Sam Houston State University
Protection of Human Subjects Committee (PHSC/IRB)

Classroom Application

Welcome to the Sam Houston State University online system for reviewing research on human subjects. This system is hosted off-campus by InfoEd, which is headquartered in Albany, New York. This program can be accessed with either a PC or a Mac, on-campus or off. An internet connection is required, but it will even work with a dial-up modem (but at slower speeds). Beginning in the fall 2008 semester, all new human subjects applications must be made with this new system. This program is more sophisticated than previous procedures used at SHSU and captures important information that was not requested on the previous systems. This is an important feature because it gives the University a better audit trail for our procedures and applications and improves compliance with Federal guidelines.

The new application system is found by pasting the following URL into your browser.

http://samhouston.infoed.org

Internet Explorer is the browser that works best with this system.

An alternate method is to go to the Office of Research and Sponsored Programs website, click the link to IRB Tab, then click on the Application tab, and then click the link to InfoEd’s IRB Application System. Please note there is also a tab for Instruction Manuals and Training, if this is your first time completing an IRB application, you should download a copy of the manual that coincides with the type of application you are completing.

Logging into the System

On the home page are two important buttons on the left margin: login and get profile. When you use this system the very first time, you must click “get profile.” You should only have to do this the first time.
Getting a profile involves 5 steps:

1. identify your state (TX) from the pull-down menu and continue;
2. select our university from the pull-down menu and continue;
3. Select your profile and continue. To select your profile, click “set” and select the first letter of your last name. From the pull-down menu select your name and click “select.” Then close that dialogue box. At this point the user’s profile should be pulled into the system from university data bases. Insure that the email listed is the account you access, since all communication through InfoEd will use that email.

4. The user will then be asked that the profile on the screen is his or hers; if yes, click “continue;”
5. Shortly thereafter the user’s login information will be confirmed by email will include the User ID (SHSU login) and password. The user is then able to use this information to log onto the system.

New Student Login

New students will not be able to get a profile so easily. At the first screen of the “get profile,” check the box at the bottom, “profile not found in list” (pg 2). Then the user will be asked to fill in

- **his/her name** – user must use the name under which he/she is registered at SHSU,
- **SHSU email address** (do not enter yahoo, aol, gmail, or any other email address, as the system does not recognize some of those carriers),
- **primary department**,
- **user ID and password**.

Once that information has been added, click “continue,” which will take the person to step five.
NOTE: Before an email is sent to the new user, the profile must be validated by the Office of Research and Sponsored Programs. This could take several days, depending upon the availability of personnel in that office. If you enter a profile on a weekend, the profile will not be validated until the early part of the following week. To avoid being delayed in starting a research project, students are encouraged to get their profiles entered weeks before they are ready to submit an application. This recommendation is particularly important for students who are conducting research for a class.

Using the Program

Once a profile has been set, the user can return to the InfoEd home page, click Login and enter name and password along the left margin (pg 2). Then click the Login button (do not just “enter”). The next screen should have the user’s name printed at the top. Along the left margin are two categories: My Human Subjects and My Profile.
The **My Human Subjects** list is the most important for most uses with this system. Here are found links to new applications, modifications of previously submitted protocols that are under review, amendments, adverse event reporting, continuing review, final reports, and help. While scrolling down the list the user should choose the link that serves his/her intent. For example, to begin a new application, click **Create New**. If clicking that link does not take the user to the application, check to be sure there is not a *popup blocker* preventing access. If so, disable it.

Selecting the **Show/List** link will take the user to a list of all his or her applications that are under review and have been previously approved. To make modifications to a previously submitted application that is still under review, click the **open folder icon** to the left of the protocol (under **Actions**).

