Where do I find the most current approved version of the consent form?

I am working on a new modification that includes revised documents (ICF, protocol, and some recruitment and patient forms). In the old IRB system, we would attach in different places the clean and tracked versions of the forms. Are we still required to do this? If so, where does each type of form get attached?

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Why can’t I submit the New Study/Modification/Continuing Review after verifying my login credentials?

What is the difference between the Biomedical or Social Behavioral protocol templates (HRP-593 & HRP 583) and the Local Protocol Addendum form (HRP-508)? What is each one for? Do I need to fill out both?

I want to add someone to my study who doesn’t have a NetID and cannot create an eIRB+ profile. How do I do this? Where do I upload their Human Subjects Protection (CITI) training documents?

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Do I close out a study in eIRB+ with a Modification or an RNI?

I filled out the RSS when I first submitted my study in eIRB+. Why am I being prompted to complete it again, now that I’m trying to submit a Modification or Continuing Review for my approved study?

I cannot locate the original approval letters for studies that were transferred over from the old system in eIRB+. How can I access these documents?

Where do I upload the clean version and the redlined/tracked-changes version of my edited consent form?

I am trying to affiliate my CITI account with NU according to the directions that were sent via email in December 2014. But I don’t see “Northwestern University” as a choice on the CITI website. Should I choose “Northwestern Health Sciences University” as my institution?

I did my CITI training for Northwestern—here’s my completion certificate that lists “Northwestern Health Sciences University” as my institution. Why can’t you see my records?

The journal I want to publish in says I have to have an IRB. But I’m not sure if my project really requires IRB review and approval. What should I do?

We received a determination letter stating “Modifications Required to Secure Approval.” Is this a conditional approval or something else?
**Q:** Where do I find the most current approved version of the consent form?

**A:** under the “Documents” tab in the study workspace. Be sure you are in the study itself, not a follow-on submission such as a modification or continuing review.

From any page:
- Click on the “IRB” tab in the dark grey bar below the eIRB+ logo near the top of the page
- Click on the “Active” tab
- Click on the study name
- Click on the “Documents” tab
- Look in the “Category” column for “Consent Form”
- Click on the document name in the “Final” column

**Q:** I am working on a new modification that includes revised documents (ICF, protocol, and some recruitment and patient forms). In the old IRB system, we would attach in different places the clean and tracked versions of the forms. Are we still required to do this? If so, where does each type of form get attached?

**A:** Study documents can be updated in the “modification details” screens of the Modification:
- **For consent forms**, upload the tracked version (be sure to use the “track changes” function, not highlight) to the consent form page. As part of the approval process, all changes will be accepted and comments will be removed, so the approved document that is saved to the study by the IRB office will be clean (http://www.irb.northwestern.edu/process/revisions/consent-form-changes)
- **For a protocol amendment**, replace the old protocol with the new one on the basic information page. If you have a summary of changes, upload that to the supporting documents page. (http://www.irb.northwestern.edu/process/revisions/protocol-changes)
- Be sure to choose “update” instead of delete/add when you are replacing these core documents—that way, the system will be able to keep track of versions. (However, if you’re
adding a separate new substudy protocol or an additional consent form, then you would select “add”

- Recruitment materials would be added/updated on the same page as the consent form, and questionnaires go on the Supporting Documents page.

Q: Are you able to help us clarify how we should be submitting deaths & “lost to follow-up” subjects in the new system? Should we just be changing the number of enrolled or are we no longer required to report these?

A: To account for non-reportable deaths (i.e. anticipated and/or not related) un-check the box for “There has been NO other relevant information regarding this study, especially information about risks” in section 4 and attach an explanation in section 5.

Regarding subjects lost to follow-up, the eIRB+ help text defines “Those who move forward with research procedures after screening and who subsequently end participation (voluntarily or involuntarily) count as withdrawn.” So if a subject is lost to follow-up, the “NO subjects have withdrawn from the study after initial screening procedures, if any.” box in section 4 should be un-checked and supporting documentation can be attached in section 5.

