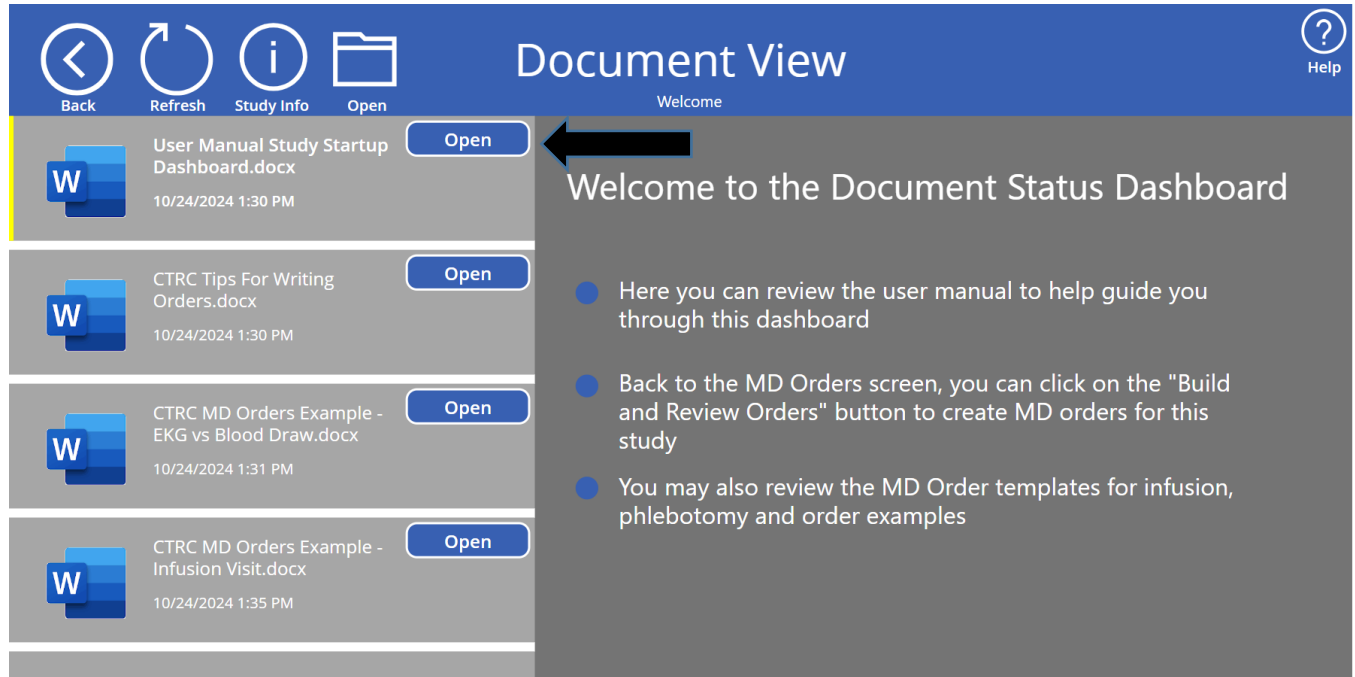
SECTION 2: BUILDING MD ORDERS

2.1: Select the "Information and Examples" Folder

2.1.2: This folder includes example templates and this manual for reference. Select "Open" to view each document. Close out of the window to return to the Dashboard. Select "Back" when review of these documents is complete.
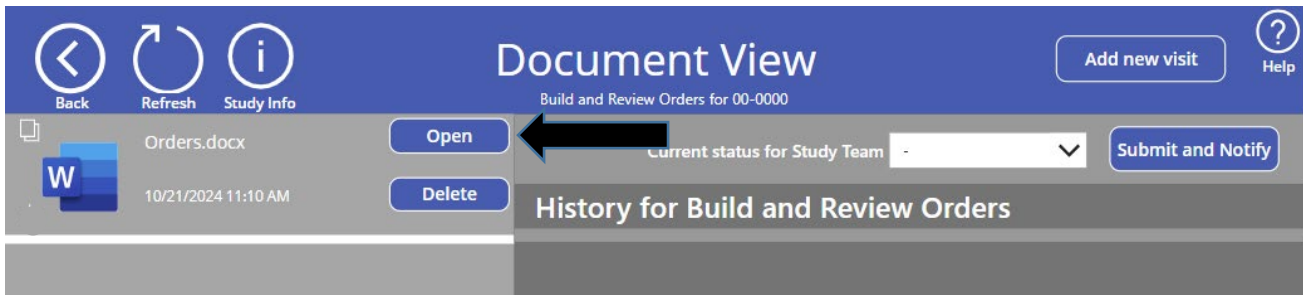

2.2 Select the "Build and Review Orders" button to open, view, and edit MD orders.

2.3: Building the MD orders in Word

2.3.1 The first visit will be called "Orders". Select "Open"

*2.3.2: Build MD orders visit **utilizing in-text comments** inserted on the right*

*2.3.3: When complete, **delete all pre-loaded comments** from Diane and Kyla. This can be done by going to "Review" on the toolbar, then to delete comments drop down and selecting **'Delete All Comments in Document'**.*
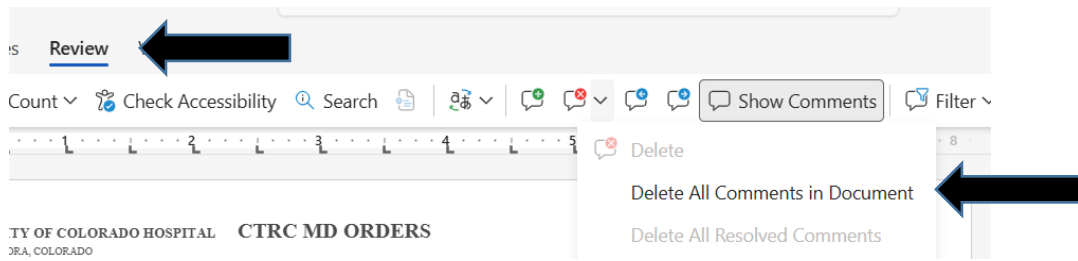

