

MENTOR IRB User Guidelines

Axiom's Mentor IRB was built by clinical researchers, Mentor is designed to deliver an intuitive and responsive interface that is easy to use and streamlines management of review, approval and post approval reporting. This software is the IRB web-based application adopted by Tribal Nations Research Group. This IRB software tracking system will enable the IRB to better serve the Tribal Nations Research Group-IRB. It is completely online and will allow the IRB to manage the review process from investigator submission to continuing reviews to amendments to publications to close-outs. We have custom-made Mentor IRB to fit the needs of the researchers that are associated with Tribal Nations Research Group. Starting in September 2017, all researchers, will be required to submit their IRB applications via Mentor IRB.

This document was designed to provide you with the basic instructions you will need to access and navigate Mentor IRB. Specific information is included that will help you create and submit your IRB application. Email notifications generated by Mentor IRB will allow you to track your submission. If you have any questions about accessing Mentor IRB or submitting your IRB application, please contact Erin Garrison, Research Liaison at 701-477-5526 or email erin@tnrg.org. If your questions pertain to ethical issues, please contact, Anita Frederick, President of Tribal Nations Research Group at 701-477-5526 or email neeta_frederick@hotmail.com or tribalnationstnrg@gmail.com

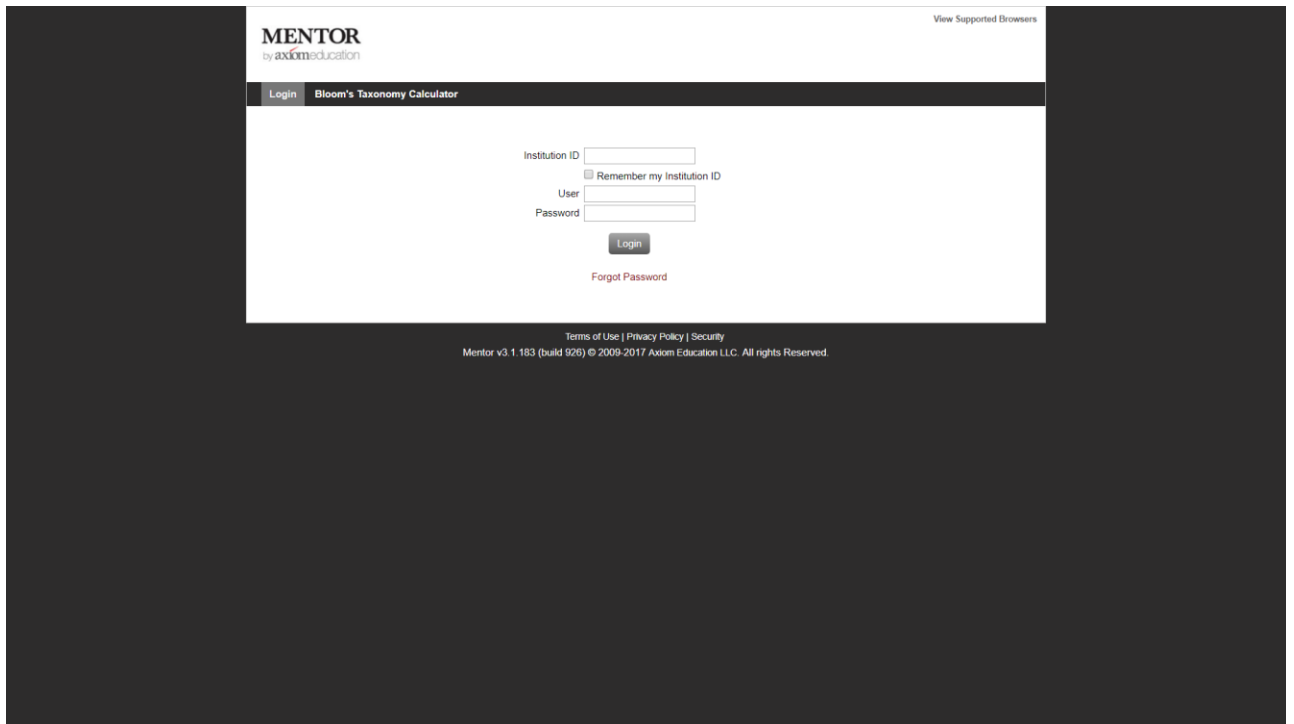
Mentor IRB can be accessed at any time and from anywhere in the world at <https://www.axiommentor.com/login/axlogin.cfm>

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Login

Go to <https://www.axiommentor.com/login/axlogin.cfm>



MENTOR
by axiomeducation

View Supported Browsers

Login Bloom's Taxonomy Calculator

Institution ID

Remember my Institution ID

User

Password

Login

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- You will be directed to **Axiom Mentor Login**
- Enter the **Institution ID**, TMBCI, then your **Username** (your email) and **Password**
- Click on **Login**
- You will be directed to **Mentor IRB Info Page**

Upon accessing the site you will first be directed to the IRB **Info Page**. On this page you will find several documents and forms specific to the TMBCI/TNRG IRB submission process.

