



ePROTOCOL
Protocol Management System

Human Subjects

Investigator User Guide

Before You Start

University of Notre Dame Network ID (NetID)

In order to access the eProtocol application you'll need a ND NetID.

Here are some tips for Success in eProtocol:

Recommended Browser

We do our best to make eProtocol compatible with the most popular browsers, including Internet Explorer, Safari, and Mozilla Firefox. However, if you do not have a strong browser preference, we recommend the following: If you are on a **Windows** machine, use **Internet Explorer**. If you are on a **Mac** machine, use **Safari**.

Allow Pop-Up Windows

Pop-up blocking software prevents the eProtocol application from opening certain windows. You'll need to make sure that your browser has all pop-up blocking software disabled while using eProtocol.

Avoid Using Browser's BACK Button

Instead, use the menus and links within the application to navigate.

SAVE Frequently

eProtocol will time out after 45 minutes of inactivity. Only actions which cause the page to refresh or reload (such as saving or navigating to a new section) are indications to the system that your session is active.

Read Instructions/Help

Many pages in the application offer instructions right on the page to help guide you and answer the most common questions.

Be Patient

Some processes can take a minute to run. Although data is loading, your browser may not indicate activity.

Sign Out When Done

Always click "Sign Out" and shut down your browser completely (close all browser windows) when you are finished using eProtocol. This will not only help keep your information secure, but will also release any edit locks you may have had on protocols, and allow your colleagues on the project to open the protocols in edit mode.

Getting Started With eProtocol

Navigate to: <https://nd.keyusa.net/userLogin.do>

Create New Protocol (also Clone, Delete, Search, and Review Approved Protocols)

1. Click on the IRB tab to create a human subjects protocol. Please note that IACUC (Institutional Animal Care U Committee) is used only for animal protocols.
2. Mouse over eProtocol options to "Create" New Protocol (or to "Clone," "Delete," "Search," "Review Non-Active Protocols," and "Review Approved Protocols")

Mouse-over "eProtocol" and "Investigator" to activate drop-down menu.

Click her to create new protocol.

Click to edit or review existing IRB protocol.

Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
11-09-026	Investigator, Principal	Resubmit the Protocol	RETURNED	Designated Reviewer Panel	
11-09-027	Investigator, Principal	Yet to Submit to IRB	NEW		

Protocol ID	Principal Investigator	Approval Date	Last Approval Date	Expiration Date	Status/Comments	Form Type
11-08-020	Investigator, Principal	09/14/2011	09/14/2011	N/A	APPROVED	NEW

3. To edit or view an existing protocol.

IACUC **IRB**

Protocols (In Preparation / Submitted) ⌵

NEW ⌵

Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
11-09-021	Investigator, Principal	Yet to Submit to IRB	NEW		
11-08-020	Investigator, Principal	SUBMITTED TO IRB	SUBMITTED		

AMENDMENT ⌵
Currently there are no Amendment protocols.

CONTINUING REVIEW ⌵
Currently there are no Continuing Review protocols.


UNANTICIPATED PROBLEM REPORT (UPIRSO/UAE) ⌵
Currently there are no Unanticipated Problem Report (UPIRSO/UAE) forms.

REPORT OF NON COMPLIANCE ⌵
Currently there are no Report Of Non Compliance forms.

FINAL REPORT ⌵
Currently there are no Final Report forms.

Approved Protocols ⌵
Currently there are no Approved Protocols.

Non Active Protocols ⌵
Currently there are no Non Active Protocols.



4. Principal Investigator (PI) information. Personnel information associated with the University of Notre Dame researchers will automatically populate the form. You can edit this information if necessary (e.g., add degree or update phone number).