Q: Why can’t I submit the New Study/Modification/Continuing Review after verifying my login credentials?

A: Most often this occurs because the RSS is not complete.

Is the RSS link noted as “Incomplete” above the study status flow diagram?
If “Complete”, please contact the IRB office 312-503-9338

If “Incomplete”:
1. Click on the RSS link number.
2. Click the “Edit RSS” button on the top, left hand side of the screen
3. Complete all of the starred questions.
   
   Note: If NMHC is not selected as a site for your study, there should be a notification highlighted in green on the NMHC page stating that the page is not required.
4. Click “Finish” button at the very bottom, right hand corner of the page
5. Return to the eIRB+ application by clicking on the IRB Submission Link number just above the “change log” table
6. You should now be able to submit the submission

**IRB staff and reviewers cannot access the RSS.** If you need further assistance with RSS questions, contact information for the RSS data owners is at the top of each RSS page:

- Operational Data page: For help with this form please send an email to: navigator@nucats.northwestern.edu. Be sure to include "RSS Operational Data Form Help" in the subject line of your email.
- NMHC page: For help with this form please contact Delores Purnell Crump at dpurnell@nm.org, or call (312) 926-1719. Be sure to include "RSS NMHC Data Form Help" in the subject line of your email.

**Q:** What is the difference between the Biomedical or Social Behavioral protocol templates (HRP-593 & HRP 583) and the Local Protocol Addendum form (HRP-508)? What is each one for? Do I need to fill out both?

**A:** The Local Protocol Addendum (HRP-508) is intended to be a supplement to sponsor-provided protocols to elaborate on how certain things will be done at the site level (i.e. details of recruitment and obtaining consent, data or file storage/security plans.) If you are writing your own protocol, you could just use 583/593 and make sure that the elements that 508 asks about are clear in your protocol—no need to fill out the second form.
Q: I want to add someone to my study who doesn’t have a NetID and cannot create an eIRB+ profile. How do I do this? Where do I upload their Human Subjects Protection (CITI) training documents?

A: External collaborators can be added to Section 2 of the study team list via a Modification. **Be sure to indicate both “Study team member information” AND “Other parts of the study” for the Modification Scope, because you will need to access the Supporting Documents page also!**

On the Study Team Members page
- Go to “2. Identify each additional external person involved in the design, conduct, or reporting of the research:”
- Click Add
- Enter the required information into the fields noted with red stars
- Click “OK”

On the Supporting Documents page
- Click “Add”
- Attach the training certificate or other approved documentation
- Select “Training Documents” for Category
- Click “OK”
Q: My new study team member has completed CITI training, why can’t I find them in the drop-down list to add them to the study?

A: CITI and eIRB+ are completely separate systems. Completing CITI training does not add someone to eIRB+.

To be eligible to be added to studies, NU/NU Affiliate staff must register with eIRB+ (instructions http://irb.northwestern.edu/eirb) and IRB Office staff will update the training section of their profile.

Researchers who completed CITI training at another institution should email a copy of their completion certificate to irbtraining@northwestern.edu and affiliate their existing CITI account with NU (instructions: http://irb.northwestern.edu/training/citi-training#other)

Q: Wait—there’s nothing in my Inbox! Where did my studies go?

A: The “My Inbox” screen only shows submissions currently needing your attention or action. To view other projects/submissions you are involved with, click on the “IRB” tab in the dark grey bar below the eIRB+ logo

On the IRB page, there will be a table of your studies and submissions, divided into tabs:
- **In-Review** – Studies the IRB has not reviewed or for which it has not communicated a decision
- **Active** – Studies approved by the IRB and currently in progress
- **New Information Reports** – Reportable New Information (RNI) submissions, possibly related to one or more studies
- **All Submissions** – all Studies, Continuing Reviews, Modifications, and Reportable New Information (RNI) that you have permissions to view
Q: I don’t understand the purpose of the Local Protocol Addendum. Why would we do anything different from what is included in the sponsor’s protocol?

