

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.

Welcome to the InfoEd eRA Portal for Electronic Grants administration - Windows Internet Explorer

http://samhouston.infoed.org/

Google Search Web Site popups allowed AutoFill Opt

Welcome to the InfoEd e... x Home - Protection of Human ...

Sam Houston STATE UNIVERSITY eRA Portal Streamlining Electronic Research Administration

Home

Help New Portal

» Home

Login

Get Profile

SPIN

GENIUS

Welcome to the InfoEd eRA Portal for Electronic Grants Administration

InfoEd is the leading provider of software solutions for managing sponsored programs.

Worldwide, over six hundred academic, medical and scientific institutions rely on InfoEd to support their grant and contract activity. InfoEd's proven web-based modules streamline processes, enable proactive monitoring of compliance, and enhance internal and external collaboration.

The company provides the most comprehensive and integrated line of sponsored programs software.

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;

Sam Houston STATE UNIVERSITY eRA Portal Streamlining Electronic Research Administration

Log Out Help New Portal

Get Profile

Home

Login

» Get Profile

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GENIUS

Get Profile Login

Step 1... Select your **State/Province**

Texas

Step 2... Select your **Institution**

Sam Houston State University

Step 3... Select your **Profile**

Profile Not Found in List

- 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.

The screenshot shows a web browser window titled "Personnel - Windows Internet Explorer". The address bar contains the URL: `http://samhouston.infoed.org/popupSelectList.asp?unique_id=&inst_code=SAMHOUS&primary=1`. The main content area has a header "Personnel" and a navigation bar with letters A through Z. Below this, a search box contains "ABSHIRE, ROGER D" and a dropdown menu shows "MGT & MARKETING DEPT". A "Select" button is visible. Below the search box, there are links for "Search for a particular entry" and "Filter by Position", each followed by an input field and a dropdown menu. At the bottom, a note states: "Profiles with more than one department are listed with Primary Department first."

- The user will then be asked that the profile on the screen is his or hers; if yes, click “continue;”

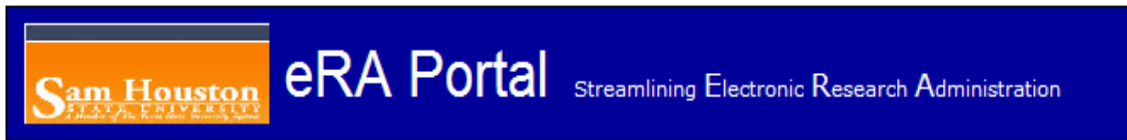
The screenshot shows the "eRA Portal" interface for Sam Houston State University. The header includes the university logo and the text "eRA Portal Streamlining Electronic". Below the header, there are links for "Log Out", "Help", and "New Portal", and a "Get Profile" button. The main content area is titled "Get Profile Login" and contains a four-step process:

- Step 1...** Select your **State/Province**: A dropdown menu shows "Texas".
- Step 2...** Select your **Institution**: A dropdown menu shows "Sam Houston State University".
- Step 3...** Select your **Profile**: A dropdown menu shows "- select -".
- Step 4...** **Is this the Profile?**: A dropdown menu shows "- select -".

Below the steps, the following profile information is displayed:

- Last Name** KERCHER
- First Name** GLEN
- Middle Name** A
- Email Address** ICC_GAK@SHSU.EDU
- Primary Department** COLLEGE OF CRIMINAL JUSTICE

A "Continue" button is located at the bottom of the form.



Get Profile

Home	<h3>Get Profile Login</h3> <p>Step 1... Select your State/Province Texas</p> <p>Step 2... Select your Institution Sam Houston State University</p> <p>Step 3... Select your Profile</p> <p>Step 4... Is this the Profile? Yes, this is my profile</p> <p>Last Name BARRUM First Name JAMES Middle Name A Email Address ICC_JAB@SHSU.EDU Primary Department COLLEGE OF CRIMINAL JUSTICE</p> <p>Step 5... Completed! Your Login information has been sent to you at the above email address. Please follow the instructions it contains to access your account. Thank You</p>
Login	
>>Get Profile	
SPIN	
GENIUS	

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.

