STUDY TEAM HANDOFF

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STUDY TEAM HANDOFF

Description: Your study has now been entered into OnCore. In addition, the calendar and/or budget have been released. The study team is now responsible for:

- Confirming Study Staff
- Documenting the Initial IRB review
- Uploading the approved IRB documents (e.g. informed consents and IRB Approval Letter)
- Completing remaining signoffs for protocol
- Opening the Protocol to Accrual
- Registering all study subjects
- Recording all consents for all study subjects
- Recording eligibility and ineligibility for all consented subjects
- Updating each Subject's Study Status
- Managing each Subject's Calendar

This tip sheet gives instructions and links to additional web-based user guides for these activities.

IMPORTANT! If you need help as you start to work on your study or would like to set up a start-up consult, please *Request a Consult* or contact *OnCore-Support@ahc.ufl.edu.*

If you have already accrued a significant amount of subjects that need to be added to this study, the OCR office can help you get caught up. Please contact *OnCore-Support@ahc.ufl.edu* - copy Benjamin White benjaminwhite@ufl.edu.

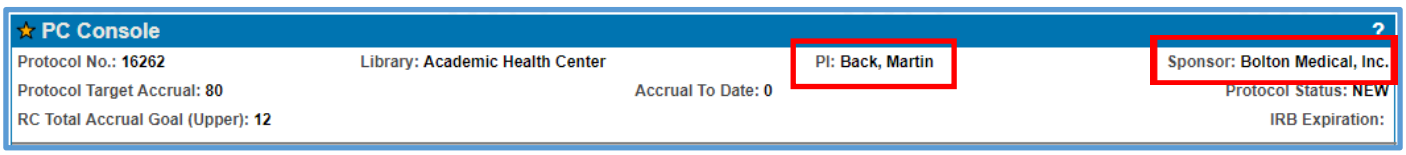
LOGIN

- Please review the online Login Browser Tips and URL user guide.
- Login URL - https://ufl-oncore-prod.advarra.app/.
- Use your Gatorlink **Username** and **Password**.

FIND YOUR STUDY

NOTE: These instructions can also be found in the online Find Your Study user guide.

1. Navigate to **Menu > Protocols > PC Console**.
2. In the **Select Protocol** field, type in any of the following study identifiers:
    - OnCore Protocol No.
    - Short Name
    - IRB No.
    - PRMC No. *(Cancer studies reviewed by the Scientific Review and Monitoring Committee only)*
    - Sponsor Protocol No.
    - FDA IND No. *(IND drug studies only)*
    - FDA IDE No. *(IDE device studies only)*
    - ClinicalTrials.gov NCT No. *(if applicable)*
    - UF "short name" or nickname
3. Select the blue study protocol number hyperlink to open your study.
4. Verify that this is the correct study by checking the **PI** and **Sponsor** fields in the header:



STUDY TEAM HANDOFF

CONFIRM STUDY STAFF

NOTE: These instructions can also be found in the online Assign Study Staff user guide.

UF study teams **MUST** keep OnCore study staff data current. Follow your **internal departmental workflow** to determine the proper OnCore study staff member(s) who should perform the review and confirmation of the initial role and staff member assignments for this study.

1. Navigate to **Menu > Protocols > PC Console > Staff**.
2. Sort the staff table by clicking on the **[Role]** column header.
3. Confirm that there is **at least one active person** assigned to the following UF required roles. Note: A staff member can have more than one role.
    - **Authorized Prescriber** - Only required for studies that involve investigational drugs dispensed by the UF Health Investigational Drug Services (IDS).
    - **Billing Coordinator** - pays patient care costs invoices
    - **Epic Charge Reviewer** - Only required for studies that are/will be in Epic
    - **Financial Coordinator** - negotiates the budget, performs coverage analysis on the billing grid, and/or will be responsible for invoicing sponsor
    - **IRB Coordinator** - responsible for IRB submissions and consents
    - **Primary Study Coordinator**
    - **Principal Investigator**
    - **Study Site Contact** - Only required for studies that will be published on the public UF website using data from OnCore (e.g. Study Connect).
4. If any staff members or required roles are missing, add by entering the following for each person: Click **[Update]** if needed.
    - **Role**
    - **Staff Name**
    - **Start Date**
    - Click [**Add**].