The **Search For** link will enable the user to access his or her protocols that have been closed. Opening an old application can enable the user to copy and paste from the old to a new application. This can also be accomplished by selecting **Create New** and checking **Copy from Existing Human Protocol**.
Creating a New Classroom Application

This application is to be used by any undergraduate or graduate student who is enrolled in a class that requires completing a research project involving human subjects. This does not include graduate students who are working on their theses, dissertations or other supervised research projects. After logging in, the Principal Investigator (PI) should go into My Human Subjects along the left margin and select Create New. At the Create dialogue box, check New Human Protocol and click continue. In the Protocol Creation box, enter the title of the research and click continue.

At the Select PI window, your name should appear in the PI box. If it is not there, click on the first letter of your last name to see if you are in the system. If so, select your name and close. If not, call the Office of Research and Sponsored Programs at X3876 for assistance. Click continue.

At the Components for Initial Review window, click the Edit icon by the Initial Application line to open an application.
To identify the application as a regular research project, select Regular Initial or Thesis/Dissertation from the drop down box beside “Is this project a:.”

At that point a blue highlighted line appears below that response which when selected, takes the user to the application itself.

**NOTE:** Along the left margin of the formal application is a **Menu** tab. When that is clicked, the PI has the option of saving the application. **Saving** an application periodically is a good idea, so that no information will be inadvertently deleted. **Printing** a copy of the completed application provides a reference for the PI and supervising faculty. It can also be sent to other participating agencies or institutions. **NOTE:** You can only print an application once it has been checked complete and the red pdf icon appears next to Complete. **To print**, simply use the Ctrl P on your keyboard.

Clicking that link will take the user to page one of the application. At the top of the application the user is asked to indicate whether the required HPPERT training has been completed. If the training has been completed, a copy of the certificate must be either faxed to 936.294.3622 or emailed to
If the HPPERT training has not been completed, the PI and all Co-PIs must take the course through the National Institute of Health at: [http://phrp.nihtraining.com/users/login.php](http://phrp.nihtraining.com/users/login.php). Users of the training must first register in that system. Once the training is completed, print a copy of the certificate and send a copy to either of the above addresses. A copy of this certificate does not have to be attached to the application.

The user’s name should pull into the application automatically. The user must type in their department, college, status/title, phone number and email address. Students must specify the faculty sponsor and that person’s contact information in Section II B. The PIs information will already have been pulled into Section II B, so it will have to be removed before entering the information for the supervising professor. Co-investigators should be listed in Section II C. By clicking the plus sign the user can add co-PIs (each co-PI must have completed the HPPERT training as well.) The contact information (including email address) for the supervising faculty and co-PIs must be added manually. To insure proper routing, check this information for accuracy.

**Settings (III 1)** - The PI may choose as many as apply. Additional information must be provided for every location other than SHSU.
Additional Reviews (IV) - Select all that apply. If approval to conduct the research has been granted by the agency or institution, that documentation should be uploaded in Section IV 3. For example, if the proposed research is being conducted at a school, attach a signed letter of support (on the district letterhead) from the school or district and attach it to the application.

Level of Risk (V A) - The PI should select of the level of risk to participants in terms of physical, emotional, legal, and reputation issues. The PHSC will review the application to determine whether the PI’s assumption is accurate.

Procedures (V C) - Check the types of procedures that will be used in the research. More than one procedure may be checked. At the Components of Initial Review dialogue box (the place where the completed application will be submitted, the PI will be prompted to upload documents related to those procedures.
Sensitive Subject Matter (V D) - Choose all that apply.

Protecting Anonymity and Confidentiality (V E) - Answer each question.

Managing Risk (V F) - This is a very important consideration and should be thought through carefully before submitting the application.

Audio or Video Taping (V G) - Yes or no. When this is to be done, the cover letter or informed consent document must specifically inform the participant.

Lay Summary (VI) - Under sections A through D, the PI is asked to summarize the research project in lay terms. Provide sufficient information so that a reviewer will have a clear understanding of the project. This will usually require at least one paragraph.

Protected Health Information (VII E) - This refers to recording or sharing protected health information (PHI). This is an issue that is regulated by federal law (HIPAA) and must be careful considered. Additional documentation is required when a study collects or distributes PHI. Students should consult with their instructors if they have questions about this.