Then rename the visit by selecting the "orders" name in the upper left corner of the document. The visit name must match exactly the naming used in OnCore and Scheduler. This will display a checkmark within the cloud when saved. You may now exit the document.
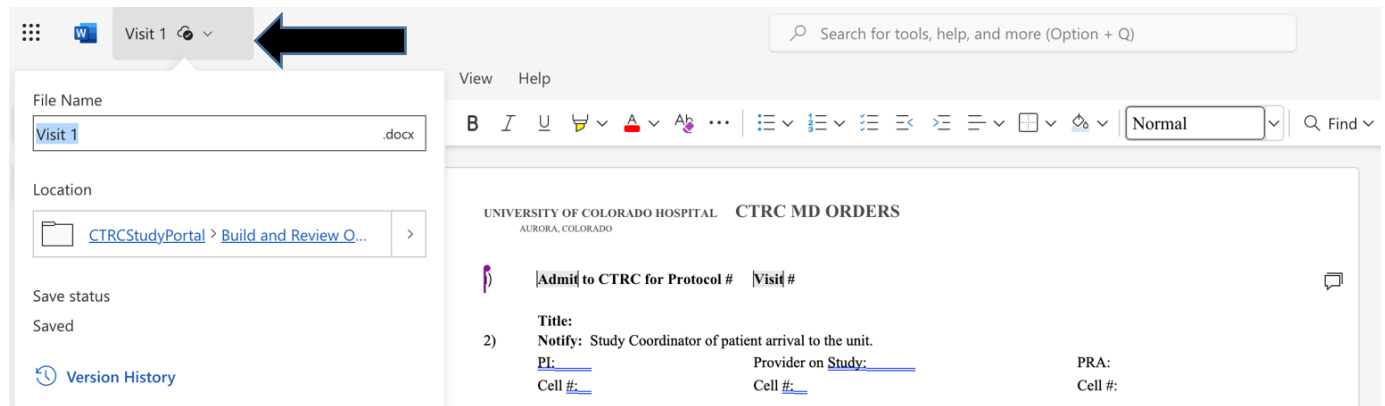

2.3.4: Return to the folder, and select refresh to display the updated visit name
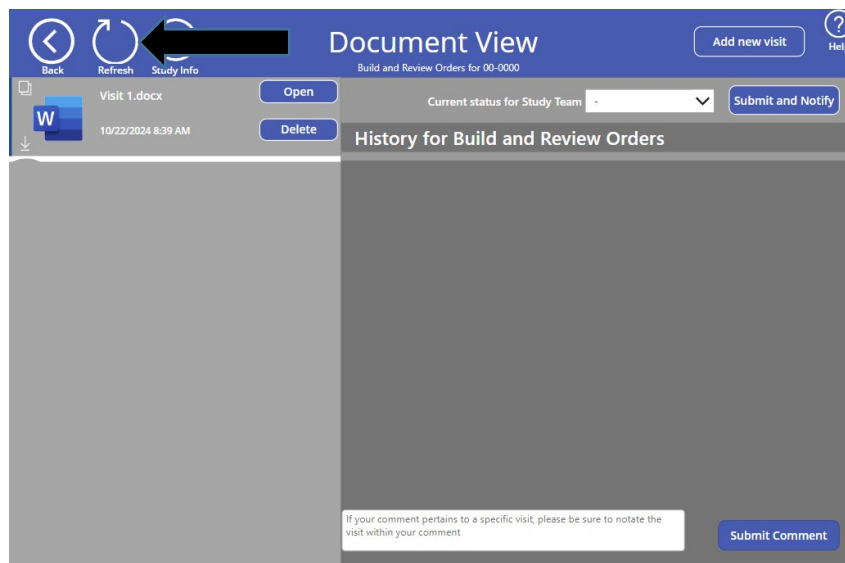
2.3.5: Select "Add New Visit" to create additional visit orders with a blank template
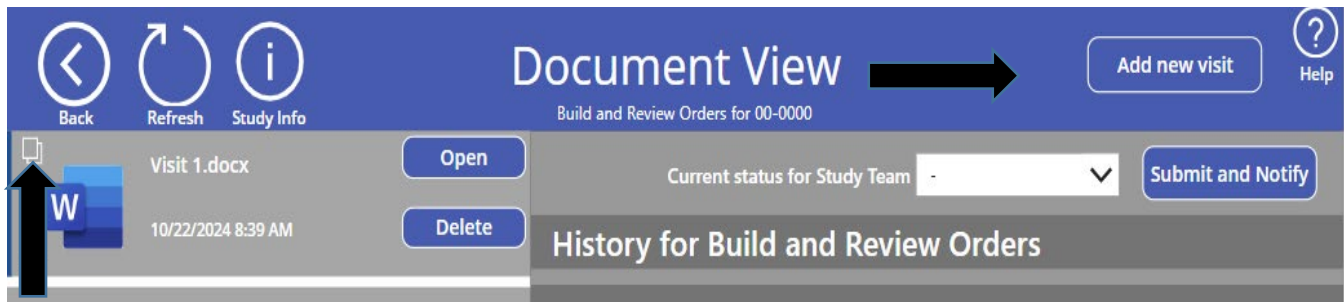
2.3.6: Select the copy icon within the Visit box if an exact copy of that visit is desired. This new document can be renamed the same as the above in **Step 2.3.3.** **To create multiple copies: rename each copy before selecting the copy function again on the same order.**
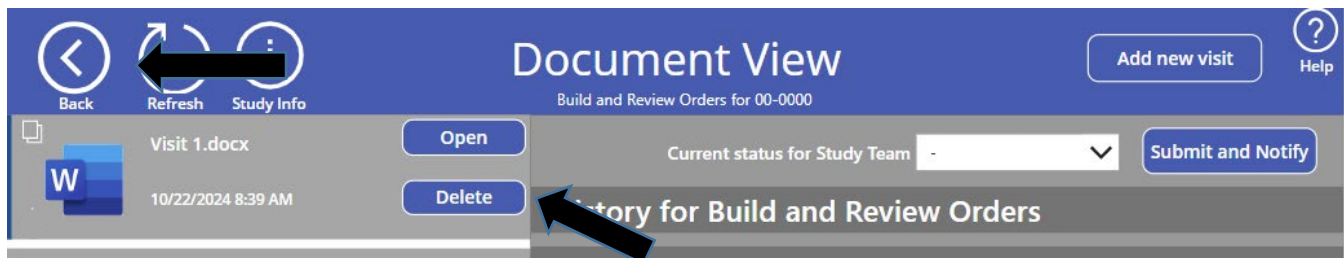
*2.3.6: Select the "delete button" to delete the visit if needed*