Get Profile Login

Step 1... Select your **State/Province**
 Texas

Step 2... Select your **Institution**
 Sam Houston State University

Step 3... Select your **Profile**
 Profile Not Found in List

Last Name Johnston

First Name Leroy

Middle Name

Email Address edu_lxj@shsu.edu

Primary Department COLLEGE OF EDUCATION **Set**

Username edu_lxj at least 6 characters

Password | | | | | | at least 6 characters

Re-Enter Password | | | | | |

Continue

***NOTE:** All new profiles are 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.

Logged in User: **GLEN KERCHER**

[Find Funding](#) [CV Database](#)

Log Out Help Portal

My Human Subjects

- Show/List
- Search For
- Create New
- Report On
- WorkFlow Admin
- Module Admin
- Program Tools
- Meeting Dates
- Help - Dev
- Help - Mgmt

My Open Action Items

4 Records Found.

Open	Assigned/Due
	Thursday, February 28, 2008 3:19:35 PM Due=
	Thursday, February 28, 2008 3:28:16 PM Due=
	Wednesday, April 23, 2008 11:19:12 AM Due=
	Tuesday, July 08, 2008 12:56:39 PM Due=

My Profile

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**.

The screenshot shows a dialog box titled "Protocol Creation". In the top left corner is a "Close" button. In the top right corner is a "Continue" button. Below the title bar, the text "Enter Title" is displayed above a text input field. The input field contains the text "SHSU".

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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**.

The screenshot shows a dialog box titled "Select PI". In the top right corner are two buttons: "Create New Profile" and "Continue". Below the title bar, there is a row of letters from A to Z, with the letter 'K' highlighted in bold. Below the letters is a dropdown menu showing "KERCHER, GLEN A (COLLEGE OF CRIMINAL JUSTICE)". Below the dropdown menu is a text input field with the label "Search for a particular entry". At the bottom, there is a section labeled "Filter by Position" with a dropdown menu.

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At the **Components for Initial Review** window, click the **Edit** icon by the Initial Application line to open an application.

000000022 - GLEN A KERCHER [Change Project Information](#)
 COLLEGE OF CRIMINAL JUSTICE
 SHSU

Components for Initial Review				Submit
		Current Submission		
Form/Document Name	Edit	Status	Upload	Remove
Initial Application		Incomplete		Mandatory

[Add Institution Forms/Supporting Documents](#)

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”:

Updated By: GLEN A KERCHER @ 16-Jul-2008 1:12:54 PM

MENU Save Check In/Out Quest Hist PAGES Form Hist Print	Initial Application <input type="checkbox"/> Complete
	Page 1 A. Is this project a: <input type="text"/> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> Classroom Project Regular Initial Thesis/Dissertation </div>

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 CITI training has been completed. If the training has been completed, a copy of the certificate is automatically generated and emailed to sharla_miles@shsu.edu. If

the HPPERT training has not been completed, the PI and all Co-PIs must take the course through the Collaborative Institutional Training Initiative at: <http://www.citiprogram.org>. 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 the above mentioned email address or fax number. A copy of this certificate does not have to be attached to the application.

Classroom Application
Page 1
Office of Research and Special Programs Sam Houston State University Huntsville, TX 77341 (936) 294-3876

A copy of your HPPERT Certification needs to be on file with the ORSP (Office of Research and Special Programs). Copies should be sent to orsp@shsu.edu or faxed to: (936) 294-3622
 I hereby certify that a copy of my HPPERT Certification has been sent to the ORSP (Office of Research and Special Programs)

I. Research Title
 * Research Title:

II. Personnel:

A. Principal Investigator (PI):
 * Name * University Status/Title
 * Department * College
 * Phone Number * Email Address

B. Faculty Sponsor - required when PI is a student:
 Name University Status/Title
 Department College
 Phone Number Email Address

C. Co-Investigators and any other Key Research Personnel (Co-PIs)

Name	Department	College	Email Address	University Status/Title
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

D. Disapproval of the Research
 * To your knowledge, has this protocol been reviewed and subsequently disapproved by any Protection of Human Subjects committee? Yes No

III. Data Collection Settings
 A performance site for SHSU research is a location at which the investigator conducts the research. SHSU may be conducting the research for another institution that receives federal funding, and therefore, the federal grants originates elsewhere. When this is the case, the originating grant holder's institution must be listed as the primary setting for SHSU and the PI for the grant must be listed as a co-investigator on the SHSU application. Additionally, the SHSU PHSC must review the portion of the grant that supports the research at SHSU.