IRB - Exempt Research Protocol ID: 11-09-021 (Investigator, Principal) Protocol Title: test

Next → Help ? Close X

Principal Investigator *

Name	Degree (MD/PhD/MS)	Title
Investigator, Principal		Principal Investigator
E-mail *	Primary Phone Number	
Golrish@nd.edu	(574) 631-0000	
Center and Institute Affiliations	Fax	
Institute for Church Life	(574) 631-0000	
Alternate e-mail address for PI	Provide mailing address for PI	

Indicate current Investigator training.

completed the mandatory human subjects training through [CITI?](#)

Undergraduate Student

Postdoctoral fellow

Faculty Advisor

Name	Degree (MD/PhD/MS)	Title
E-mail *	Primary Phone Number	Alternate Phone
Center and Institute Affiliations	Fax	
Alternate e-mail address for Faculty Advisor	Provide	

Indicate current Sponsor training.

Has the Faculty Advisor completed the mandatory human subjects training through [CITI?](#)

Are you?

Faculty

Staff

Undergraduate Student

Graduate Student

Postdoctoral fellow

Other:



Identify center, institute, or program affiliation.

Each label corresponds to a section of the protocol.

Check here if you have completed CITI training. Click the link to go to the CITI website. All researchers are required to complete the CITI certification.

All students are required to have a faculty advisor, and faculty advisors are required to sign-off on students' protocols.

5. Primary Subject Pool Population Checklist. This form is for listing the types of subjects involved in your study.

IRB - Exempt Research
Protocol Title: test
Protocol ID: 11-09-021 (Investigator, Principal)

Previous Next

Help Close

Primary Subject Pool Population(s) Checklist

Select All That Apply:

- College students (i.e., University of Notre Dame, St. Mary's College)
- Community research (i.e., local organizations)
- Individuals within organizations (i.e., NGOs, military)
- Individuals residing in a foreign country
- International population
- Internet based research
- Patients (i.e., Epworth Center, Oaklawn, Memorial Hospital)
- Students - Secondary + Elementary (need Letter Approval)
- Other, please indicate in the text box

Previous Next

6. On the Funding screen, indicate if the research is funded and the source of funding.

IRB - Exempt Research
Protocol Title: test
Protocol ID: 11-09-021 (Investigator, Principal)

Previous Next

Spell Check Help Save Close

Funding Administration

Is it funded? Yes No

If Yes, by whom?

Personnel Information
Subject Population
Funding
Protocol Information
Attestation
Check For Completeness
Submit Form
Print View
Event History

7. You must now select the Expedited Review Criteria that is appropriate for your protocol. Leaving the expedited criteria blank indicates that protocol must be reviewed by full IRB Committee.

IRB - Exempt Research
Protocol Title: test

9-021 (Investigator, Principal)

Previous Next

Close

Review type selection

Purpose, Study Procedures, Background

Add Attachments

Exempt Paragraph(s)

1-3

4

Personnel Information

Subject Population

Funding

Protocol Information

Attestation

Print View

Event History

Please Read Carefully Before Answering the Questions

Applicability:

If you are requesting Exempt Status, your research activities must:

- Present no more than minimal risk (Minimal risk means that the risks or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or tests; and
- Involve only procedures listed in one or more of the Exempt Research Categories listed below. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for exemption when the specific circumstances of the proposed research involve no more than minimal risk to human subjects
- Not involve prisoners as participants
- Not be subject to FDA regulations except in accordance with 45 CFR 46.101(b)(6).
- Not involve children under category 2(b) UNLESS research involves observations of public behavior AND the investigators do not participate in the activities being observed

The categories in this list apply regardless of the age of subjects, except as noted.

Please indicate which of the following categories are applicable to your research (within some categories, additional information must be provided).

1. Educational Research 45CFR46.101(b)(1) - This research will be conducted in an established or commonly accepted educational setting, involving normal educational practices, such as: (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
AND (All of the following must be true, please read and enter a check mark for each):
(These statements must also be applicable to the research using this category)

- This research is minimal risk. AND
- This research does not involve prisoners as participants. AND
- This research is not FDA regulated human research

Complete each section of the protocol. Click "previous" or "next" will save your work.