NOTE: **All visit names must match both OnCore and Scheduler template names.**

2.3.7 Once MD orders are completed, select the back button in the document view screen.

SECTION 3: STATUS CHANGES AND COMMENTS

3.1 Status Changes

3.1.1 When ready to submit the orders for CTRC Nursing review select the status drop down listed under "Study Team" in CTRC MD Orders Screen
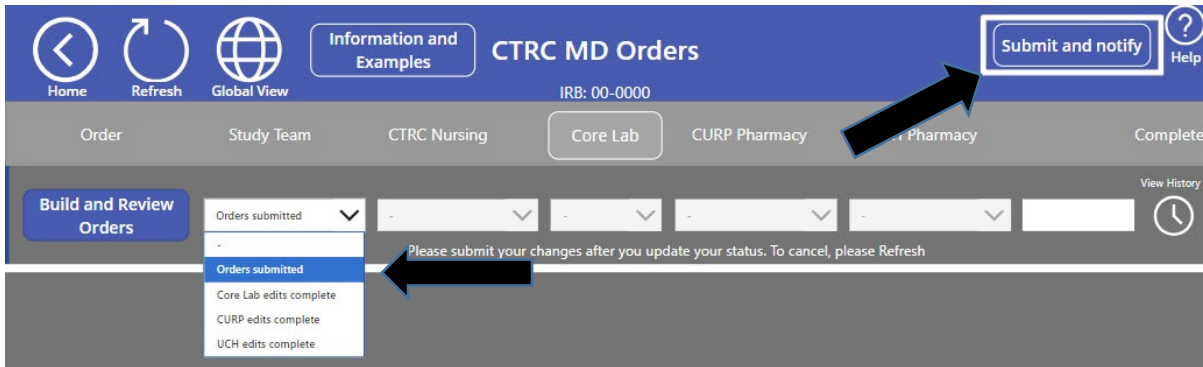

*3.1.2 Select the "orders submitted" status, **then select "submit and notify"** in the right-hand corner. This will notify the CTRC nursing core that MD orders have been submitted.*

3.1.2a Orders can alternatively be submitted within the Document View page. Select the appropriate status and "Submit and Notify" button.
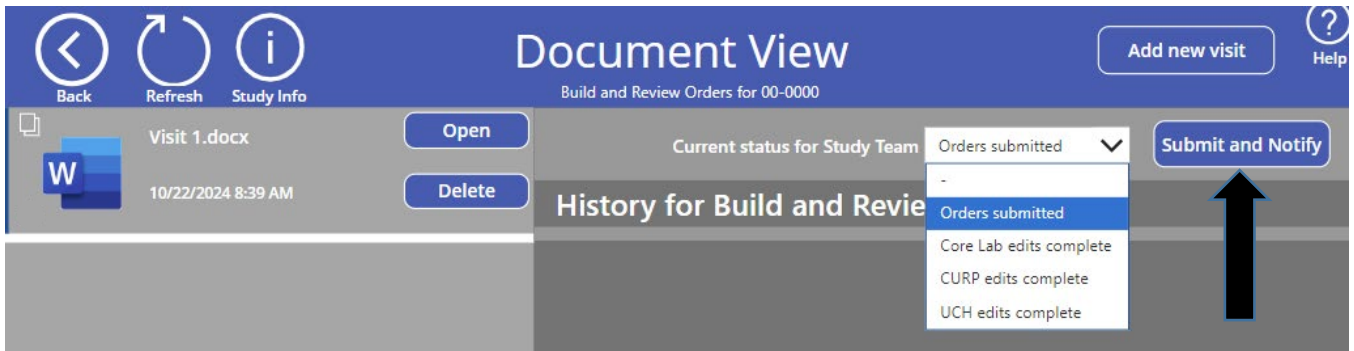

3.1.2b Upon initial order submission an automatic notification will be sent to CTRC Research Administrator to set up a PI meeting. The PI meeting, once scheduled, will display in the box to the far right in global view.
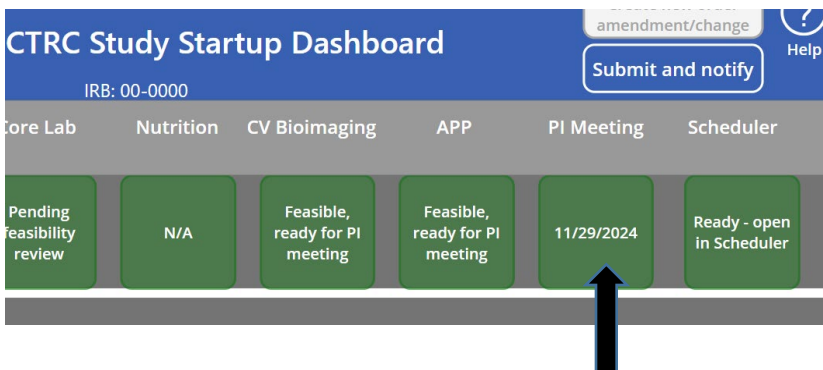
*3.1.3 CTRC nursing will be notified and review the orders. Then, select the appropriate next status step. If the orders require additional information from the study team, the CTRC Nurse Liaison will select "Needs study team changes" creating an email notification to the lead CRC(s) listed within the dashboard. This will reset the status drop down under study team to "-" (null). <u>Review comments for necessary changes both within the document and within the history and comments field for information needed. The study team is responsible for making all necessary changes to the document (1.6).</u> Follow step **3.1** to submit.*
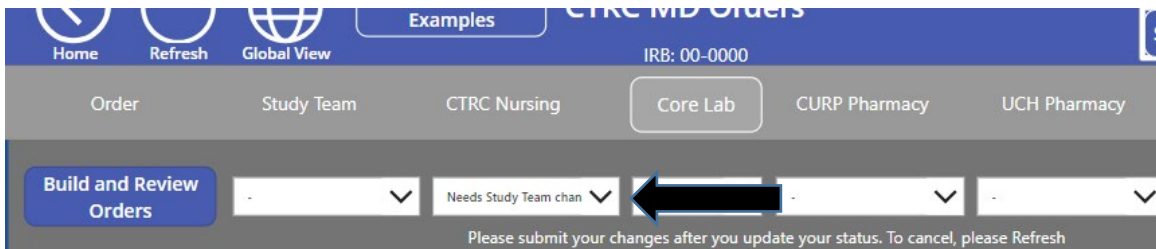