Deception - If deception is used, a debriefing document should be uploaded where indicated.
**Research Participant Selection and Recruitment (VIII)** - Check all that apply. The user will be prompted at the **Components of Initial Review** dialogue box to upload any and all forms of consent that are indicated by the application.

**Accessing Records (VIII C)** - When intending to access records about participants outside the University, appropriate documentation for cooperation/permission from the custodian of the records should be uploaded. Clicking on the plus sign will provide an icon for uploading the necessary documentation.
Obtaining Participant Consent (IX) - There are different kinds of consent documents: adult signed consent, adult unsigned consent/cover letter, signed parental consent, signed assent (participants between the ages of 12-17), and waiver of assent. Check the appropriate types and upload those documents into the application.

Waiver of Consent, Alteration of Consent, or Waiver of Documentation (X) - Check the appropriate justification for the request.

Investigator Assurance - Carefully read this section and check the box at the bottom if you agree to abide by these terms.

Be sure to save the application, even if more information is needed to Complete it. When returning to an application started earlier, do not start a new application for the same project. Go to My Human Subjects and click Show/List to find the application. To open the application, click the “folder” under Actions, this will open to the Submissions page, and then click the folder under Open, this will open to the Components for Initial Review page, and there you will the Edit icon beside the Initial Application.

If everything has been completed and documents uploaded, check the Complete box in the upper right hand corner of the application. If information needs to be added, the user will get an error message that lists where the missing data are. Once the system accepts a protocol as complete, the user must wait for the system to accept it. Follow the progress bar at the bottom of the screen. When it is accepted, a pdf icon will appear next to the complete button at the top of the application. Then the user can close that screen.

The next dialogue box that appears will be the very first page of the application. There is a complete button here too that must be checked. When the system accepts it, another pdf icon will appear next to the complete box. When that appears, close that screen, and the user will be taken to the Components for Initial Review screen. The application and accompanying documents are listed here and can be reviewed. The PI may edit the submission by clicking the icon.

If the Complete box and the red pdf icon do not appear, the application may not be readable. Attempt to check the document back in by clicking the Check In/Out button in the red Menu tab on the left side of the screen. This may need to be done a couple of times until a message indicates that the user has ownership of the application. At that point, check the “Complete” box again. If that does not work, send an email request to Trisha Allen (trishaallen@shsu.edu) describing the difficulty encountered. When sending an email, the user should be sure to include his/her complete name and, if possible, the
application number. Sometime afterward, the PI will receive an email containing information about the status of the application.

**Accessing other documents and forms, such as consent/assent forms,** click the blue hyperlink highlighted in the dialogue box below (Add Institution/Supporting Documents). Then select whichever forms are relevant to the application. The consent form templates are available here.

*Uploading other documents,* give a name to the document being uploaded and select where it is located on the user’s computer. Then choose the appropriate category. Then click **Upload.** Word document to be uploaded must be saved at Word 2003 (doc), not Word 2007 (docx). Pdf documents can be uploaded.

Before submitting an application the user should be sure that all necessary documents are attached to the application (e.g., surveys, interview protocols, consent forms and letters of cooperation). Letters of cooperation must be signed by the person having the authority to grant permission, and the document should be on the official letterhead of that agency.
Once the PI is ready to submit the application, click the **Submit** button (thumbs up icon). After that, the PI will be asked to accept a certification that the information is correct and will be asked for login credentials, the user must then click on a gray Continue button and then a gray Submit button. Once that is done, the user should click **Done** (upper left hand corner) and then **log out** of InfoEd.

