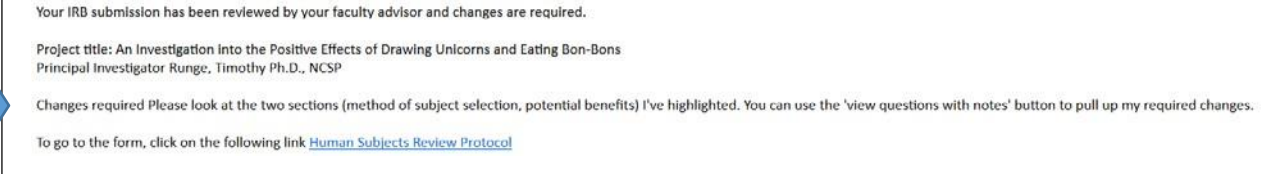


## IRBManager Instructions for Researchers

### The IRB asked for revisions to my protocol, now what?

You will learn in one of two ways that a protocol/application (or other submission) requires changes.

- 1) You will receive an **email notification** that your form was reviewed and requires changes. You can go directly to the form by clicking on the link in the email. Below is a sample email notification:



Your IRB submission has been reviewed by your faculty advisor and changes are required.

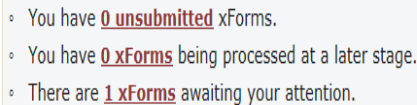
Project title: An Investigation into the Positive Effects of Drawing Unicorns and Eating Bon-Bons  
Principal Investigator Runge, Timothy Ph.D., NCSP

Changes required Please look at the two sections (method of subject selection, potential benefits) I've highlighted. You can use the 'view questions with notes' button to pull up my required changes.

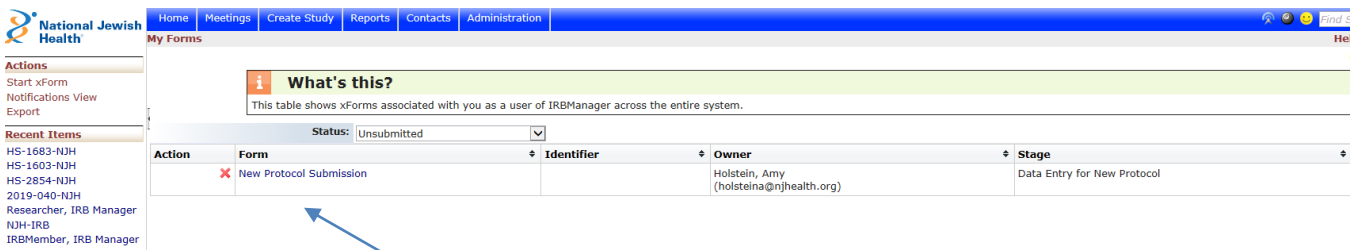
To go to the form, click on the following link [Human Subjects Review Protocol](#)

After clicking the link, you will be asked to log in using your NJH username and password.

- 2) You can also find the submission on your IRBManager home page under **xForms** using the link titled **"# xForms awaiting your attention"**.

- 
- You have **0 unsubmitted** xForms.
  - You have **0 xForms** being processed at a later stage.
  - There are **1 xForms** awaiting your attention.

Clicking on the underlined **"# xForms"** link will bring up the specific studies and forms requiring changes.



The screenshot shows the 'My Forms' page in the IRBManager system. A table lists the user's forms. A blue arrow points to the 'New Protocol Submission' row.

| Action | Form                    | Identifier | Owner                                     | Stage                       |
|--------|-------------------------|------------|---|-----------------------------|
| ✖      | New Protocol Submission |            | Holstein, Amy<br>(holsteina@njhealth.org) | Data Entry for New Protocol |

Click the form that you need to revise by clicking on the form name. The form (i.e., New Protocol, Request for Change, Request for Continuing Review) will launch in a new window.

Once in the form, you will find notes from the IRB/DRB/Faculty Advisor highlighted in blue (see below for an example note). In these areas, you'll want to make changes.

|  |  |                       |
|--|--|-----------------------|
| <b>Purpose of the study</b>  |  | Add Note   View Audit |
| <p><b>Entered:</b> 09/08/16 <b>By:</b> Faculty, Test <span style="float: right;">✖</span></p> <p>You need to better establish the background of the study. Make sure you cite work related to the topic. You need to provide enough background for a reader who is not familiar with your research questions</p> |  |                       |
| <p>To investigate how many office supplies are taken from the workplace without permission each year.</p>  | <p><i>In a few sentences, describe the purpose of the study. This section need not be elaborate, but does need to clearly indicate the purpose of the study in a way that is clear to persons not familiar with the project.</i></p> |                       |

NOTE: If you want to review all of the note made for this submission, you can click on the “**View Questions with Notes**” button at the bottom of the screen.



Clicking that button will open a *new window* that allows you to see all of the notes created by the IRB for this protocol/application. This will allow you to focus on the specific sections that require changes.

View xForm - Human Subjects Review Protocol

**Please use this Human Subjects Review Protocol form when submitting to the IUP IRB.**

New protocol data entry  
- Submitted 9/8/2016 1:21:34 PM ET by PI, Test

Project Information

Funding Information

Project Description

|   |  |
|---|--|
| <b>Purpose of the study</b>   |  |
| <p><b>Entered:</b> 09/08/16 <b>By:</b> Faculty, Test</p> <p>You need to better establish the background of the study. Make sure you cite work related to the topic. You need to provide enough background for a reader who is not familiar with your research questions</p> |  |
| <p>To investigate how many office supplies are taken from the workplace without permission each year.</p>   | <p><i>In a few sentences, describe the purpose of the study. This section need not be elaborate, but does need to clearly indicate the purpose of the study in a way that is clear to persons not familiar with the project.</i></p> |

Subject Population

Methods and Procedures

Risks/Benefits

Privacy/Consent/Nature of Risk

Exemption Qualification

Expedited Review Qualification

Attachments

|  |   |
|--|---|
| <b>Please attach any site approval letters</b>   |   |
| <p><b>Entered:</b> 09/08/16 <b>By:</b> Faculty, Test</p> <p>Since your study takes place outside of IUP, you will need a site approval letter. Contact Company X and ask that they produce one. The site approval letter needs to come on THEIR letterhead, contain a statement that clearly indicates they understand what's being asked of them/what the research subjects will be asked to do, and be signed by a person with the authority to provide such approval (e.g., President). You will attach that letter here.</p> |   |
| <p>No answer provided.</p>   | <p><i>The site approval letter <b>must</b> be on the official letterhead of the site and endorsed by the person responsible for the site.</i></p> |

Faculty advisor review and signature

Faculty advisor review

Remember that you can use the **drop down menu** at the top of the screen to navigate to specific sections of the form.

After you make your revisions, you are given the choice to **'save for later'** or **'submit'**. If you choose 'save for later', you can access that protocol on the IRB Manager dashboard under "# unsubmitted xForms."

Please NOTE, if required changes are incomplete, IRB Manager will provide an 'issues' message and direct you to the sections that must be completed. Incomplete protocols cannot be submitted.