3.1.4 While orders are under nursing review, the status under nursing will display as "Under Nursing Review".
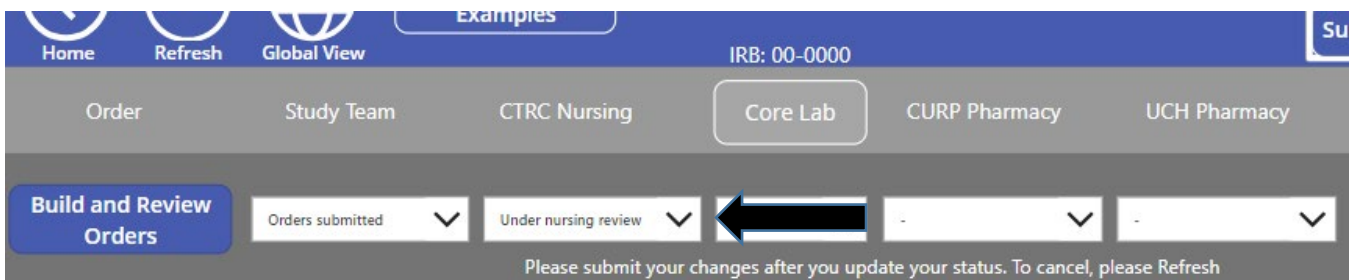

## 3.2 Core Lab Review and Manual submission (if applicable)

3.2.1 Core lab will complete MD orders review simultaneously with CTRC Nursing and select "Needs Study Team Changes" if additional information or changes are needed to the lab section of the orders. This will create an email to be sent to the lead CRC(s) listed in the dashboard. When edits have been completed by the study team, select "Core Lab edits complete" to notify the CTRC Core Lab of finalized edits.
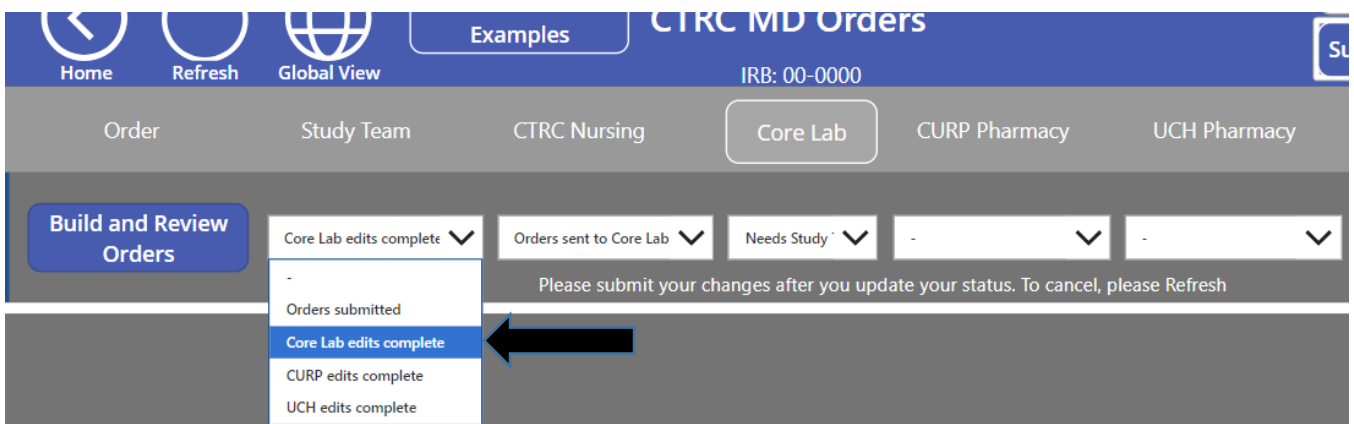
3.2.2 If a lab manual is requested, the Core lab will select "needs lab manual". This will create an email to the lead CRC(s) listed on the study.
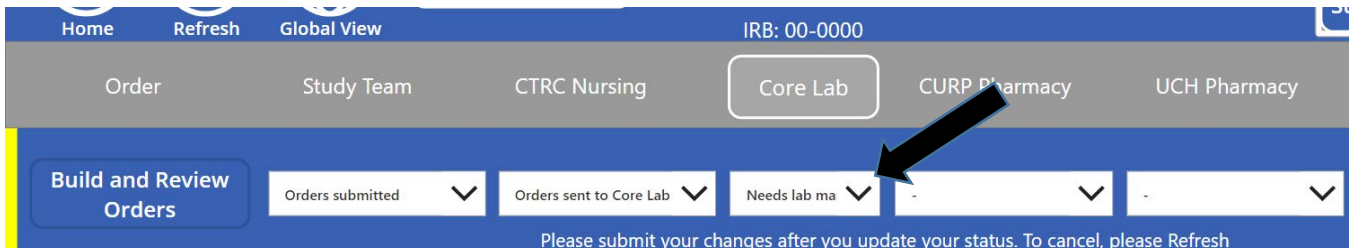