I. Settings:
 a. SHSU
 b. Schools
 c. Community
 d. Prisons/jails
 e. Another university
 f. Nursing homes
 g. Hospitals
 h. Another State
 i. Another country
 j. Web survey/chat
 k. Other

If you selected b, d, e, f, g, h, or k, then please provide specific details:

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.

The screenshot shows a web browser window with the URL <http://samhouston.infoed.org/EForm/EFORMPreview.asp?EFORMFormId=C5A2228D-B343-4371-AEE6-D710B23>. The page content is as follows:

IV. Additional Reviews Required
Reviews beyond that of the PHSC may be required for this study (e.g., agency approval). Please indicate which of the reviews below apply to this study.

* 1. Faculty sponsor Yes No

* 2. Institutional Review (e.g. school, prison, agency, business) Yes No

3. If you have already received approval documents, please attach.

V. Project Risk

A. Level of Risk

No more than minimal risk

Participation presents a minimal threat to safety, health and well-being of participant(s)

May cause severe injury, major damage or loss, damage a person's reputation, and/or result in negative public and well-being of participant(s)

C. Procedures

None used Test (attach a copy to your application)

Biological samples Survey (attach a copy to your application)

Physical measurements Interview (attach a copy to your application)

Review of medical/mental health records Phone Interview (attach a copy of script to your application)

Review of medical, treatment, academic, and/or criminal records Other

Psychological Inventory (attach a copy to your application)

D. Sensitive Subject Matter

None used

Abortion

AIDS/HIV

Alcohol

Drugs

Criminal activity

Body composition

Depression

Learning disability

Other

E.

Will the research data be coded to protect the identity of the subject when shared? Yes No

1. If the data will be de-identified or destroyed during or after the research (including audio and videotapes, and photographs), when will this occur? This information should be included in the consent document, particularly if links or identifiers will be maintained indefinitely. Yes No

2. Will you or any of the research team need to access the participant's record? Yes No

2a. If yes to question 2, explain what information will be obtained, by whom, and how.

F. Methods to manage risk (including the risks related to loss of confidentiality or psychological risks).

Explain:

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.

The screenshot shows a web browser window with the URL <http://samhouston.infoed.org/EForm/EFORMPreview.asp?EFORMFormId=CSA2228D-B343-4371-AEE6-D710B23-5E689&System=HS>. The form content is as follows:

F. Methods to manage risk (including the risks related to loss of confidentiality or psychological risks).
 Explain:

G. Will you be using audio or video taping during the data collection stages (include a statement in the consent form) Yes No

VI. Lay Summary
 Summarize the proposed research using non-technical language that can be readily understood by IRB members whose primary concerns are scientific. The complete summary (parts A-F) must not exceed a total of 500 words. Use complete sentences.

A. Statement of purpose/and background information necessary to understand the study:

B. Description of procedures/methods

C. Statement of duration of subject participation.

D. Anticipated benefits:

VIII. Research Participant Selection and Recruitment

A. Participant Population

1. Expected number of participants

2. Age Range (check all that apply):

Newborn to 2 years of age* 7 to 11 Years* 12 to 15 Years* 16 - 17 Years* 18 - 64 Years 65+ Years

(*Submit parental consent form, and verbal and/or written assent documents, where appropriate)

3. From the list below indicate which populations are the focus of recruitment efforts for this research. (Check all that apply)

People with Intellectual Disabilities or Mental Illness
 People who are Decisionally Impaired
 Minors (< 18 years of age)
 K-12 Students in a Classroom Setting
 SHSU students
 SHSU psychology subject pool
 Pregnant Women when Pregnancy is the Primary Focus of the Research
 Prisoners (complete form for involving prisoners in research)
 SHSU employees
 Economically disadvantaged
 Other