If you are trying to add a staff member and their name does not appear in the **Staff Name** drop-down menu, please complete an **"Add New Staff"** request via the OnCore Support webpage **https://clinicalresearch.ctsi.ufl.edu/oncore/oncore-support/add-update-staff/.**

DOCUMENT THE INITIAL IRB REVIEW

NOTE: These instructions can also be found in the online Document an IRB Review user guide.

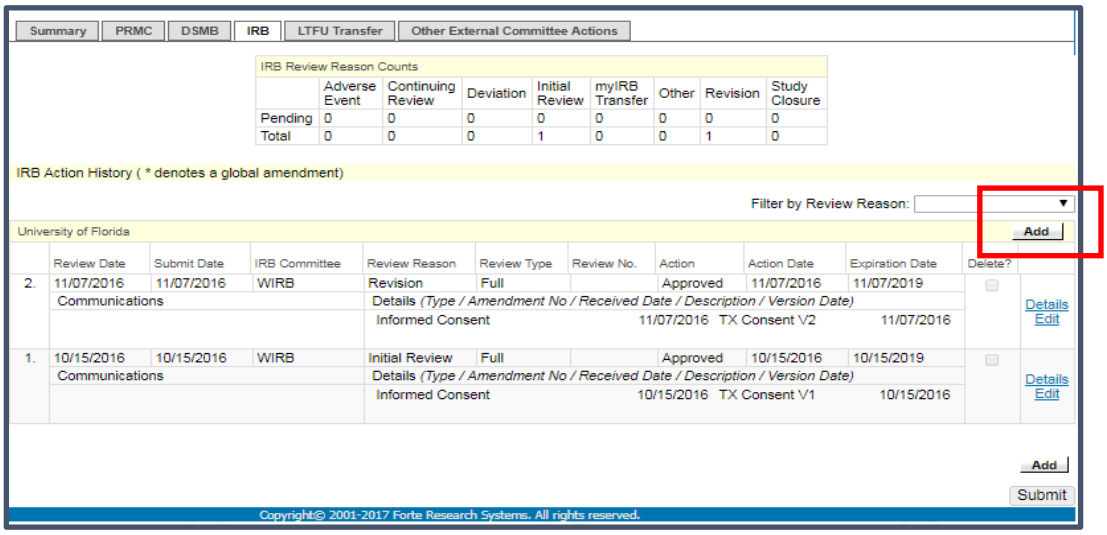
All IRB reviews and consents need to be recorded in OnCore. At UF, the approved consent forms should also be uploaded and attached to the applicable IRB review record; this makes them available for review when registering a subject to the study.

Other review documentation (e.g. IRB approval letters, Financial Language Assessments, approved advertising, subject surveys/questionnaires, etc.) can also be attached to the appropriate review record.

NOTE: It is recommended that the **IRB Coordinator** perform these tasks.