Mentor IRB Info Page

General Guidelines for submitting a new protocol, TMCBI Research Protection Act, documents on the Ethics of Research, Frequently asked questions, amendment/modifications, annual report/continuing review, adverse events, templates, waiver on modifications of informed consent, and certificates of confidentiality are also found on this page. In addition, **Federal Regulations** to determine exempt, expedited and full board research review are provided.

On the top left hand side of the **Info Page** you will see several tabs:

- **Documentation:** Several resource documents are available to help you prepare your IRB application. All forms including Applications forms/TMBCI IRB, Federal Policies and Regulations/Miscellaneous Items, Historical documents, Informed Consent Documents, Meetings, OHRB Items, TMBCI IRB Policies/Regulations, and NIH Protecting Human Research Subjects Tutorials can be accessed via this tab.
- **My Protocols:** Submit and manage your protocols.
- **Protocol Reports:**
- **Research Coordinators:**
- **Reviewer:**
- **PI Documentation:** This tab allows you to upload the Completion Report (certificate) indicating that you have completed CITI training. If you did not save a copy of your certification, go to www.citiprogram.org and upload it through the PI Documentation. You will be required to renew your certification every three years. Mentor IRB will notify you one month prior to your renewal date. However, if you are submitting an IRB application prior to the above date and have not yet completed CITI training, you will need to include (copy/paste) your NIH certificate at the end of your Protocol Summary Form.
- **Meetings:** This tab will give you information about past and future meetings.
- **IRB Members:** This tab will show a list of the IRB Members with their title that they hold on the TNRG IRB.

Procedure for Submitting a Protocol

The following steps below will help you create a protocol. Throughout the procedure instructions, there are side notes that are typed up for your benefit so that you don't make a mistake in the process as it isn't possible to correct or fix some mistakes in Mentor Software and side notes are always bolded. Please do read them and take your time as haste makes waste! **Side note: DO NOT** click "Submit Protocol for Review" tab until you are ready to submit your Protocol to the IRB! In the event you accidentally submit a protocol, it is there forever in the system, and there is no way to make changes other than submitting a protocol amendment or creating another protocol.

1. When you log in, you will see the following headings to the top left part of your web page:

Home Institutional Tools IRB Docs

2. Click on the heading **IRB**, and it will bring you to the Info Page.

3. Looking to the left, you see a number of tabs labeled in the following order:



Info Page



Documentation



My Protocols



Protocols Reports



Research Coordinators



Reviewer



PI Documentation



Meetings



IRB Members

4. Click on the tab labeled **My Protocols** and it will bring to the page titled My Protocols.

5. Located above the heading My Protocols is a tab titled: **"Create New Protocol"**, click the tab. The tab resembles something like this:


Create New Protocol

6. It will open a popup web page titled "Create IRB Protocol". When it opens up, fill in the required information that pertains to your research project. Anything with a red Asterisk * is required to create the protocol.

7. If you are a student you will be asked to include the name of your faculty advisor who will serve as co-PI on the protocol. You will receive a message if Mentor IRB is unable to find/create an account for the selected faculty advisor in which case you will need to contact Ashley Parisien (Tribalnationstnrg@gmail.com) and she will assist you in getting your faculty advisor into Mentor so you can proceed with your IRB submission.

8. Make sure to use the pull down menu to indicate on this form the appropriate Review Type category (full review, expedited review, exemption). The IRB will make the final judgment on the

eligibility of your protocol for these categories, but it is helpful to have the investigator make an initial choice.

