Aloha! The purpose of this training session is to give you the opportunity to experience the eProtocol submission process, have your questions answered, and result in you being an eProtocol expert!

Copy information from this document and paste into the eProtocol online application as we go along. You are welcome to explore this test application assignment before the training session.

Go to the eProtocol website at https://uhmanoa.keyusa.net/

Log in using your UH user name and password. All users of the portal must have a UH username. If you do not have a UH username, please call us at 956.5007 or email us at uhirb@hawaii.edu.

Once logged in, you should find yourself on the **Investigator Home page**.

You will automatically be signed in as an Investigator, even in situations where your role on a given project or projects, is as a coordinator, manager, or a student – co-investigator. This will allow you to view and edit applications. Something to keep in mind - the eProtocol program automatically restricts access to the application, based on the permissions associated with your role on that project.

At the top right corner of the webpage, you should see listed your last name and your University affiliation. Under this, see the link to sign out, and a help link. The help link will open a new webpage with an online version of the Investigator's manual.

At the top left of the page, there is the eProtocol link. Hover your mouse over this link, and you will see a drop down menu.

***After each section, hit "Next" (top or end of page, right) to move to the next page.**

Creating a New Application/Protocol

There are two ways to launch the "Create Protocol" window.

1. The Investigator Menu
2. Create Protocol button on the Investigator Home Page.

The first page brought up is not part of the application, but is to register the P.I. Once you complete this page, you will have created an eProtocol application/entry, and your protocol will be assigned its unique ID.

You can list someone other than yourself as the Principal Investigator (*which student researchers are required to do*). eProtocol will require that you list yourself as the 2nd Investigator or contact. You need to do this regardless of whether you are actually an investigator (for example, if you are a study coordinator). You can change your role on the Personnel page immediately

following. Your study/protocol information will be saved each time you save, or click *next* to exit the page. Note: The "Unified IRB Form" is the IRB application. This button will remain checked for all new applications, as well as renewal and modification requests.

***Save often – there is a button at the end and the top of the page.**

Personnel information

Be sure to answer the student research item at the top of the Personnel Page.

As noted above, you may revise the roles of study personnel on this page. For example, if you have listed yourself as Principal Investigator, but realize now that you need to list your faculty advisor in this role instead, you can make that change on this page.

Please note that you will not be able to directly type the name into the line, but instead must use the binocular icon to look up the investigator.

You will need to select study personnel by clicking on the drop-down menu icons, to bring up the personnel search panel. All study personnel must have a UH username. If you wish to add study personnel without a UH username, you need to contact the Human Studies Program (HSP) office.

The Study Coordinator and Administrative Contact entries are optional. Some researchers are part of programs or Departments where there will be a person or persons given this role. If it does not apply to you, simply leave these blank. An investigator may also be listed as Administrative Contact.

The CITI training information should automatically download to your application if you logged in to the CITI website via the SSO. If the CITI certificates of completion do not automatically download, save them as PDF files and attach them to the attachments page. The HSP does accept NIH training, in lieu of CITI training, but only for NIH funded research.

Protocol information

Sub-Sections: You may navigate quickly through your application using the menu on the left side of the protocol window. Clicking on "Protocol Information" will expand the menu to open up additional sub-sections of your application.

When addressing consent and assent information, you will also attach your consent and assent documents on those pages. Be sure to scroll down to address additional items in the Consent attachment pop-out window, as appropriate.

On the attachments page, remember to attach the protocol, flyers/recruiting materials, study instruments, translated documents, CITI training certificates of completion, and as appropriate. Clearly but concisely label your attachments. eProtocol will save all attachments, making subsequent revisions easier to track, however, a clear labeling scheme will make this easier.

The live eProtocol application will automatically gray out areas relating to the boxes you check and information you provide, making them unavailable. This is usually beneficial to the researcher as the live application adjusts based upon relevance. If a section of the application is grayed out that should not be, such as HIPAA or Drugs and Devices, you may need to revisit and revise responses on the General Checklist, to enable them.