RECORDING THE REVIEW

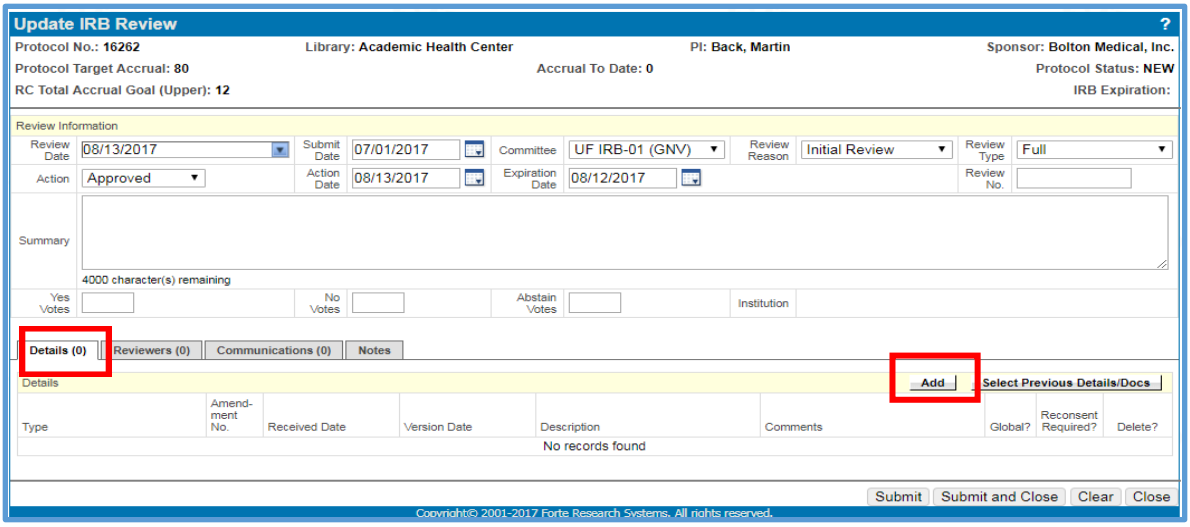
1. Navigate to **Menu > Protocols > PC Console > Reviews > IRB.**
2. Click the **[Add]** button.



3. In the **Review Date** field, type in the date of the IRB Review, using the following date format **MM/DD/YYYY** and then hit the "Tab" key.
4. Continue by entering the following required fields:
   - Submit Date
   - Committee
   - Review Reason
   - Review Type
   - Action
   - Action Date
   - Expiration Date
5. Click **[Submit].**

ADD CONSENT DETAILS AND CONSENT DOCUMENT

1. If you are not currently in the applicable IRB record, Find the IRB Review where the consents were approved.
2. Click on the little blue **Edit** hyperlink next to the applicable review line.
3. In the **Details** section at the bottom, click the **[Add]** button.

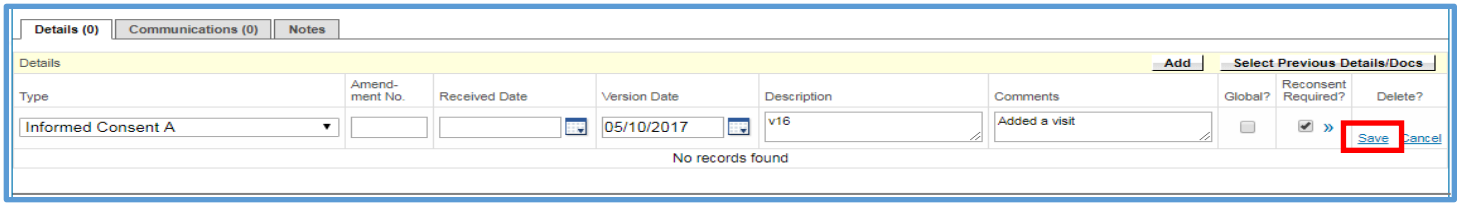


4. In the detail item row that appears, select the review item from the **Type** drop-down list (e.g. **IRB Approval Letter, Informed Consent** for a single consent, **Informed Consent A**, **Informed Consent B**, etc. for multiple consents).
5. Enter the **Version Date** of the consent.
6. Enter a **Description** for the consent (e.g. **Screening Consent**, **Treatment Consent**, etc.).

   This description is very important for protocols with more than one consent. A good description will help the consenters find the correct consent (and the correct consent version) to use later in the **Subjects** console when they are consenting subjects to this study.
7. The **Comments** field is a good place to provide additional details about the consent.
8. If this is a revised consent and the IRB has required that all subjects be reconsented, select the **[Reconsent Required]** checkbox. This will place an "RR" flag on all enrolled subjects until they have signed the new consent and the reconsent has been recorded in OnCore. For details, see the Reconsent Subjects user guide.