Review Type 

* Based on Please choose the option that you think best fits your project:

- 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office; or
 - (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- 5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures; or
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- 6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- Once you click on the appropriate **Review Type**, you will need to select one of the options that best describes your study and complete several additional questions specific to your proposal.
- If you need help in determining the review type, please refer to the **Definitions on the Info Page**.
- There are a set of questions pertaining to HIPAA. Regardless of whether or not your research proposal falls under HIPAA, you will need to answer these questions.
- If HIPAA review is required, then complete and attach all five forms for review. These forms can be found under **IRB Documents** in the HIPAA folder.

9. When you are finished filling in your information and ready to create the protocol, click the **“Save”** tab at the bottom. Once you clicked the save tab, it will bring you back to the My Protocols page. **Side Note:** Your protocol that you just created may not immediately appear. It should appear within 3-6 seconds. If it doesn't appear within that time, refresh your webpage and you will see your protocol near the bottom and it will resemble something like this:

IRB # ^	Title	PI	Status	Approved A.R. Due
9	TMBCI Health Priorities	Anita Frederick	New - Full Review	

Page 1 of 1 [First](#) [Prev](#) [Next](#) [Last](#)

10. Next, click on the name your protocol and it will bring you to your protocol page.

11. If you need to attach additional documents or provide additional documentation as part of your protocol such as the consent form, another IRB application, or survey instruments click on the tab titled **“Upload Docs”** and attach any additional documents as needed. **Side Note:** When you attach additional documentation, it may not immediately appear. It should appear within 3-6 seconds after clicking save. Upload Docs will resemble something like this:

Upload Docs

12. To fill out the rest of the application process, locate the Green Arrow with words titled **“Application Sections”** and click on it. It will resemble something like this:

➔ Application Sections

13. It will bring to the Application Sections, and fill out each section as it pertains to your research project. When finished filling out a question within a section, click save to move onto the next question. **Side Note:** When you are finished filling out each section, you will get a popup section giving you two options. Click on **“Review Answers before Submitting”** tab and it will give you the option to review and change your answer if needed. In the event you clicked on the submit survey tab, it will not give you the option to change your answers in that section. Afterward, move on to the next section. It may resemble something like this below:

Question

Submitting your Survey will prevent you from making any further changes to your answers.
How do you wish to proceed?

Submit Survey

Review Answers Before Submitting

13. When you are finished filling out the Application Sections, you may want to review your work and make changes as needed. To review information back on the Protocol page click on the word titled **“View Protocol Page”** located at the top of the page and to the right. It will resemble this:

[View Protocol Page](#)

14. When you are ready to submit your protocol, click the tab titled **“Submit Protocol for Review”** located on the view protocol page and it will resemble something like this:

Submit Protocol for Review

HIPAA:

Does your research involve the collection, use, and/or dissemination of health (either physical health or mental health) data?

- Options:** 1. Yes (If Yes, proceed to next question)
 2. No (HIPAA forms do not need to be included in your protocol)


Is the data from a healthcare provider (hospitals, doctors' offices, health departments, and many others who transmit patient health information electronically), clearinghouse, and/or healthcare plan?

- Options:** 1. Yes (If Yes, proceed to next question)
 2. No (HIPAA forms do not need to be included in your protocol)

Does the healthcare provider, clearinghouse and/or healthcare plan do one or more of the following transactions using electronic media:

(Transaction means the exchange of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information exchanges):

1. Health care claims or equivalent encounter information (insurance forms).
2. Health care payment and remittance advice (patient bills).
3. Coordination of benefits.
4. Health care claim status.
5. Enrollment and disenrollment in a health plan (selecting health insurance).
6. Eligibility for a health plan.
7. Health plan premium payments.
8. Referral certification and authorization.
9. First report of injury.
10. Health claims attachments.
11. Other transactions that the Secretary may prescribe by regulation.

- Options:** 1. Yes (Complete HIPAA forms and attach to protocol after submission of this form) 
 2. No (HIPAA forms do not need to be included in your protocol)

- At the bottom of this form, you will find an **Upload Protocol** field. Click the **Browse** button and locate your completed IRB **Protocol Summary Form** on your computer.
- Double click the file to select it. Repeat this process to upload your Consent Form (s). If you need to upload additional documents, you will need to first click on **Save**. Then scroll to the top of the menu bar and click on **Upload Documents**. Use the file upload on the **Drop-Down** menu box to upload any additional documents. You must click **Save** for final protocol submission.
- At the end of the form, you will see a text box. If you would like to send a **Message to IRB Chair**, then use this text box to write your message.

