Quick Reference Guide to the Updated Protocol Submission Form

February 8, 2017

About

Beginning February 20, 2017, submission of new studies to the University of Notre Dame (ND) Institutional Review Board (IRB) will be done through a new form within the eProtocol system.

The new form was created to allow researchers to provide more specific information to the IRB at submission, with the goal of reducing the time it takes for a new submission to receive approval. This guide has been developed to provide users with more information about the specific changes.

Previous Form (*New study submissions prior to February 20, 2017*)

Research proposal submissions to the IRB previously used one of three different forms to submit information specific to the proposal. This process included many open text fields that allowed users to respond to questions without limitation. In addition, some areas lacked specific questions targeting information necessary for IRB review.

New Form (*New study submissions on or after February 20, 2017*)

New research submissions will use a form that has integrated all levels of review into a single form. While content remains similar in some ways to the previous form, changes have made it easier for a researcher to provide information the IRB needs to complete its review.

Table 1: Summary of Changes

	PREVIOUS FORM	NEW FORM
Submission Form	Three different forms	Single form
Level of Review	Different form selected, depending on the level of review (Exempt, Expedited, Full Board)	Level of review can be selected within the single form
Non-Human Subjects Determination	Submitted Word document to compliance@nd.edu	Submit through the single form
"Clone" Feature	Studies can be "cloned" to make new submissions	Old studies (approved before 2/20/17) cannot be "cloned" into the new form
CITI Training	User manually entered completed CITI training	CITI training automatically pulled for ND-affiliated accounts
Data Entry	Primarily free text entry	Specific selection lists added to many categories

It is important to note that most of the protocol submission process remains unchanged. Submissions are still accessed using the eProtocol system and already-approved studies can be found through searches. Users can navigate through the new form much as they did using the previous form and the general subject areas of questions are substantially similar.

Notre Dame Research Compliance (NDRC) will provide a step-by-step user guide to the updated form as soon as it is available and will also provide additional guides to help answer questions that may arise.

For more information, please see compliance.nd.edu or email compliance@nd.edu.