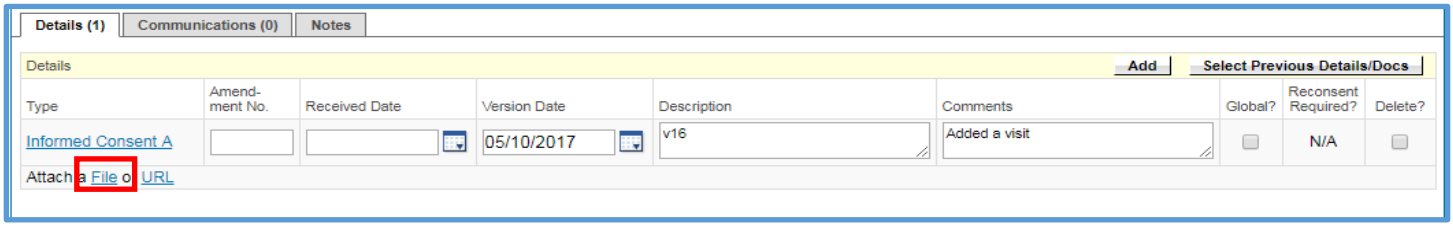
IMPORTANT: *In order to activate the OnCore reconsenting functionality, the revised consent form you add must have the exact same document "**Type**" as the original version of the consent in the initial IRB review.*

9. Click the small blue **Save** on the far right.

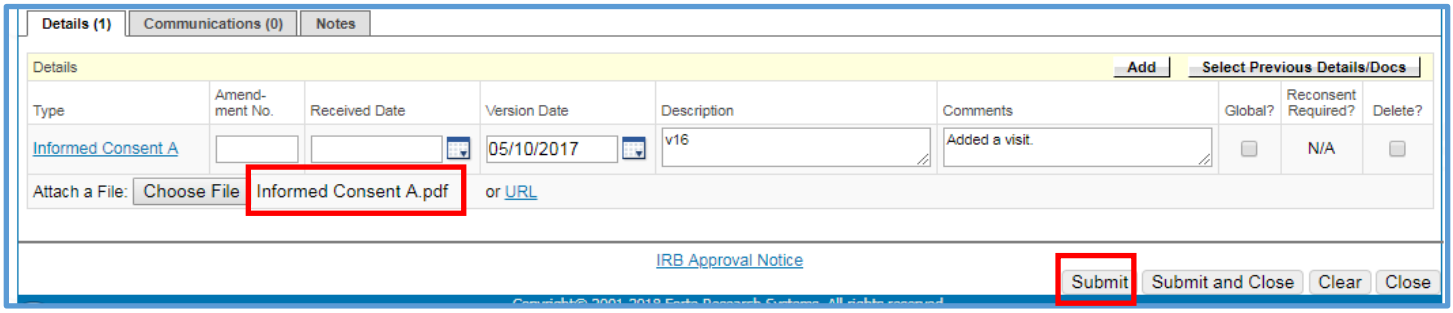


This creates a detail line that only describes the consent. **You will still need to attach the actual consent document** (*see next steps*).

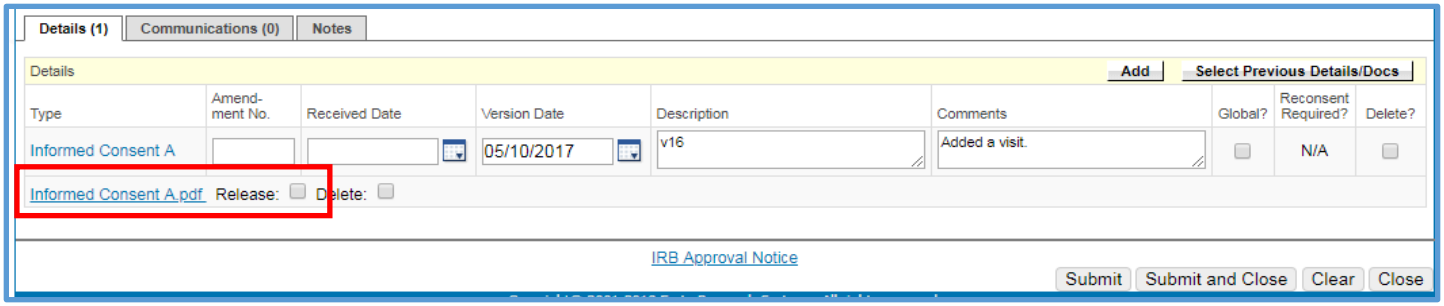
10. Under the consent detail line you just created, click the blue **File** hyperlink.



