NORTHWESTERN UNIVERSITY

NU eIRB+ Implementation
New Protocol Template Information for Research Personnel

This document contains important information about new protocol templates that have been developed in conjunction with the launch of eIRB+. The first section describes the new templates and considerations for their use. The second section includes a guide for updating your current protocol or for populating one of the new protocol templates with information from your legacy eIRB application. Please refer to the "Study Conversion Checklist for Research Personnel" regarding general expectations and timing for submission of a modified protocol in eIRB+.

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

New Protocol Templates

The IRB Office has developed three new protocol templates for use by the Northwestern University research community to describe human research activities:

- **Template Local Protocol Addendum (HRP-503)**: This document contains local information not represented in the main protocol document received from a study sponsor or non-Northwestern University research collaborator. The Local Protocol Addendum should be uploaded along with the main protocol document in eIRB+ and modified as necessary throughout the duration of the study to account for local changes to the research.

- **Social Behavioral Template Protocol (HRP-583)**: This document is intended for use primarily by those conducting social, behavioral, or educational research. If your research involves physical procedures or devices, you may need to include sections that are contained in the biomedical template protocol.

- **Biomedical Template Protocol (HRP-593)**: This document is intended for use primarily by those conducting biomedical research.

If your department has a standard protocol template it has developed to describe human research activities, you may continue to use that template for new research in lieu of one of the IRB templates. Departments are encouraged to compare departmental templates to the IRB templates mentioned above to ensure that they are asking for substantially similar content, so as to reduce requests for additional information during IRB Office pre-review.

If your department does not have a standard protocol template, you must use one of the IRB templates mentioned above for new research.

NORTHWESTERN
UNIVERSITY

Instructions for Protocol Update/Conversion

1. Compare your currently approved protocol to the protocol template that best captures your research activities. If your protocol already contains information described in each section of the new template, then your protocol is considered complete. If not, update (using Track Changes in Microsoft Word) or convert your protocol.

2. Use the guide below to populate your protocol with information from legacy eIRB as needed. Use your judgment as to whether you need to convert to using the new template. For example, if your protocol is largely incomplete, it may be more efficient for you to populate the new template rather than to modify your current protocol. Once you have finished updating or converting, create a modification in eIRB+ to submit the protocol for review.

3. In general, if updating your current protocol or converting to a new template is limited to copying and pasting already approved content and very minor editing to enhance clarity or readability, your modification will be reviewed and approved by IRB Office staff.

4. If, while updating or converting your protocol, you decide to substantially modify the currently approved content (i.e., you go beyond the basic activities described above), you must carefully describe those changes in your modification description. Although this option is available to you, your modification may be reviewed by the convened IRB (depending on the nature of your research), which may delay your updating or converting efforts.

NORTHWESTERN UNIVERSITY

IRB Template to Legacy eIRB Guide

Use the guide below for protocol update or conversion efforts described above.

Biomedical Template Protocol (by section)	**Social Behavioral Template Protocol (by section)**	**Local Protocol Addendum (by section)**	**Legacy eIRB (by page title)**
Objectives	Objectives		Project Identification Information
Background	Background		Project Identification Information
Inclusion and Exclusion Criteria	Inclusion and Exclusion Criteria	Inclusion and Exclusion Criteria	Subject/Participant Population
Study-Wide Number of Subjects	Study-Wide Number of Subjects		Subject/Participant Population
Study-Wide Recruitment Methods	Study-Wide Recruitment Methods		Subject Recruitment
Multi-Site Research	Multi-Site Research		Multi-Center Sites and Coordinating Center
Study Timelines	Study Timelines		
Study Endpoints	Study Endpoints		
Procedures Involved	Procedures Involved		Special Study Considerations and linked pages (e.g., Deception)
Data and Specimen Banking	Data and Specimen Banking	Data and Specimen Banking	Collection of Human Biological Specimens
Data and Specimen Management	Data and Specimen Management		Confidentiality
Provisions to Monitor the Data to Ensure the Safety of Subjects	Provisions to Monitor the Data to Ensure the Safety of Subjects		Risks/Benefits
Withdrawal of Subjects	Withdrawal of Subjects	Withdrawal of Subjects	

NORTHWESTERN UNIVERSITY

Biomedical Template Protocol (by section)	Social Behavioral Template Protocol (by section)	Local Protocol Addendum (by section)	Legacy eIRB (by page title)
Risks to Subjects	Risks to Subjects		Risks/Benefits
Potential Benefits to Subjects	Potential Benefits to Subjects		Risks/Benefits
Vulnerable Populations	Vulnerable Populations	Vulnerable Populations	Minors; Pregnant Women and/or Fetuses; Prisoners
Community-Based Participatory Research	Community-Based Participatory Research		
Sharing of Results with Subjects	Sharing of Results with Subjects	Sharing of Results with Subjects	Genetic Research
Setting	Setting	Setting	Subject Recruitment; Project Sites
Resources Available	Resources Available	Resources Available	Authorized Research Personnel; International Research
Prior Approvals	Prior Approvals	Prior Approvals	Special Study Considerations; Project Sites
Recruitment Methods	Recruitment Methods	Local Recruitment Methods	Subject Recruitment
Local Number of Subjects	Number of Subjects	Local Number of Subjects	Subject/Participant Population
Confidentiality		Confidentiality	Confidentiality
Provisions to Protect the Privacy Interests of Subjects	Provisions to Protect the Privacy Interests of Subjects	Provisions to Protect the Privacy Interests of Subjects	Expedited Review Criteria
Compensation for Research-Related Injury	Compensation for Research-Related Injury	Compensation for Research-Related Injury	Financial Information
Economic Burden to Subjects	Economic Burden to Subjects	Economic Burden to Subjects	Financial Information
Consent Process	Consent Process	Consent Process	Consent
Process to Document Consent in Writing	Process to Document Consent in Writing	Process to Document Consent in Writing	Consent
Drugs or Devices		Drugs or Devices	Drugs/Biologics; Devices