8. This screen is for entering the details of the study and research design.

IRB - Exempt Research
Protocol ID: 11-09-021 (Investigator, Principal)
Protocol Title: test

Previous Next
Spell Check Help Save Close

Exempt Paragraph(s) 1-3 4

Personal Information
Subject Population
Funding
Protocol Information
Attestation
Check For Completeness
Submit Form
Print View
Event History

Study Title

Please do not leave any required sections blank. Specify N/A as appropriate.

1. Purpose and Objectives - List the purpose and objectives: insert purpose, objectives and research questions/hypotheses here.

2. Background - Describe past experimental and/or clinical findings leading to the formulation of your study. Critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. Ensure background includes references.

3. Research Plan/Description of the research methods

3.a. Provide a comprehensive narrative describing the research methods.

3.b. Describe the plan for data analysis.

4. Attestation

Previous Next

1. Enter (or copy/paste) purpose, objectives, research questions, and hypotheses here.

2. Enter (or copy/paste) literature review and previous results here.

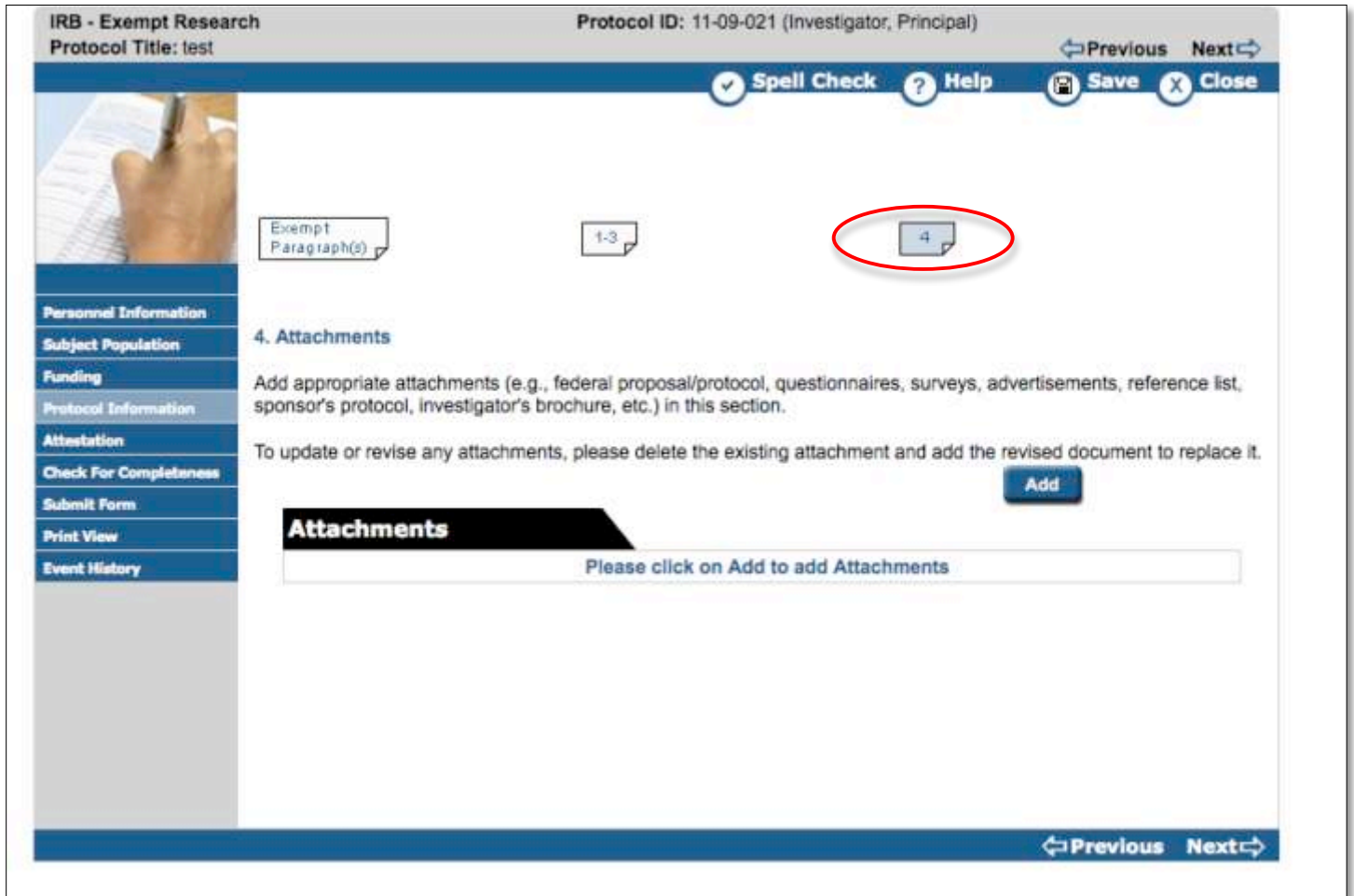
3. Enter (or copy/paste) a detailed description of plans for collecting data.