*3.2.2a To submit a lab manual select the "Core Lab" heading above the status drop down and attach the appropriate document(s). Attach the file and select "submit" within attachment window. Once the manual is uploaded, the CTRC Core Lab will receive an email notification of its completion automatically. **<u>No status change is required for a lab manual upload.</u>***
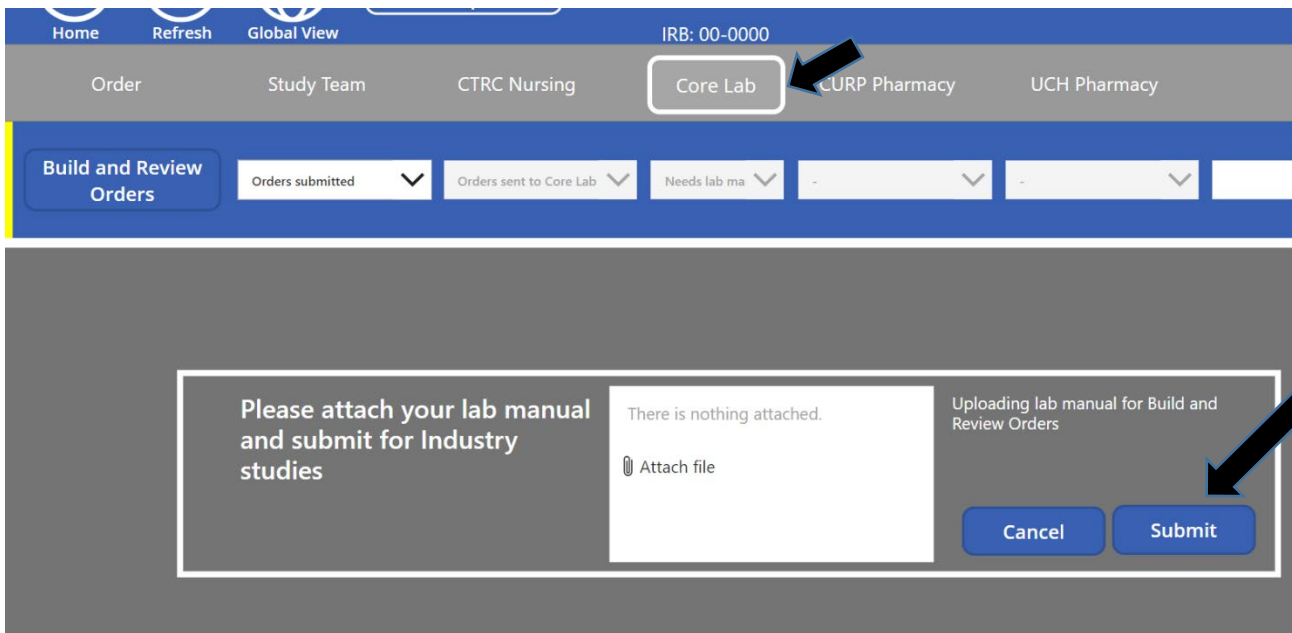
3.2.2b The attached manual is now viewable as the page icon above the Core Lab status drop down. The manual can be removed and updated at any time by selecting the Core Lab heading and selecting Remove manual and resubmit the new manual as described above.
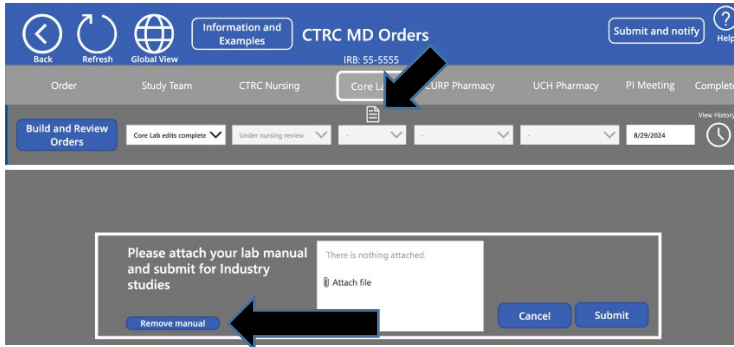
3.2.3 When Core lab review is complete the status will be updated to "Review Complete" by the Core Lab. CTRC Nursing and the Lead CRC will be notified automatically.
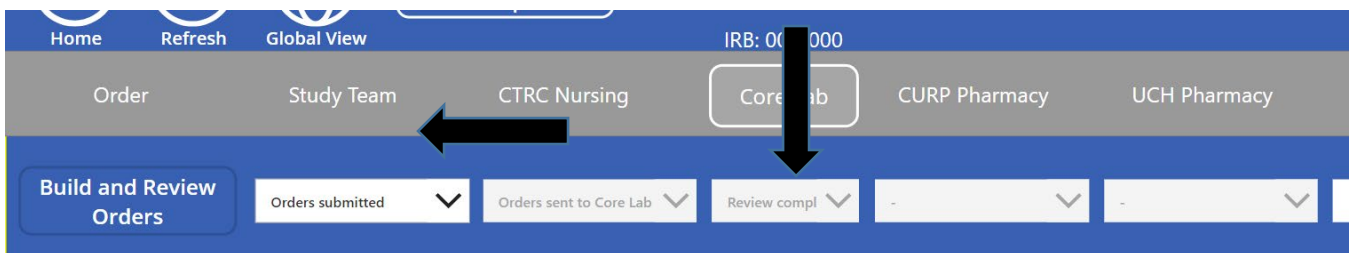

3.3 Pharmacy Review and sign-off (CU Research Pharmacy or UCHealth IDS Pharmacy)

3.3.1 CTRC nursing will create a status change for the Pharmacy review with the designated pharmacy. When documents are submitted to the pharmacy for review, documents will be locked (greyed out) for editing until pharmacy review is completed.
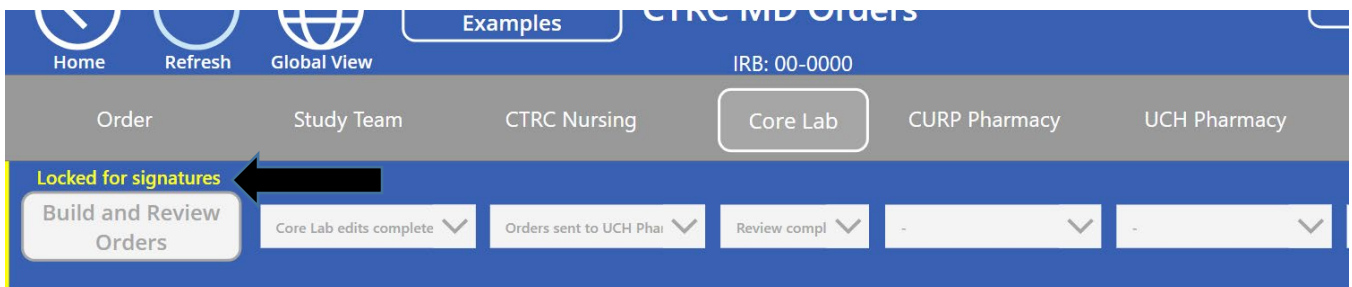