If the Conflict of Interest (COI) section is grayed out, but you need to notify the IRB of a COI, you may just add an attachment to address this.

Research Protocol/ Proposal for Initial Approval

Non-Exempt Research

Subject checklist

For this exercise, choose "**University Employees**."

When actually filling out this section, be sure to carefully review responses on the "Subject Checklist." Selected items on the subject checklist, such as "Prisoners" or "Pregnant Women" will open up additional items in the application. Omitting these items may cause delays in the review process.

Study location

The study location is the location at which the research takes place. For example, a study in which specimens are collected at a community clinic, and analyzed at UH Hilo, should have both UH Hilo and Other selected.

For this exercise, choose "**University of Hawaii, Manoa, University of Hawaii, Hilo, University of Hawaii, West O'ahu**"

General Checklist

For this exercise, choose "**Interview**" Section 2, Methodologies

Funding

For this exercise, choose ☐ **NONE – This project does not have any funding**

Application Type Checklist

For this exercise, choose "Expedited/Full Board"

Expedited Review

For this exercise, choose "**7b"**

Title

For this exercise, type “Test Application (Your last name)”

Proposed Start Date 06.22.16 **Proposed End Date 06.22.17**

Summary

For this exercise, type “The proposed study will assess job satisfaction of University of Hawai’i employees on the UH Mānoa, UH Hilo and UH West O’ahu campuses (N= 50 participants per campus) before and after a two month intervention involving expressive arts therapy, interpretive dance, ho'oponopono, massage, and individual and group positive feedback. In addition, the study will explore participants’ perceptions of their work environments, work relationships, and work hierarchy structures, including their opinions about ways to improve work environments and relationships. Using statistics, the study will compare perceptions and experiences before and after the job satisfaction program and using both quantitative and qualitative data will determine best ways to improve job satisfaction in the sample population. The interviews and interventions will be video recorded. Interview video recordings will be analyzed for non-verbal responses as well as to verify the transcriptions, and video recordings of the intervention sessions will be made available on a public website as a resource for future workplace job satisfaction intervention programs.”

Purpose

For this exercise, type “The purpose of the pilot study is to explore: 1) the feasibility of using art therapy modalities, ho'oponopono, the healing arts, and positive feedback in a sample of University of Hawai’i employees to improve job satisfaction 2) participants’ perceptions of their work environments and relationships; 3) changes in reports of job satisfaction before and after the intervention, and 4) best ways to improve job satisfaction in the sample population.”

For the rest of the questions/sections, based upon what you already entered for the Summary and Purpose above, make up the answers as you go along. For those sections that do not pertain, enter “N/A.” To speed the process up (and if you are not feeling particularly creative), you can also just enter “test.”

You will need to attach the test consent document on the consent page (included with this document.) You will also attach the test interview questions document on the attachments page.

Obligations

This is your agreement page and must be filled out before you submit.

Check for Completeness

When you are ready to submit your application, you will need to select the "Check for Completeness" tool, to verify there are no outstanding items or issues. Please note, this will bring up another pop-up window. If there are multiple windows open on your computer, you may need to look behind some to find the window. If there are outstanding issues, these will be listed in the "Check for Completeness" tool. You may navigate to these sections using the regular menu, or the "Check for Completeness" tool.

Once all items have been addressed, you will be able to submit the application for review.

*** The name listed as the P.I. is the person who must submit the application.**

Submitted Application

You will receive email notification that you successfully submitted your application. Once an application has been submitted, you will no longer be able to edit that application.

HSP personnel may respond with requests for clarification or additional attachments. This "cycle" of correspondence will open the application, or portions of the form, for your edit again. There may also be correspondence from the IRB reviewer, which will also require additional attachments or clarification.

Please note, however, other than in response to HSP correspondence, if you need to make revisions to your application, you will need to withdraw the application. To do this, you would need to communicate with HSP staff directly. This will apply to renewals and modification applications as well.

Notification of approval will be via email.

Thank you! Mahalo!