In order to upload additional documents, such as recruitment flyers, survey instruments, HIPAA documents, etc., you must first click on "save". Then scroll to the top of the menu bar and click on "Upload Documents". Use the file upload on the Drop-Down box to upload any additional documents. You must then "save" your final protocol for submission.



- Once you have completed all fields and uploaded your IRB proposal and any other pertinent documents, Click **Save** at the bottom to submit your information and IRB proposal.
- After you submit a new protocol, Mentor IRB will automatically notify the IRB via email of the new submission. An IRB Representative from your School/College will review your protocol and accept it as is or request revisions. Once the IRB Representative accepts your protocol, the IRB Chair will be notified via Mentor IRB. The IRB Chair will send you notification of the IRB's action once final review has been completed.

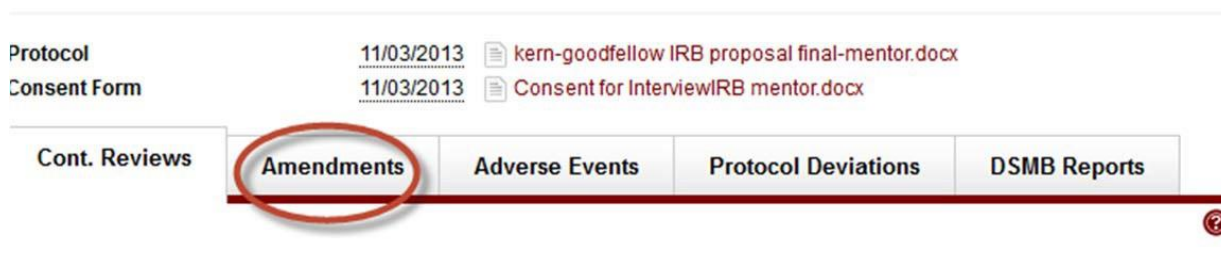
IRB Review Process

- If you are a student researcher submitting a new protocol, your advisor will receive an email notification **via Mentor IRB**. Your advisor (**see Advisor Guidelines**) will need to log on to Mentor IRB and then accept your protocol.
- Once your advisor accepts your protocol, an email notification will be sent to one of the IRB representatives from your School or the College.
- Regardless of whether you are a student or faculty, one of the IRB representatives from your School or the College will be automatically assigned by Mentor IRB to review your IRB submission. Exempt and Expedited reviews require only one reviewer. If your protocol requires a Full Board review, then a second reviewer will be automatically assigned via Mentor IRB to review your protocol.
- Your IRB representative will review your protocol and send you an email via Mentor IRB indicating revisions are needed or will approve your protocol in which case an email notification will be sent to the IRB Chair for final review.
- The IRB Chair will review your protocol and send you an email via Mentor IRB indicating the specific revisions needed or send you an approval letter with attached consent form(s) and recruitment flyer if applicable.

- ❑ All consent forms and flyers will be stamped with Duquesne University Approval and include an expiration date if your protocol required an Expedited or Full Board Review. Exempt reviews do not require an expiration date.
- ❑ Researchers cannot begin recruitment activities or data collection until the approval letter and stamped documents are received.

How to Submit an Amendment


- Any changes to existing protocols should first be reviewed by the IRB as they may impact the risk/benefit ratio of the protocol.
- To submit an amendment, complete the **Amendment Submission Form** that can be accessed via the **Info Page** or via **IRB Documents**.
- Then, click on the **My Protocols** tab. You will see the title of the Protocol you propose to amend. Click on the title and then scroll down to the set of tabs at the bottom of the page.



- ❑ Click on **Amendments** and upload the completed **Amendment Submission Form**.
- ❑ Please include all necessary documents in the **Amendment Submission Form**. For example, if your amendment includes modification of the consent form or recruitment flyer then include those documents with the completed form.
- ❑ The IRB Chair will review the amendment and send you an email via IRB Mentor indicating that additional information is needed or send you an approval letter with attached consent form (s) and recruitment flyer if applicable.
- ❑ All consent forms and flyers will be stamped with Duquesne University Approval and include the original expiration date if applicable.
- ❑ Researchers cannot implement the proposed changes to your original protocol until the approval letter and stamped documents are received.
- ❑ Please note that if your original protocol required a full board review, it may be that your amendment will need to be reviewed at the next full board meeting.