3.3.1a If additional edits are required, pharmacy will select "Needs Study Team Changes". This will create an email notification to the lead CRC(s) on the study.
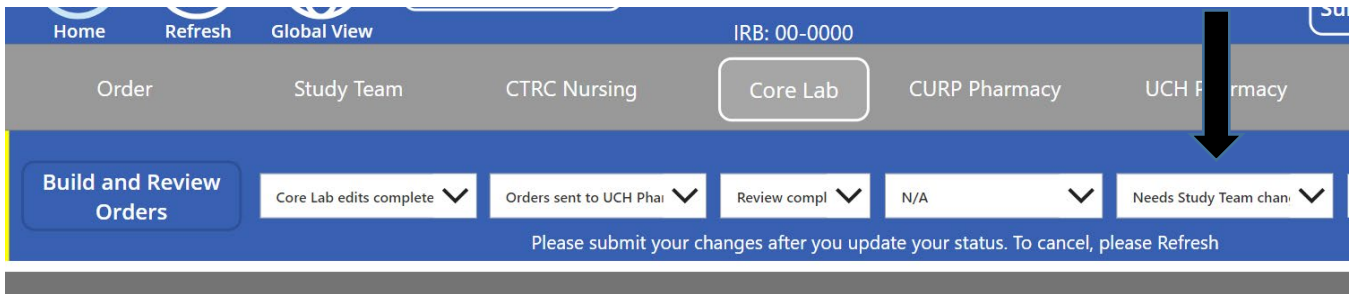
3.3.2 If the orders require additional information from the study team for Pharmacy use, <u>review comments for necessary changes both within the document and within the history and comments field for information needed and make the appropriate changes, see section</u> (1.6).

3.3.3 Once edits are finalized, select "Pharmacy edits complete" under the study team drop down for the __appropriate Pharmacy__ to notify the pharmacy of finalized edits.
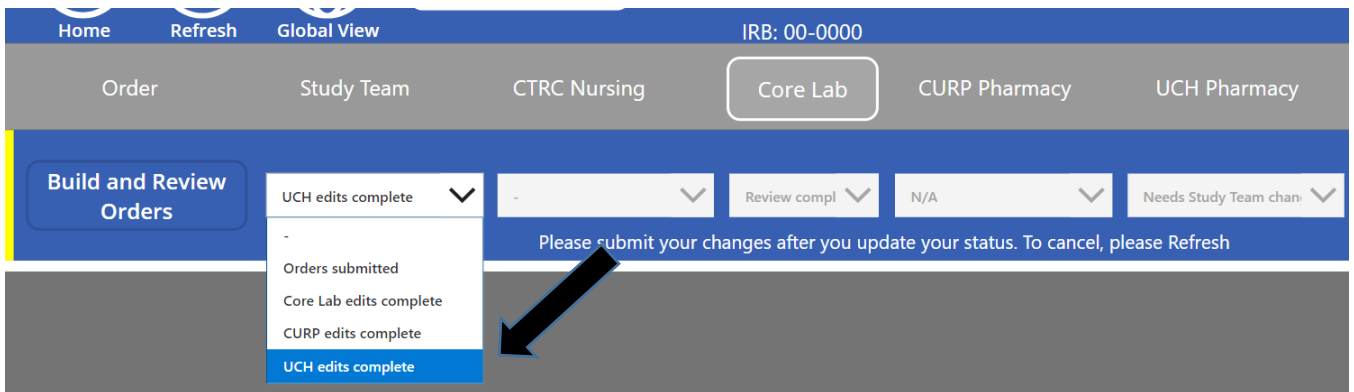

3.3.4 When the Pharmacy review is complete, the pharmacy status will display as "Review Complete" and will automatically notify CTRC Nursing and the Lead CRC
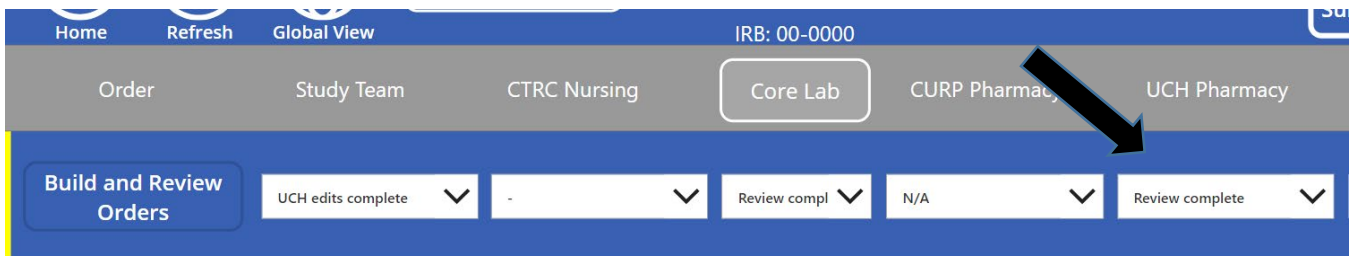
Note: If Pharmacy review is not required for the documents, CTRC nursing will manage completion of orders.

3.3.4.1 You must go to null or "-"status if you need to trigger notification while keeping the status the same. So if current status is 'orders submitted' and you wish to trigger a notification then go to "-"then back to "orders submitted" and click submit and notify. This will send the email notification. <u>Without changing to null will not notify the needed team and hence this step is important.</u>
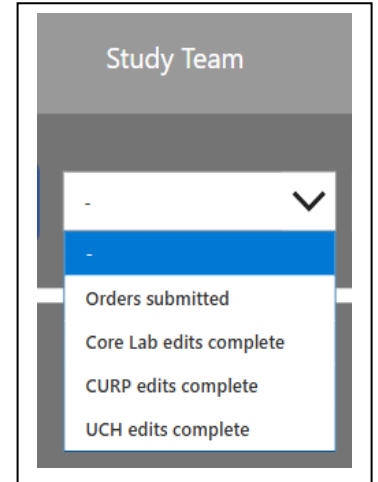

3.4 Upon completion of Pharmacy review (if required), CTRC nursing will notify CTRC Leadership to create a docusign for all study MD documents. The study MD will sign along with pharmacy, nursing leadership, and upon completion, the lead CRC and the study MD will receive a signed PDF copy from DocuSign. The email will arrive from DocuSign with the study COMIRB in the title. This can be utilized to build any future MD order changes or amendments by referencing and placing into the new order document. See Section 5.