A: The Local Protocol Addendum serves the purpose of letting the IRB and potentially our clinical affiliates know about NU specific nuances to the protocol. It is meant to clarify any specific needs, restrictions, processes, etc. related to the performance of the protocol here at NU. If you find yourself cutting and pasting from the protocol, you are likely adding unnecessary information.

Some examples include:

**Recruitment**
- The Industry Sponsored or Federally Funded protocol may define recruitment as including “print and electronic recruitment materials.”
- The NU site specific information could include “recruitment flyers will be placed in physician offices and emailed to potential subjects via an IRB approved subject recruitment registry.”

**Inclusion/Exclusion Criteria**
- The Industry Sponsored or Federally Funded protocol may indicate “Inclusion criteria includes individuals 16 to 86 years of age.”
- The NU site specific information may indicate “At NU we will only include subjects 18 – 86 years of age.”

**Consent Process**
- The Industry Sponsored or Federally Funded protocol may not indicate a process for enrolling/consenting subjects who do not speak English.
- The NU site specific information could outline a plan for enrolling/consenting Spanish and Russian language speakers including the use of a translator.

For sections in the Local Protocol Addendum where the Industry Sponsored or Federally Funded protocol is accurate as written, you may simply indicate “See Attached Protocol.”

Q: Do I close out a study in eIRB+ with a Modification or an RNI?
A: Neither! To close a study in eIRB+, submit a Continuing Review form.

- Click on “Create Modification/CR” on the study page

- Select “Continuing Review” on the “Modification/Continuing Review/Study Closure” page

- Select at least the first four checkboxes in Question #2 Research Milestones of the “Continuing Review/Study Closure Information” page

- Attach any supporting documents to Question #5.
  - For multi-site studies, provide supporting documentation including closeout visit documentation from the sponsor or lead site indicating that the study may now be closed and that a data lock is in place at NU.
Q. I filled out the RSS when I first submitted my study in eIRB+. Why am I being prompted to complete it again, now that I’m trying to submit a Modification or Continuing Review for my approved study?

A. New questions have been added to the RSS that must be completed for all studies. For studies with PIs who are affiliated with Feinberg School of Medicine, a page addressing Data Security is also required now. 

First check to see if the RSS link is noted as “Incomplete” above the study status flow diagram. 

If “Complete”, please contact the IRB office 312-503-9338 for assistance.

If “Incomplete”:
- Click on the RSS link number.
- Click the “Edit RSS” button on the top, left hand side of the screen
- The new questions (#13 and #16) on the Operational Data Page must be answered for all studies. If the conditions in the question do not apply to your study, answer “No.”

13. Feinberg School of Medicine faculty collecting health information on research participants are required to complete the Data Security section of the RSS and submit a documented Data Security Plan. The Plan will help guard against accidental disclosure of personal data, which could harm not only study participants but the also the University’s research efforts. The Plan will also help investigators comply with university, state and federal regulations. Data Security Plan documents (Policy, template, examples) are available at http://www.feinberg.northwestern.edu/it/standards-policies/information-security/index.html

* Is the PI a Feinberg School of Medicine faculty member collecting health information on
research participants?
☐ Yes ☐ No Clear
If you answer “Yes” to question #13, you must also complete the FSM Data Security page-- see http://www.irb.northwestern.edu/news/2015/new-data-security-questions-rss-fsm-studies

16. Participant Recruitment Policy:
   * a. Is this study required to enter participants into Study Tracker (formerly eNOTIS) per the FSM Participant Tracking Policy?
      ☐ Yes ☐ No Clear
   * b. Has this study been granted an exemption from participant entry per the FSM Participant Tracking Policy?
      ☐ Yes ☐ No Clear
   * c. Has this study been granted a pseudonym exemption per the FSM Participant Tracking Policy?
      ☐ Yes ☐ No Clear

For more information about Study Tracker (formerly eNOTIS) and the FSM Participant Tracking Policy see: http://www.nucats.northwestern.edu/resources-services/data-informatics-services/software-tools/nitro-study-tracker-formerly-enotis-faqs