4. Enter (or copy/paste) plans for analyzing data, data security, and

After each field is completed proceed to the next screen, "Attestation."

9. The last section to complete before signing the obligation is the attachment section. This is where you attach all supplemental material for your research. These could include: Flyers, Collaborating Investigator's IRB approval and approved documents; Conflict of Interest information; Survey instrument and Questionnaires; Interview/Focus Group Questions; Letters of Agreement/Cooperation from organizations who will help with recruitment; HIPAA Authorization or Waiver Form from HIPAA-covered entity; and other files associated with protocol.

Most standard files can be uploaded (.xls, .pdf, .jpg, .tif, etc.).



10. The next screen, "Attestation," (NOT SHOWN) reminds researchers of their ethical responsibilities, federal guidelines, and University of Notre Dame's policies regarding research. It also utilizes a check box as the researcher's electronic signature.

Once the form is complete, submit the protocol by clicking on Submit Form in the blue side panel menu. A pop-up will appear asking if you want to submit. Click on YES.

11. Click on the Check for Completeness left-hand menu option when you believe you have finished entering all of the necessary information. The system will then check to make sure that all of the sections in the protocol application have been completed.

Note: The check for completeness feature cannot check to see if all of the necessary supporting documents have been attached. Be sure to double-check that this has been done before you submit the protocol.