To return to an application that was either started or submitted earlier, login and choose the **My Human Subjects** tab on the left. Clicking **Show/List** takes the user a list of his or her protocols. To add to a protocol, click the **Open folder** icon, and the submission dialogue box will appear. Open the folder to be taken to the application. To make changes it is necessary to uncheck the **Complete** box on the application. When finished with the revisions, click the **Complete** boxes again and wait for the red **pdf** icon to appear and then close out of the application screens. At the **Components for Initial Review** screen, click the **Submit** button. Before leaving the system, click **Done** and then **log out** of the system.

If a student has not received any feedback from Ms. Allen in the ORSP or from the supervising faculty member, he/she should contact either person to insure the application was submitted properly.

*Your supervising faculty instructor will not be able to access your application to make changes for you.*

A new submission is always identified as **Version 1**. The **date of submission** is not necessarily the date when the PI checked “completed.”

If the user is submitting a revised edition, type 2 in the version box. The version needs to be changed only if the initial submission is returned for modifications.
Routing an Application.

Once a Classroom Application is submitted, it will follow the route illustrated in the following diagram.

A user can check on the status of an application by logging into the system, opening My Human Subjects, and clicking Show/List. Opening the folder to the application will bring up the Submission folder. The status of the application will be listed here. If the status says “In Development,” then the application has not been submitted correctly or it has been returned for changes and/or corrections. Always remember to click done (upper left hand corner of the screen) when the application has been closed again. Then log out of the system.
If a PI wishes to delete an application, they should email the Office of Research and Sponsored Programs PHSC coordinator, Trisha Allen (trishaallen@shsu.edu) with the application # and a brief explanation as to why the application needs to be deleted.

**Review Results**

At any point in the review routing (i.e., supervising faculty, department chair, dean, PHSC), the PI may be asked for modifications. When those are required, an email will alert the user to log into the system to find out what is being requested.

Click the **Open Submission Package**, and the user will be asked to log into the system. When that is done, the user is taken to the **Components of Initial Review** dialogue box.
To find out what modifications are requested, the PI should
1. Open the initial application,
2. Read the reviewer comments,
3. Open the application itself,
4. Un-click the Completed box in the upper right hand corner,
5. Make the modifications,
6. Re-click the Completed box,
7. Save the changes made to the application and wait for the system to recognize the changes (see blue progress bar at bottom of screen),
8. Re-submit the application.

The revised protocol will be sent through the routing process again.

A PI will not automatically be alerted about comments reviewers have made or the current status of his or her application. **The PI is only notified when changes are required and when a protocol has been approved by the PHSC.** In the latter case a decision form will be sent to the PI (with notification). **Do not begin collecting data for a project involving human participants until the protocol has been officially approved by the SHSU PHSC.** No one other than the PHSC has the authority to give you permission to start data collection.

A PI may also receive a **Modifications Letter** resulting from a review by the PHSC (pdf format). Respond to those modifications in the same way as above.
When opening the applications, the **Submissions** screen appears which will have at least 2 lines, Initial Review and Request for Modifications. Click the blue hyperlink **Respond** on the latter line and the user will be taken to the application itself to make changes.

**Approved Research**

When a protocol has been approved by the PHSC, the PI will receive a letter by email that so states (pdf format). After opening it, save the letter so that appropriate documentation can be given when requested by faculty or participating agencies. Approvals for research studies are only good for one year. If the study extends beyond that period, an Amendment must be completed.

**NOTE:** Research should not begin before receiving this approval letter.
Amendments, Adverse Events, Continuing Review, Final Report

Once a protocol has been approved, the PI may want to amend it, but will not be able to change the already approved protocol. Changes are made through amendments. A PI may want to report an adverse event, ask for approval to continue the research past the time limit set in the approval letter, and submit a final report when the research is completed. To do these things, log into InfoEd and open the My Human Subjects tab. Click Show List and select the protocol you wish to address. After opening it check along the right side of the dialogue box and select submissions. There are found links to these three documents. Open the document you need, complete it, save it and submit. These submitted documents go directly to the Chair of the PHSC for review.

NOTE: Amendments, Adverse Event, Continuing Review, and Final Report documents should only be used after an application has been approved by the PHSC.