11. Click **[Browse]** or **[Choose File].**
12. Locate the consent form on your local computer or network hard drive and select it.
13. Click **[Open]** to upload the file to OnCore.
14. Confirm that you now see the consent document file name next to the **[Choose File]** button.



15. Click **[Submit]** to save this consent document to this record.
16. Confirm that you now see a **blue hyperlink** for the consent to the left of a **Release** checkbox.



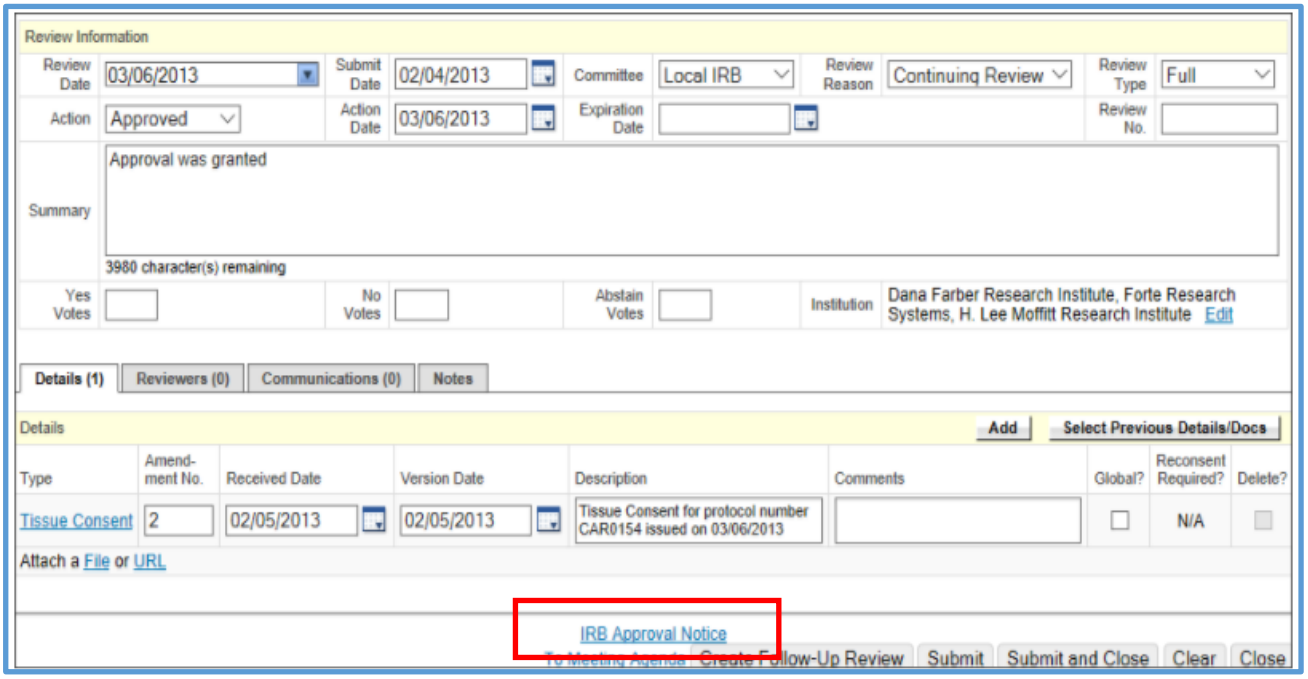
17. Select the **[Release]** checkbox.

> *If you miss selecting the **Release** checkbox, the new document will **NOT** show up in document search.*

18. Click **[Submit]**.
19. Repeat steps 1 – 18 above to add each consent (or any other document applicable to this review).

IRB APPROVAL NOTICE

If "**IRB Approval Notice**" is configured for the protocol, a **blue hyperlink** link appears at the bottom of the **Details** section after the review is saved with an **Action** of "**Approved**".