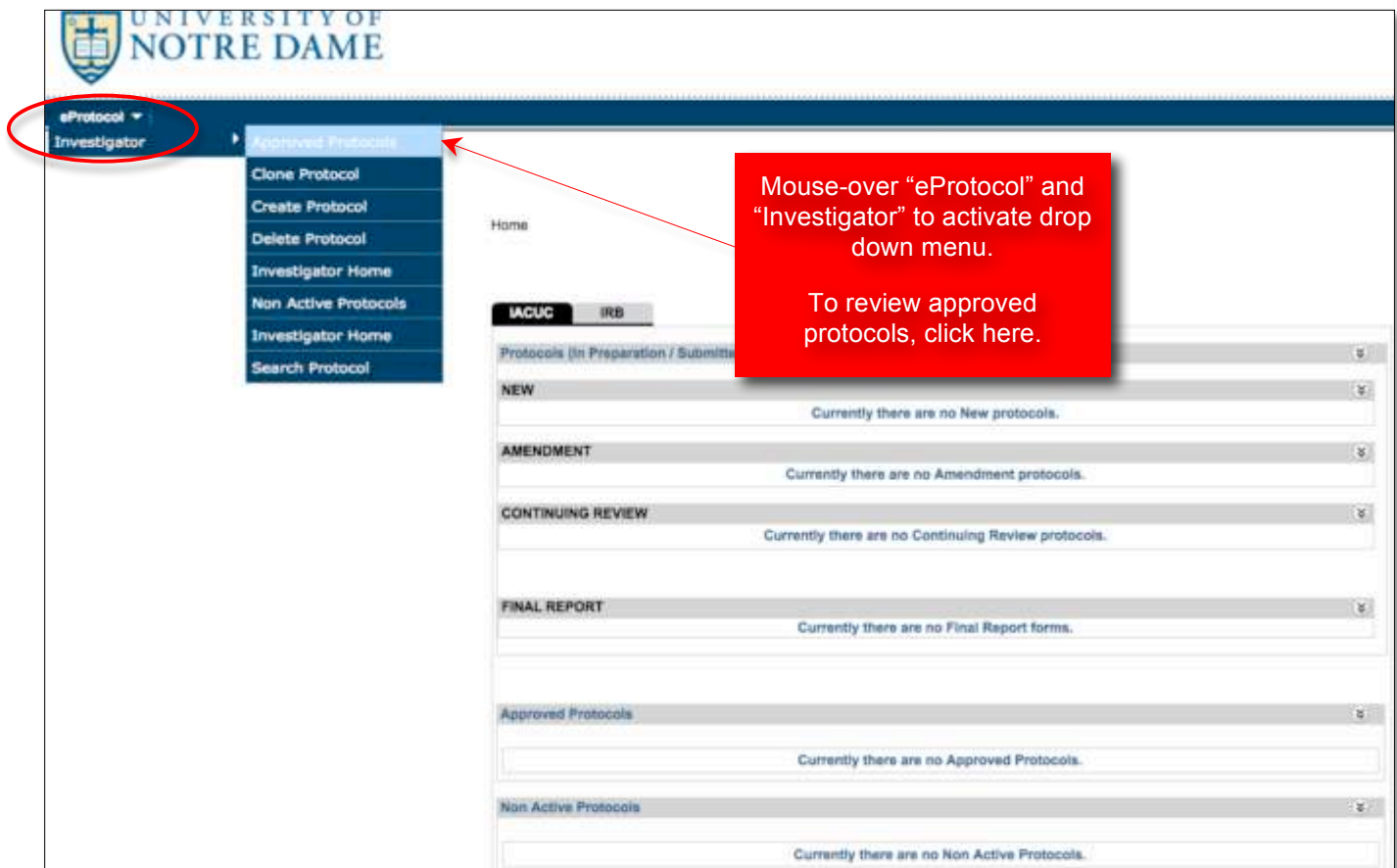
A. If any section is incomplete, the protocol will not be submitted and another pop-up will appear including a link to the incomplete section. You will need to click on the link to add the missing information, and repeat steps 6-8.

B. If the protocol application is complete, a message will appear on your Investigator Homepage thanking you for the submission and the Protocol Event will change to read "SUBMITTED TO IRB."

Once your protocol has been accepted, it will be assigned to the IRB for review, either exempt, expedited, or full committee review. You will receive an email for each major event in the review process. You can also see the status by looking at the protocol listing on your HOME page in the eProtocol application.

Approved Protocol Applications

Once the protocol is officially approved in the system, it will no longer appear on the top of your home page in the Protocols (**in Preparation/Submitted**) section, but will be visible in the **Protocols (Active)** section. To see the listing of your approved protocols, you will need to click the arrow on the right-hand side of the **Protocols (Active)** section header bar, to expand this section.



IRB Approval Letter

You will receive an email notification when your protocol application is approved with instructions on how to access the approval letter on-line.

The screenshot shows the IRB - Exempt Research interface. At the top, it displays "Protocol ID: 11-08-020 (Investigator, Principal)" and "Protocol Title: Testing Protocol (1)". A navigation bar includes "Help" and "Close" buttons. On the left, a sidebar menu lists options: Personnel Information, Subject Population, Funding, Protocol Information, Attestation, Print View, and Event History. The main content area features an "Event History" table with the following data:

Date	Status	View Attachments	Letters
08/30/2011	PROTOCOL CREATED		
08/30/2011	SUBMITTED		
09/13/2011	PANEL ASSIGNED		
09/14/2011	APPROVED		Approval Letter

Two red callout boxes provide instructions: one points to the "Event History" menu item, and the other points to the "Approval Letter" link in the table.

