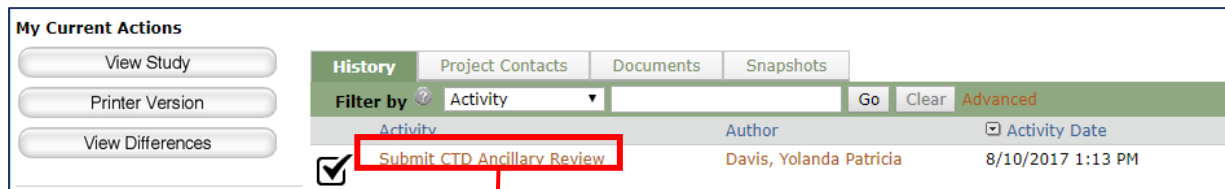


Steps to follow if you receive a letter from IRB7 saying that your ICF language requires modification

STEP 1: Login in to IRB7

1. Open an Internet Browser (Internet Explorer, Google Chrome, etc.) and type <https://eprostat.miami.edu>.
2. Click login and enter your Cane-ID and Password.
3. Navigate to the eProstat ID corresponding to the notification received.
4. Once on the **History Tab** click “CTRL + F” enter CTD Ancillary in the search bar.
5. Once the search has successfully found the CTD Ancillary Review click on the ‘Activity’



6. The CTD Ancillary Review form will open.
7. Go to item ‘9. Comments:’ this is where you will find what changes are needed to the version of the ICF indicated in item ‘7. EProstat ICF Version’.

Form:

1. * **Select the review you are submitting:**

Organization	Person	Review Type	Required
Clinical Trials Disclosure Committee (CTD)		Clinical Trials Disclosure Committee (CTD)	yes
2. * **Do you accept the proposed study?** Yes No
3. * **An NCT number is:**
Required
4. **Responsible Party:**
Investigator (UM)
5. **The following business rules apply:**
Rule 1a
6. **Informed Consent Reviewed:**
Language requires modification (corrections needed documented in comments section below)
7. **eProstat ICF Version: 2**
8. **Federally Funded Plan for Dissemination:**
 Yes
 No
9. **Comments:**
 Modify the language in the ICF to:

 "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
10. **Supporting Documents:**
There are no items to display

Documents:

STEP 2: Modifying and resubmitting ICF

1. Make the changes in your ICF as recommended by the CTD Ancillary Review Committee.
2. Upload the document to IRB7 and have the PI resubmit for review.
3. The IRB Coordinator will follow-up if needed.