3.5 Comments and History(review)

3.5.1 Comments and History can be viewed by selecting the "View History Clock" on the right side of the screen (above). Comments are displayed chronologically from the top and include both status updates and comments. If a comment is specific to a visit, please include the visit name and all details. ___*Comments do not trigger a notification; they must accompany a status drop down change.*___
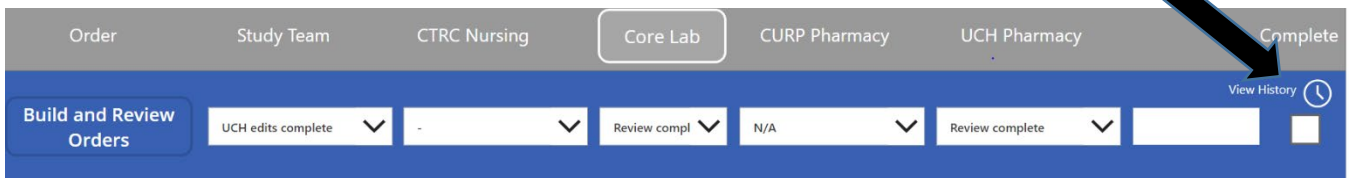
3.5.1a Comments can also be viewed from the Document View Page.
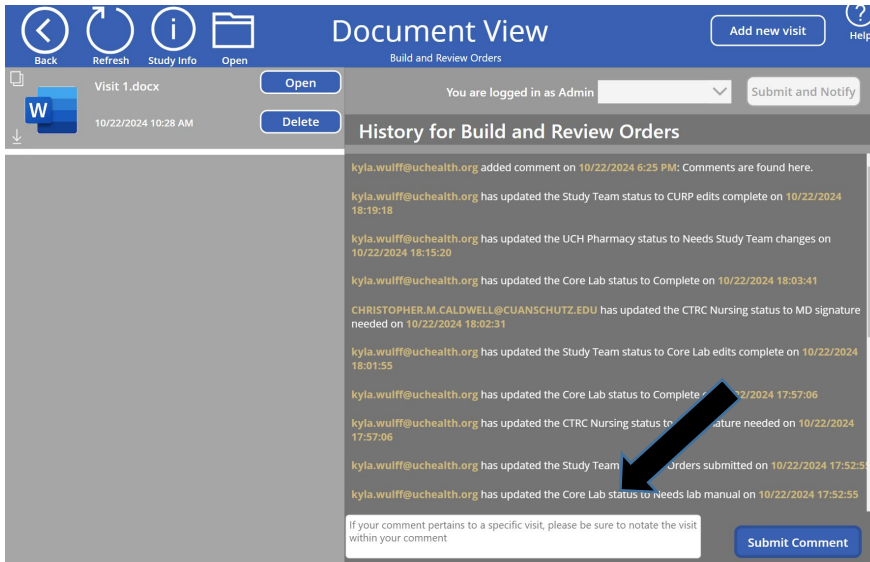
*3.5.2 Comments can be made by selecting within the white box in this screen and clicking "Submit comment".*

NOTE: **Comments do not create notifications. Please ensure comments are thorough and specific. They must be associated with a status change.**

IMPORTANT: Email notification when complete gets posted in the history tab. You must review 'view history' tab regularly to ensure that email notifications went through and also if any comments were added by any members.

SECTION 4: HOW TO ADD/EDIT TEAM MEMBERS

The CTRC Welcome Letter will be emailed to the PI and lead contacts listed in the Protocol Assessment Form and will include a link to the study folder on this dashboard. The study team can follow the steps below to designate the right team member as the lead Clinical Research Coordinator as needed. The study team can also add team members to view the study documents using the steps below. **The Lead CRC(s) assigned to the study will receive all study notifications and status changes via email.**

4.1 To make changes and updates to the study team, first, select the study COMIRB, then select the "Manage Users" Button on the main page in the left-hand corner.
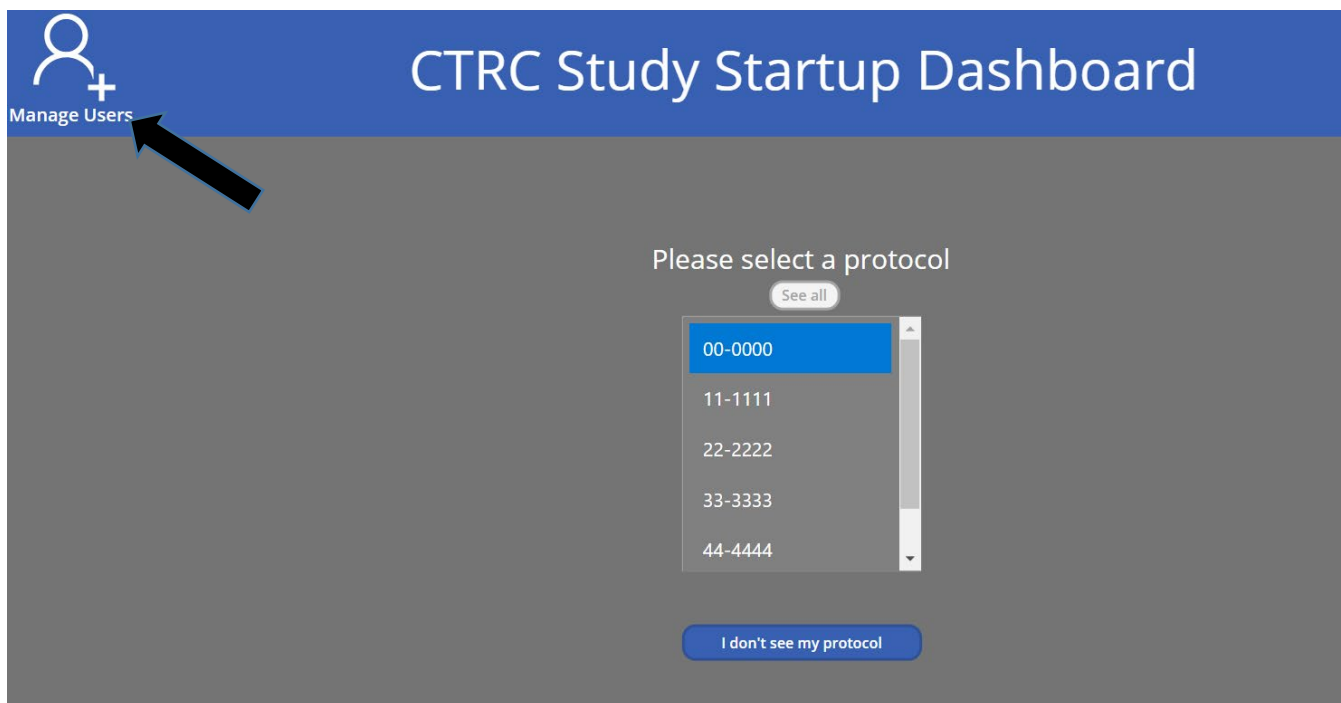
4.1.1 To add a team member, select your COMIRB number in the left column, then select "new team member". Type in the email address (ensure accuracy) and select "Submit New".

