NU eIRB+ Implementation
Study Conversion Checklist for Research Personnel

This document contains an inventory of action items you will need to complete when you submit your first modification or continuing review in eIRB+. If your first submission in eIRB+ is a continuing review, we ask that you submit a combined "Modification and Continuing Review" that includes the changes requested in this document.

For general questions on your converted study data or the manual SmartForm changes required, please consult the Study Conversion Summary for Research Personnel located on the IRB website, or contact Michael Kelley at m-kelley@northwestern.edu.

For questions related to protocol template changes, please contact the IRB Office at IRBTraining@northwestern.edu.

Manual Changes Required on the eIRB+ SmartForm

Although all active studies will be converted into eIRB+, there will be a handful of manual changes you will have to make when you submit your first Modification or Continuing Review in eIRB+. An inventory of these changes is listed below. <u>We conservatively estimate that completing these changes will take 1-2 hours.</u>

#	Manual Conversion Component	Estimate for Completion	Details
1	Affiliate/External Site Details	10 minutes (if applicable)	Answer two yes/no questions related to IRB Review for External Sites in the new system.
2	Affiliate/External Site Details	10 minutes (if applicable)	Replace any "placeholder" values converted for contact information on External Sites, including Email, Name, Phone Number, and Location with the correct information.
3	Affiliate/External Site Details	5 minutes (if applicable)	Enter the "Site Type" of each External Site.
4	Affiliate/External Site Details	10 minutes (if applicable)	Upload the IRB Authorization Agreement (category: "Executed Agreements") and Site Approval Letter (category: "Approval/Authorization Letters") to the **Supporting Documents** page, if applicable.

#	Manual Conversion Component	Estimate for Completion	Details
5	Consent Form	5 minutes	Manually remove the merge field in the footer when submitting a modification to the consent form (this merge field, if left in the revised consent, will cause overlapping watermarks). Use the unmerged consent document to make this modification. *Be sure to leave the page number in the footer.* A tutorial video will be posted with instructions for this task on the IRB website.
6	Drugs/Devices Details	10 minutes (if applicable)	For studies that require an IND, IDE, or HDE, check to see if the IND/IDE/HDE Holder should be changed from "Other" to "Industry Sponsor", if appropriate.
7	Funding/Department Details	5 minutes (if applicable)	Replace placeholder values for "External Funding: Funder Not Specified (conversion)". This value represents funding sources that were either blank or could not be determined from legacy eIRB. **If the eIRB+ Funding Page includes all applicable Funding Sources, simply delete the placeholder.**
8	Funding/Department Details	5 minutes	Replace placeholder value for "Internal Funding Source: Department Not Specified (conversion)" with the Principal Investigator's Home Department.
9	Research Supplement Submission (RSS)	30 minutes	Complete the information on the Operational Data page. While we have pre-populated some information for you, please be sure you have reviewed and completed each question.
10	Research Supplement Submission (RSS)	30 minutes	Complete the information on the Northwestern Memorial HealthCare (NMHC) page. While we have pre-populated some information for you, please be sure you have reviewed and completed each question.

Protocol Template Changes

With the launch of eIRB+, the IRB office is also implementing new protocol templates for Social Behavioral and Biomedical research, as well as a "Local Protocol Addendum" template for sponsored studies. All complete protocols that use the previous template will still be valid, but action will be required for studies with incomplete or non-existent protocols, as well as for studies using a sponsor protocol.

Please assess the status of your protocol according to the set of options below, and make the requested changes at the appropriate time. A more detailed guide to help you make these changes will be available on the IRB Website.

Note: For all template changes, please note in the modification description where you have added new content not previously represented in legacy eIRB.

#	Protocol Status	Timing	Estimate for Completion	Action Item
1	Studies with complete protocol	N/A	0 min	No action. Study teams will be able to use existing protocols for the duration of their studies.
2	Sponsored studies with no Local Protocol Addendum	Continuing Review (unless a Modification changes local information)	60 min	Study teams will need to create a Local Protocol Addendum to the protocol with information compiled from legacy eIRB.
3	Studies with incomplete protocol	Continuing Review	90 min	Study teams will need to revise their protocols to include new protocol template sections with information compiled from legacy eIRB. Alternatively, study teams may choose to create a new protocol altogether.
4	Studies with no protocol	At first submission	120 min	Study teams will need to create a protocol using one of the new templates with information compiled from legacy eIRB.

Other Notes
- Study teams will be allowed to use legacy protocol and consent form templates until January 1, 2015 for all new studies. After that point, the new protocol and consent form templates will be required.
- Study teams will not be required to retrofit approved consent forms to the new consent form template.