- Click the “Continue” button at the bottom right hand corner of the page
- If appropriate, complete the NMHC and/or FSM Data Security page/s
- Click the “Finish” button at the very bottom, right hand corner of the page
- Return to the eIRB+ application by clicking on the IRB Submission Link number just above the “change log” table

**IRB staff and reviewers cannot access the RSS.** If you need further assistance with RSS questions, contact information for the RSS data owners is at the top of each RSS page:

**Operational Data page:** For help with this form please send an email to: navigator@nucats.northwestern.edu. Be sure to include "RSS Operational Data Form Help" in the subject line of your email.

**NMHC page:** For help with this form please contact Delores Purnell Crump at dpurnell@nm.org, or call (312) 926-1719. Be sure to include "RSS NMHC Data Form Help" in the subject line of your email.

**FSM Data Security page:** Please address all questions and requests for IT resources required (e.g., storage and storage estimates, backup storage, archiving storage, granting access to date) of the Data Security Plan to FSMHELP@northwestern.edu.

Please address all questions, request for clarification and all other forms of assistance regarding Data Security Plans to FSMIT-policy@northwestern.edu.

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Q. Where is the original IRB approval letter housed within eIRB+? For studies that were created in the new system, you can locate the approval letter in the history tab, but for studies that were transferred over from the old system I cannot locate the original approval letters in eIRB+. How can I access these documents?

A. Any submissions or approval letters processed in legacy eIRB can only be accessed in legacy.

From the main study page (make sure you’re not in the workspace for a Modification or a Continuing Review) click on the blue STU number next to “Legacy Study Link:” above the study status flow diagram.

Log into legacy eIRB with your NetID and password

The initial study approval letter can be found in the table below the study description, in the field labeled “Letter.”

Click on “view” to see the original approval letter.
For other approval letters, click on the tab for the kind of submission you are looking for (i.e. Revisions, Periodic Reviews, or Safety/Others) in the table below the red “Migrated Study” box. Click on the name of the submission for which you need the approval letter. The approval letter will be under the history tab, in an entry labelled “Correspondence Sent to Research Staff. Motion: Approved”. Click on “View Correspondence Letter” to see the approval letter.

To get back to eIRB+, go back to the main study page in legacy eIRB and click on the purple STU number in the red “Migrated Study” box.

Q. Where do I upload the clean version and the redlined/tracked-changes version of my edited consent form?

A. There is no need to upload a clean version of the modified consent form in eIRB+. Upload the tracked version (be sure to use the “track changes” function, not highlight or strikethrough) to the consent form page in your modification. As part of the process of finalizing the document and adding the approval watermark, all changes will be accepted and comments will be removed. So the approved document that is saved to the study by the IRB Office will be clean.

Q. I am trying to affiliate my CITI account with NU according to the directions that were sent via email in December 2014. But I don’t see “Northwestern University” as a choice on the CITI website. Should I choose “Northwestern Health Sciences University” as my institution?  

-OR-

Q. I did my CITI training for Northwestern—here’s my completion certificate that lists “Northwestern Health Sciences University” as my institution. Why can’t you see my records?

A. Despite the deceptively similar name, “Northwestern Health Sciences University” is not related to NU in any way. It is a chiropractic school in Minnesota. We cannot access records for other institutions, so please affiliate your CITI account with NU according to the instructions on our website (http://irb.northwestern.edu/training/citi-training#other):

1. Go to the Collaborative Institutional Training Initiative (CITI) web site (www.citiprogram.org)
2. Click on the grey “Log in via SSO” button on the right-hand side of the screen.
3. A list of institutions will appear. Click on “Northwestern University”.
4. An NU validation screen will come up. Enter your NU NetID & password.
5. As part of the account setup, you will be asked if you have an existing CITI account. Answer yes and provide the requested information.
6. Your existing account will be affiliated with NU, and you will be able to log in via SSO with your NU NetID & password going forward.

