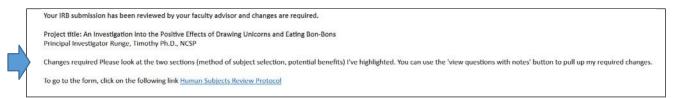
IRBManager Instructions for Researchers

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:



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

 You can also find the submission on your IRBManager home page under xForms using the link titled <u>"# xForms awaiting your attention</u>".



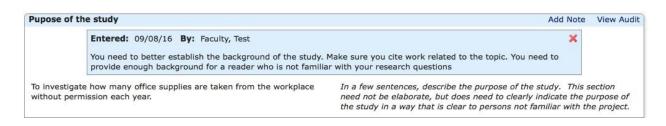
Clicking on the underlined <u>"# xForms</u>" link will bring up the specific studies and forms requiring changes.

Pational Jewish Health	Home My Forms	Meetings Create Study	Reports	Contacts	Administration					🔗 🥝 🙂 Find s He
Actions Start xForm Notifications View Export	What's this? This table shows xForms associated with you as a user of IRBManager across the entire system.									
Recent Items	1	State	us: Unsubmit	tted	~					
HS-1683-NUH HS-1603-NUH HS-2854-NUH 2019-040-NUH Researcher, IRB Manager NH-IRB IRBMember, IRB Manager	Action	Form			÷	Identifier	Owner		+ Stage	\$
		X New Protocol Subm	ission				Holstein, Amy (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.

NJH IRB MANAGER



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.

	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							
	Pupose of the study							
	Entered: 09/08/16 By: Faculty, Test							
	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							
	To investigate how many office supplies are taken from the workplace without permission each year.	In a few sentences, describe the purpose of the study. This section need not be elaborate, but does need to clearly indicate the purpose the study in a way that is clear to persons not familiar with the project the study in a way that is clear to persons not familiar with the project the study in a way that is clear to persons not familiar with the project the study in a way that is clear to persons not familiar with the project the study in a way that is clear to persons not familiar with the project the study in a way that is clear to persons not familiar with the project the study in a way that is clear to person the study of the study the study in a way that is clear to person the study the study in a way that is clear to person the study the study in a way that is clear to person the study the study in a way that is clear to person the study the study in a way that is clear to person the study the study in a way that is clear to person the study the study in a way that is clear to person the study the study in the study the study is the study the study in a way that is clear to person the study the stud						
	Subject Population							
	Methods and Procedures	Methods and Procedures						
	Risks/Benefits							
	Privacy/Consent/Nature of Risk							
	Exemption Qualification							
	Expedited Review Qualification							
	Attachments							
	Please attach any site approval letters							
	produce one. The site approval letter needs to come on TH they understand what's being asked of them/what the rese	Entered: 09/08/16 By: Faculty, Test 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.						
	No answer provided.	The site approval letter must be on the official letterhead of the site an endorsed by the person responsible for the site.						

VI

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

S National Jewish	de Collaborators	General Information	Page 1 of 26	
Vew Protocol Submission General Information		General Information		
	Instructions: Please submit this comp application must be accompanied by a and justification, inclusion and exclus considerations, provisions for the prov	Applicable Regulations Research Description	al Jewish Health. This Add Note r, objectives, sample size description ing plan, analytic plan, regulatory	
	**In addition to this form, please i	Research Setting/Performance Sites Collaborative Research	the NJH website, for other items to	
	Form created by:	Subject Population	Add Note View Audit	
	Holstein, Amy Email: holsteina@njhealtr	Research Involving Children as Subjects Research Involving Pregnant Women, Fetuses or Neonates		
	cindit. Noiscenta@njiteatu	Research Involving Prisoners		
	HS# (Required)	Research Involving Adults with with Impaired Decision-Making Capacity	Add Note View Audit	
	2019-006	Identification/Recruitment of Subjects		
	Protocol Title (Required)	Informed Consent Informed Consent Process and Documentation	Add Note View Audit	
		Request for Waiver, Alteration and/or Documentation of Consent		
		Data/Confidentiality		
	If you enter an email address for a stu say the contact is not found. If this ha	Provision of Results Risks/Risk Mitigation	ceive an error message to Add Note	
	Add a New Contact	Benefits Costs		
	Principal Investigator (Required)	Compensation	Add Note View Audit	
		Non-Monetary Gifts/Tokens of Appreciation		
	COI & Scientific Misconduct Form (Rec Add Attachment	Privacy Clinical Trial Other Supporting Information		
	CV (Required) Add Attachment	Principal Investigator Signature and Certification Check & Submit Form		
	PI Department (Required) If your department is not listed, please of	contact the IRB Office.		
	PI status at NJH (Required)			

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.

You've complete	d the form. You can now either save the form for later revision, or submit it.	
Save for Later	Print Submit	
Save for Later	Print	