Re-Submitting the Protocol Form (responding to IRB information requests)

If you receive an email that your protocol was returned, check the IRB Return Notes section to see why. The IRB may ask for more information, updates, or clarifications. When you complete the necessary adjustments to the protocol, you will need to re-submit the protocol, by again clicking the SUBMIT PROTOCOL option in the left-hand menu.

The screenshot shows the IRB system interface with the following components:

- Navigation tabs: IACUC, IRB (selected)
- Buttons: Create Protocol, Clone Protocol, Delete Protocol
- Section: Protocols (In Preparation / Submitted)
- Section: NEW
- Table with columns: Protocol ID, Principal Investigator, Protocol Event, Status/Comments, Panel, Meeting Date
- Table Row 1: 11-09-026, Investigator, Principal, [Resubmit the Protocol](#), RETURNED, Designated Reviewer Panel, (empty)
- Section: AMENDMENT (Currently there are no Amendment protocols)
- Section: CONTINUING REVIEW (Currently there are no Continuing Review protocols)
- Section: UNANTICIPATED PROBLEM REPORT (UPIRSO/UAE) (Currently there are no Unanticipated Problem Report (UPIRSO/UAE) forms.)
- Section: REPORT OF NON COMPLIANCE

A red callout box points to the 'Resubmit the Protocol' link with the following text:

Notification of a returned protocol. The IRB may require more information.
Click here to return to the investigator page.

IRB - Exempt Research Protocol ID: 11-09-026 (Investigator, Principal)
 Protocol Title: How To Use eProtocol? Next →

Spell Check
 Help
 Save
 Close

Principal Investigator *

- Personnel Information
- Subject Population
- Funding
- Protocol Information
- Attestation
- Return Notes**
- Check For Completeness
- Submit Form
- Print View
- Event History
- Email History

Name	Degree (MD/PhD/MS)	Title
Investigator, Principal		Principal Investigator
E-mail *	Primary Phone Number	Alternate Phone
	(574) 631-1389	
Center and Institute Affiliations	Fax	
Institute for Church Life	(574) 631-1389	
Alternate e-mail address for PI	Alternate e-mail address for PI	
Indicate current Investigator training.		
<input checked="" type="checkbox"/> Has the PI completed the mandatory human subjects training through CITI?		
Are you?		
<input type="checkbox"/> Faculty	Select One	<input checked="" type="checkbox"/> Staff

Click Return Notes to review the requested information.

On the return notes screen, the PI can review the requested information. To respond to the IRB requests, the PI will simply edit the existing protocol and resubmit it following the process outlined above.

Protocol ID: 11-09-026 (Investigator, Principal) OK

Return Notes

Return Note	Added By	Date Added
This protocol needs an update consent form. Please resubmit.	Alexander, Nakesha (Manager)	09/27/2011

Making Modifications to Approved Protocols

If you would like to make changes to a protocol that has already been approved, you will need to submit a Modification (revision) and wait for IRB approval before implementing the change. Expand your Protocols (Active) section. Click on the link for the protocol that you would like to modify.

Once you select Start Modification (Revision) and click OK, a new window will open. This is your Modification Application Form. It is a “clone” of your most recently approved protocol, with an additional section in the front, the Modification Form. Make the necessary changes to the appropriate sections of the protocol and click submit when complete.

Continuing Review

Federal regulations require an IRB to conduct continuing review at least annually. You will need to submit a Continuing Review (Renewal) application approximately 1-2 months prior to the expiration date of your protocol to allow time for processing and review.

A Continuing Review (Renewal) is started/submitted in the same manner as a Modification described above. However, in place of the Modification Form section, there will be a Continuing Review Form section that you will need to complete.