Q. The journal I want to publish in says I have to have an IRB. But I’m not sure if my project really requires IRB review and approval. What should I do?
A. If you are unsure that your project is Human Subjects Research requiring IRB review and approval – OR if you know that your project is Not Human Subjects Research but you need documentation, use the Human Research Determination Form HRP-503 found on the IRB website (http://www.irb.northwestern.edu/templates-forms-sops)

Review
• Section 1: Definitions
• Section 2: Examples of projects that are not considered Human Subjects Research

Complete
• Section 3: Description of Activity
  o Include enough detail so the IRB Office can make a determination
  o Refer to HRP-310 WORKSHEET Human Research Determination to review what the IRB Office will be looking for (http://www.irb.northwestern.edu/templates-forms-sops#worksheets)

Submit the form in eIRB+ -- Please do not email the form to the IRB
• Select “Create New Study” from your Inbox
• Upload your completed Human Research Determination Form in place of a protocol
• Complete the rest of the application
  o Sections that do not apply can be skipped unless noted with a red asterisk (*)
• Complete the RSS
  o Sections that do not apply can be skipped unless noted with a red asterisk (*)
• Submit the project in eIRB+

The NU IRB Office will review your submission according to the requirements found in HRP-310 WORKSHEET Human Research Determination

If your submission meets the requirements listed in the worksheet, you will receive an email notification of the IRB’s Not Human Research Determination.

The formal IRB determination letter can be downloaded from the main study page in eIRB+. The letter can be found in the table below the study title, in the field labeled “Letter:”

Click on the link “Correspondence_for_STU#####.pdf” to see the letter.

See http://www.irb.northwestern.edu/training/researcher-resource-library#HSRDetermination for instructions and screenshots.

Q. We received a determination letter stating “Modifications Required to Secure Approval.” Is this a conditional approval or something else?

A. A determination letter stating “Modifications Required to Secure Approval” is equivalent to the old “Pending Modifications” letters from the legacy system. The new template letters are phrased differently, but the overall categories for IRB determinations have not changed. These determinations are explained at http://www.irb.northwestern.edu/process/continuing-review/post-process

• **Approved:** This means the application has been approved by the IRB. The approval letter with links to the approved study documents, and newly stamped consent forms, when applicable, will be sent to the PI via eIRB (unless your research is conducted at the Jesse Brown VAMC, in which case the IRB Office will forward your stamped consent document to the R&D Committee—which will release it upon R&D Committee approval).

• **Modifications Required to Secure Approval:** This means that the application is approved on the condition that the PI meets specific conditions set forth by the IRB. These conditions will be sent in a letter to the PI in eIRB. The PI’s response will be reviewed by an IRB Chair or
designee to ensure that the conditions for approval have been met. If they have been met, an approval letter with links to the approved study documents, and newly stamped consent forms, when applicable, will be sent to the PI via eIRB. If the conditions are not met satisfactorily, the study will require further review at a convened meeting.

- **Deferred:** This means that the application is lacking the information the IRB requires in order to approve the study. For example, the IRB may be missing information about research risks and benefits, the adequacy of privacy and confidentiality protections, or the adequacy of the informed consent process because the research protocol provides insufficient information related to these aspects of the research. The PI will be sent a letter which explains the basis for the deferral and the information that the IRB needs to review the project. After the PI responds to the letter, the study will be sent back for review to the same IRB that originally reviewed the continuing review. If the study expires during this time, the research may not continue until the IRB reviews the research project and approves it. Once approval is granted, an approval letter with links to the approved study documents, and newly stamped consent forms, when applicable, will be sent to the PI via eIRB.

- **Disapprove:** Disapproval means that the application did not meet the criteria for approval as set forth in the regulations and the IRB cannot describe modifications that might make the research approvable. The PI will be sent a letter in eIRB which explains the basis for the disapproval. The PI will be given an opportunity to respond to the IRB. The response will be reviewed by the same IRB that disapproved the study. In rare cases, the disapproval may be overturned, and approval granted. If however, the IRB concludes that the submission should remain disapproved, the study will be closed in eIRB.