4.1.2 To remove a team member, select your COMIRB number in the left column, then select "Edit Team Member", select the team member name, and finally select "Remove" near their email address.

4.1.3 To change or designate the Lead CRC status, select your COMIRB number in the left column, select "edit team member", then select the team member you would like to edit, and select the "Check Box" for the Lead CRC to select or de-select. Then select "submit edit" to finalize the update. There can be multiple Lead Clinical research coordinators on a study. The study PI can be listed as the Lead CRC as well. **The Lead CRC(s) assigned to the study will receive all study notifications and status changes via email.**

Note: Select the "cancel edit" button if an entry is made in error prior to submission.

SECTION 5: HOW TO CREATE AN AMENDMENT/CHANGE

5.1 If an amendment is required for MD orders, enter the Dashboard and select from the CTRC MD Orders page "Create New Order Amendment/Change" in the right-hand corner. This button will only display once an initial set of orders has been created and completed.
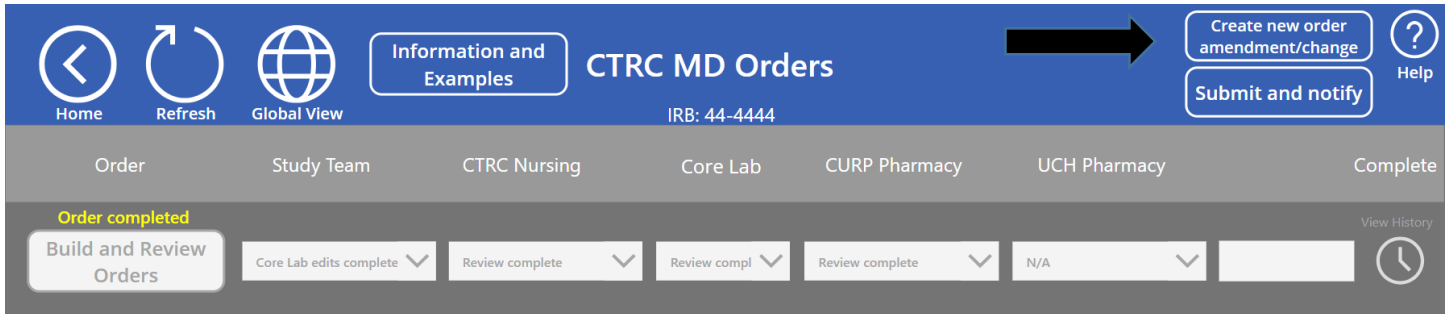
*5.1.1 A text box will populate asking if an amendment has been submitted. Links for both COMIRB and HSR portal web pages are included for review on what requires and official amendment. Then select "Yes" or "No". **If Yes**: Provide applicable amendment approvals from COMIRB/HSR. The study can then immediately begin building their amended orders in the Dashboard. **If No**: The study must provide rationale for the reason an official amendment is not necessary and a general summary of changes. The study can then begin building their updated orders.*

*5.1.2 The study/PI received a copy of the signed orders through DocuSign and can build their updated orders based on this document with the blank template auto-populating into each new folder. If the study is unable to recover their signed set of orders, a **signed** set can be provided to them from the nursing team outside of the Dashboard as a PDF file only.*

*5.1.3 When reviewing all change/amendment orders, **<u>ensure Track Changes or highlighting are provided by the study team outlining what has been changed from the original/prior order set</u>**. Changes/amendments without Track Changes or highlighting will not be accepted and will need to be edited.*

5.1.4 Begin building MD orders the same as referenced above in <u>Section 2.3.</u>

SECTION 6: STUDY STARTUP PRIOR TO DASHBOARD

6.1 All studies are to be managed through the dashboard. Please review and utilize this document for any studies with Startup prior to the Dashboard inception.

Resources & Contacts

Website	Contacts
CTRC Administration	cctsi.helpdesk@ucdenver.edu
CTRC Billing/MicroGrants	Kristen.House@cuanschutz.edu
Adult CTRC Nursing	CTO-CTRC.RNProtocols@cuanschutz.edu
Adult CTRC APP	ctrcapp@cuanschutz.edu
CTRC BioImaging	CCTSIBioimaging@cuanschutz.edu
CTRC Scheduling – OP, IP, mobile	CTRCScheduler@ucdenver.edu
CTRC Core Lab, CHCO	CoreLab@childrenscolorado.org
CTRC Core Lab, AHSB	CTRCCoreLab@cuanschutz.edu
CTRC Nutrition core	CTRC.Nutrition@ucdenver.edu
CCTSI Informatics Core	INFORM ticket
CU Research Pharmacy	Research.Pharmacy@cuanschutz.edu
UCH Investigational Pharmacy	IDSPharmacist@uchealth.org