How to Submit a Report for Continuing Review or Termination of Study

- ❓ Continuing reviews on an annual basis are not required of Exempt protocols but researchers are required to submit an **Annual Report/Renewal Form** for all protocols approved by Expedited or Full Board review procedures.
- ❓ Termination of study is required regardless of the type of review the study received.
- ❓ Mentor IRB will automatically notify you of an impending report due date.
- ❓ To request a continuation of your research study or to submit a final report, click on My Protocols and then on the title of your research study.
- ❓ Scroll to the bottom of the screen and click on continuing review record context menu.

Protocol 10/23/2013  Test.doc
 Consent Form 10/23/2013  Test (1).doc
 Notifications 10/23/2013  Expedited Review Approved by Chair - IRB ID: 2013/10/3.pdf

Cont. Reviews | Amendments | Adverse Events | Protocol Deviations | DSMB Reports

Year	Status	Due Date	Date Received	Date Approved	Submitted By
1	Due	09/25/2014			



- ❓ Click on edit and complete the information requested.
- ❓ Please upload all consent forms and recruitment flyers so that the documents can be stamped with Duquesne University Approval and new expiration date.
- ❓ Do not forget to click **Submit Report**
- ❓ The IRB Chair will review your request for continuation and send you a letter via Mentor IRB indicating that you have IRB approval to continue conducting your study for an additional year.
- ❓ If you have completed your study, the IRB Chair will send you a letter indicating that your study is terminated and thus, no longer active.
- Please note that even when the research is permanently closed to the enrollment of new subjects and all subjects have completed all research-related interventions, continual review is required as long as the research remains active for long-term follow-up of subjects and continues to involve non-exempt human subjects' research. Furthermore, continuing IRB review of research is required when the remaining research activities are limited to data analysis of individually identifiable private information.

How to Submit an Adverse Event

- ❓ If unanticipated risks or hazards are discovered during the course of the research, the PI shall immediately suspend research activities and notify the IRB chair in writing.
- ❓ Click on the **My Protocols** tab and then, click on your protocol.
- ❓ Scroll down to the set of tabs at the bottom and click on the **Adverse Events** tab.
- ❓ Click on the **New Adverse Event** tab to upload a description of the event.



- ❓ You should include in your summary your judgment of whether the harm to the subject was a result of their participation in the project or incidental to it. You should also indicate if you think that the event warrants any changes to your protocol or consent form. If so, you should then submit an amendment to your protocol.
- ❓ It is best to talk with the IRB Chair before submitting your amendment.
- ❓ The Chair will consult with the original IRB reviewer or reviewers to determine what actions to take.
- ❓ The researcher may not continue research activities until receiving written permission from the IRB Chair.

Faculty Advisor Guidelines

- At Duquesne University, faculty advisors are required to serve as co-PIs on student initiated research involving human subjects.
- The student researcher will enter their faculty advisor's name as co-PI during the Mentor IRB submission process. Once the student submits the protocol, the faculty advisor will receive an email notification generated by Mentor IRB.
- The faculty advisor will be required to review and accept the student's IRB protocol prior to further IRB review.
- To review and then accept the student's IRB protocol, you will first need to login to Mentor IRB.
- ❓ Then, click on the **Student Protocols** tab on the left hand side of the **Info Page**.
- Click on the title of the student's protocol.
- ❓ Review the form. At the bottom of the form, you can download the protocol, consent form and any other additional attachments that the student submitted.

- As faculty advisor/co-PI you have all rights and can edit, copy, upload other documents or print the form.
- ❓ If you want to send your student a message requesting revisions, click on **Messages** at the top right corner of your screen.
- ❓ Click on the **New Message** button. Write your message and then click on **Save** at the bottom of the screen.
- After you have reviewed the student's protocol and are ready to accept it, click on the **Faculty Advisor Action** Button at the top of the Student Protocols screen.
- From the pull down menu, select **Accepted**. **Please note that by accepting your student's protocol, you, as the faculty advisor/co-PI, acknowledge that you have reviewed and approved your student's IRB protocol submission. In addition you are assuming responsibility for your student's research and the research activities associated with it.**
- ❓ To complete the process, click on the **Update Status** button.

IRB Action

Acceptance Status Not yet accepted ▼



As Advisor, you acknowledge that you have reviewed and approved your student's IRB protocol submission. In addition, you are assuming responsibility for your student's research and the research activities associated with it.



- Mentor IRB will automatically generate an email notification to one of the IRB representatives from your School or the College indicating that the student's protocol needs reviewed.
- As faculty advisor/co-PI, you will be automatically included on all emails sent to the student via Mentor IRB.