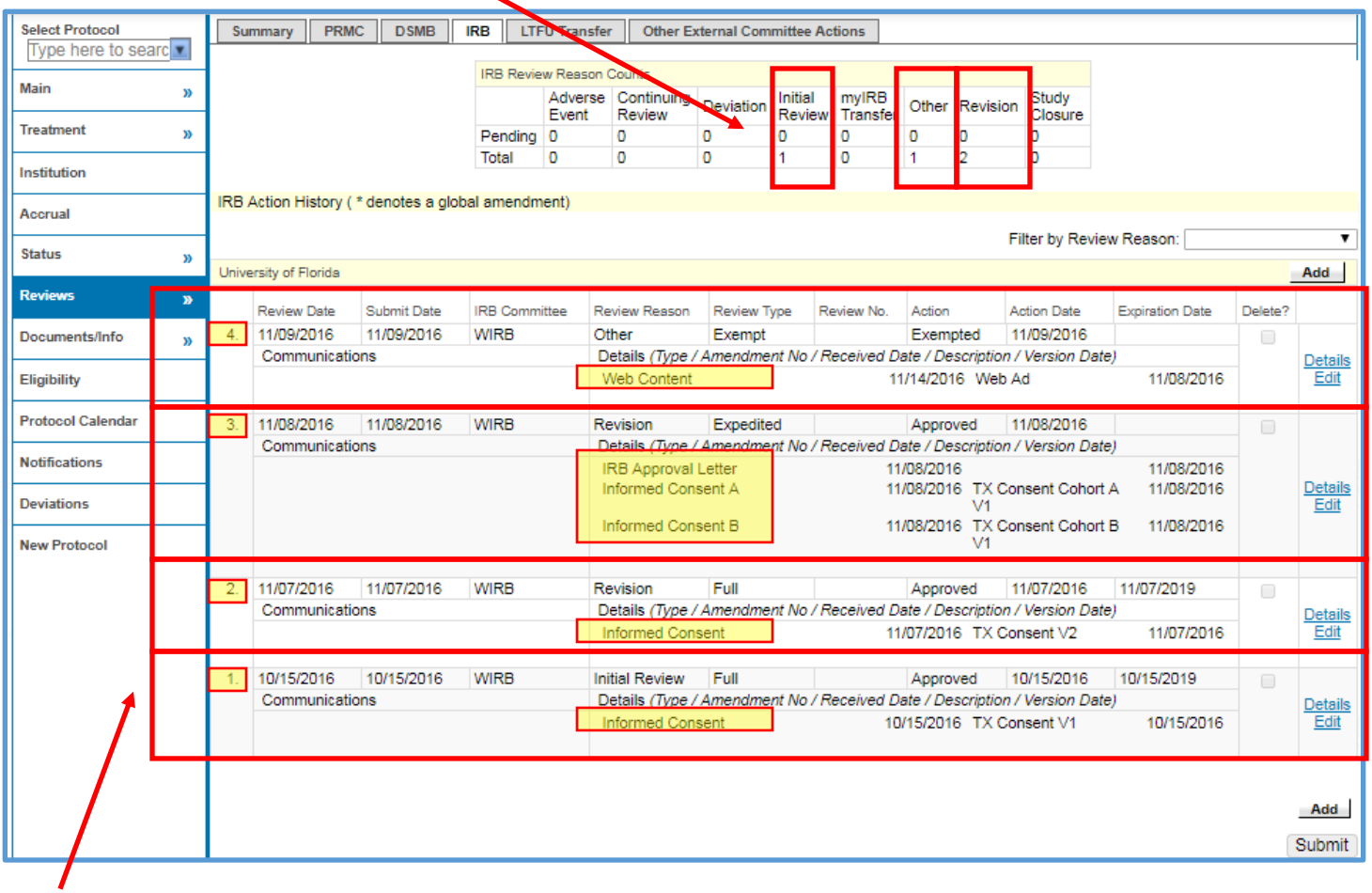
This is an optional, manual notification; clicking the link displays an **IRB Approval Notification** page, where the notification can be edited before sending. Files that have been uploaded to the review can be selected to send as attachments with the notification.