IRB Reviewer Guidelines

- ❓ Once an IRB proposal has been submitted via Mentor IRB, the IRB Representative by School or College will receive an email notification indicating that a new protocol has been submitted for review.
- ❓ To review the new submission, you will first need to login to Mentor IRB.
- ❓ Click on the **Reviewer** tab on the left hand side of the **Info Page**.
- ❓ The protocol will be listed on the **Review Protocols** page.

The screenshot displays the Mentor IRB Review Protocols interface. The main content area shows a table of review protocols with the following data:

IRB Number	Title	PI	Status	Review Type
2013/11/2	Test 2: Mentor	Linda Goodfellow	Exemption Requested	Nursing Reviewers (P)
2013/11/4	test 4 Mentor	Linda Goodfellow	New - Full Review	Nursing Reviewers (P)

The interface also includes a sidebar with navigation options: Info Page, IRB Documents, My Protocols, Student Protocols, Reviewer, PI Documentation, Meetings, and IRB Members. The footer contains the Mentor logo and copyright information: "MENTOR by axiomeducation Terms of Use | Privacy Policy | Help | Contact Support Mentor v3.1.84 (build 510) © 2009-2013 Axiom Education LLC. All rights Reserved."

- Click on the title of the protocol you wish to review. If you are not able to review the protocol, click on **Decline**. Mentor IRB will automatically assign another IRB representative from the researcher's School or the College to review the protocol.
- ❓ Review the form completed by the faculty or student researcher. At the bottom of the form, you can download the protocol, consent form and any other additional attachments that were submitted.
- ❓ After you have reviewed the protocol, click on the **Reviewer Action** Button at the top of the **Review Protocols** screen. If you are accepting the protocol without revisions, then use the pull down menu to select a change in status to **Accepted**. Click on **Save** at the bottom of the screen. An email will be generated via Mentor IRB and sent to the IRB Chair for final review and approval.

IRB Admin IRB Setup My Grants

Info Page **Edit Review** **Upload Revisions** Back

IRB Documents **Test 2: Mentor**

My Protocols Reviewer Louise Kathleen Sekula (Nursing Reviewers)

Student Protocols Review Status Pending

Due Date 11/20/2013 8:41 AM EST

Review Text:

Reviewer

PI Documentation

Meetings

IRB Members

- ? If after reviewing the protocol, you want to send the researcher a message or request revisions, click on **Messages** at the top right corner of your screen and then click on the **New Message** button. You can also copy the message to others if needed.

Edit Reviewer Status Cancel

Edit Reviewer Status

Reviewer Louise Kathleen Sekula

Due Date 11/20/2013 8:41 AM EST

Review Text

body p

Save **Close**

- ? You can key in the requested revisions in the message box, or you can upload the protocol document, consent form or any other documents using track changes. You will also need to select a change in status to **Revisions Pending**.

IRB Admin IRB Setup My Grants

Info Page **Edit Review** **Upload Revisions** Back

IRB Documents **Test 2: Mentor**

My Protocols Reviewer Louise Kathleen Sekula (Nursing Reviewers)

Review Status Pending

Due Date 11/20/2013 8:41 AM EST

Review Text:

PI Documentation

Meetings

IRB Members

- Click on **Save** at the bottom of the screen and the message will be sent to the researcher. If this is a student researcher's protocol, the faculty advisor/co-PI will be automatically copied on the message.

Reviewer Revisions Files Cancel

Reviewer Revisions Files

* File type Reviewer Protocol Revisions

* File Browse... No file selected.
Allowed Extensions: doc, docx, pdf

Rename File to

Leave blank to use original file name

Save Cancel

Reviewer Revisions Files Cancel

Reviewer Revisions Files

* File type Reviewer Consent Form Revisions

* File Browse... No file selected.
Allowed Extensions: doc, docx, pdf

Rename File to

Leave blank to use original file name

Save Cancel

- You will receive an automatic email notification after the researcher submits their revisions. Follow the same process as directed above to log in and review the revised IRB submission.
- After you have reviewed the revised protocol, click on the **Reviewer Action** Button at the top of the **Review Protocols** screen. If you are accepting the protocol without further revisions, then use the pull down menu to select a change in status to **Accepted**. Click on **Save** at the bottom of the screen. An email will be generated via Mentor IRB and sent to the IRB Chair for final review and approval.

11/18/2013 goodfellow.final