EXAMPLE OF A RECORDED IRB REVIEW

For studies that have had many reviews and/or documents, the review section can get very busy. It may take practice and exposure before you can quickly identify a review and its attached documents.

Here is an example of a study that has had four reviews, which are summarized in the IRB reason counts at the top of the page:

- One **Initial Review**
- One **Other Review**
- Two **Revision Reviews**



The list of documented reviews is displayed in reverse date order, with the first review appearing at the bottom of the page, and the most recent review always showing at the top of the history section.

Practice finding each of these reviews and the attached documents in the example above:

4. 11/09/2016 **Other Review** is the most recent review. It has a **Web Ad** document attached.
3. 11/08/2016 **Revision Review** is third from the bottom. It has an **IRB Approval Letter** and two consents attached (**TX Cohort A Version 1** and **TX Cohort B Version 1**).
2. 11/07/2016 **Revision Review** is second from the bottom. It has one consent attached (**TX Version 2**).
1. 10/15/2016 **Initial Review** is on the bottom of screen. It has one consent attached (**TX Version 1**).

Reminder: To edit a review (e.g. you need to add more documents), click on the little blue **Edit** hyperlink next to the applicable review line.

STUDY TEAM HANDOFF

OPEN THE PROTOCOL TO ACCRUAL IN ONCORE

NOTE: These instructions can also be found in the online Open a Protocol to Accrual user guide.

Follow your **internal departmental workflow** to determine the proper OnCore study staff member(s) who should open the study to accrual. **NOTE:** It is recommended that either the **Protocol Coordinator** or **Primary Study Coordinator** perform this task.

1. Navigate to **Menu >Protocols > PC Console > Status.**
2. Click the **[Open]** button.
3. In the **Status Date** field, enter the actual day the study was opened for **accrual outside of OnCore** (i.e. if this date fell prior to today's date, you must back date so that you can enter historic data on any accrued subject visits).
4. Click **[Submit]**.
5. Confirm that the protocol now has a status of **OPEN TO ACCRUAL** in the PC Console header.

ENTER SUBJECT DATA

Follow your **internal departmental workflow** to determine the proper OnCore study staff member(s) who should be entering subject data into OnCore. These tasks include:

- Register a New Subject
- Record a Subject's Consent
- Record a Subject's Eligibility
- Place a Subject On Study
- Check in Study Visits
- Re-consent Subjects

For detailed instructions for these tasks, see the **Subject Administration** section of the OnCore User Guides webpage.

NOTE: If you have a significant amount of previously accrued subject data to enter into the study, the Office of Clinical Research can help you get caught up. Please contact *OnCore-Support@ahc.ufl.edu* (copy Benjamin White benjaminwhite@ufl.edu).

POST-AWARD BILLING

Please contact OCR-Financials@ahc.ufl.edu (352) 273-8292 before you attempt to use the Post-Award financials consoles.

HOW TO GET HELP

ONCORE **WEB PAGES**

- https://clinicalresearch.ctsi.ufl.edu/oncore/
- Includes web-based **User Guides**, **Tip Sheets, Videos**, **OnCore Dictionary**, and **Support Desk Information.**

ONCORE **USER GUIDES**

- UF OnCore User Guides

ONCORE **SUPPORT DESK**

- Phone: (352) 273-5924
- Email: OnCore-Support@ahc.ufl.edu

ONCORE **ONLINE HELP DESK TICKET SYSTEM**

The UF OnCore Support webpages provide a way for UF OnCore users to easily create trackable help desk tickets for:

- Adding or Updating Staff Contacts in OnCore
- Requesting an OnCore User Account
- Other Support Requests (technical support, report requests, etc.)

ONCORE **SUPPORT CONSULTS**

The UF OnCore support staff love to work "face-to-face" with new UF OnCore users, especially when they need help with their first "real study". Our most popular consults involve showing new users how to:

- Review the protocol calendar and budget
- Enter an IRB review
- Upload approved study consents
- Open the study to accrual
- Register new subjects
- Check-in visits
- Enter visit variations and deviations

To schedule a consult, please complete an OnCore Request Form.