B. Recruitment of Participants

1. How will potential participants be initially identified for this research study?
 Direct person-to-person contact Existing documents not in the public domain

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 carefully 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.

http://samhouston.infoed.org/EForm/EFORMPreview.asp?EFORMFormId=C5A2228D-B343-4371-AEE6-D710B23 - Windows Internet Explorer

http://samhouston.infoed.org/EForm/EFORMPreview.asp?EFORMFormId=C5A2228D-B343-4371-AEE6-D710B235E6898&System=HS

Prisoners (complete form for involving prisoners in research)

SHSU employees

Economically disadvantaged

Other

B. Recruitment of Participants

1. How will potential participants be initially identified for this research study?

Direct person-to-person contact Existing documents not in the public domain

Telephone contact Internet

Posted notices (attach copy) E-mail

Letter (attach copy) Mass mailing

Media advertising (newspaper, radio) (attach copy)

Existing documents in the public domain Other Specify

C. Records

1. If participants are to be selected from records outside SHSU, indicate who gave approval for the use of the records. If the records are "private" medical, mental health, criminal history, academic, or student records, provide the protocol, consent documents, letters, etc., for securing consent of the participants for the use of the records. Written documentation for cooperation/permission from the holder or custodian of the records should be attached

IX. Procedures to Obtain Informed Consent/ Assent

A. Indicate all of the types of consent processes to be used in the research, and attach copies of all relevant documents to this application.

Participant signed Informed Consent Assent - Written

Waiver of Informed Consent Waiver of Assent

Parental Permission Prospective Written "Short Form"

Waiver of Parental Permission

Cover Letter

B. Please indicate whether the Principal Investigator will personally perform the consent process, including the documentation of informed consent and/or assent, or whether the PI will retain responsibility for overseeing this process, but delegate the authority to perform these duties to others:

Only the PI will obtain consent PI, Co-PIs will obtain consent

Only Delegates will obtain consent

If the PI will allow delegates to obtain informed consent, please indicate through a list of individual names, by titles, or by classes of persons who will be designated to obtain consent. Please note that these persons must be listed as Key Research Personnel. Please also include a description of the training that will be required or given to these persons prior to their participation in this research.

Investigator Assurance

I certify that the information provided in this application is complete and correct. I understand that as Principal Investigator, I am ultimately responsible for the protection of the rights and welfare of human subjects and the ethical performance of the research. I agree to comply with all applicable UIC policies and procedures, and applicable federal, state and local laws. I also agree to the following: • The research will only be performed by qualified personnel as specified in the approved research application and/or protocol, • No changes will be made to the research protocol (except when necessary to eliminate apparent immediate hazards to the subject), or the consent process (if one is required) without prior approval by the SHSU PHSC, • Legally effective informed consent/assent will be obtained from all human subjects, unless this requirement is waived by the SHSU PHSC, using only the recruitment materials and informed consent/assent documents that have been approved by the SHSU PHSC. The potential benefits of participation will not be overstated and reasonably anticipated risks will not be minimized. Subjects will be asked open-ended questions to try and ensure adequate comprehension of the information so as to allow for truly informed consent to participate. • Unanticipated problems involving risks to subjects or others (including adverse events), other reportable events, and subject complaints will be reported to the SHSU PHSC in a timely manner. I certify that I have completed the required educational program on ethical principles and regulatory requirements in Human Subject Protections. I further certify that the proposed research is not currently underway and will not begin until PHSC approval has been obtained.

* I agree with the above:

* Date Application Completed:

Done Internet 100%

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 Sharla Miles (sharla_miles@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.

Components for **Initial Review**
Submit

	Current Submission			
Form/Document Name	Edit	Status	Upload	Remove
Initial Application		Completed		Mandatory
Consent Form(s) <i>Consent Forms</i>		Completed		

[Add Institution Forms/Supporting Documents](#)

Upload

Upload new document

Name

Location






Category

Add Initial Review Components

Form Name	Type	Add
Assent Form	Conditional Use	<input type="checkbox"/>
Consent Form(s)	Conditional Use	<input type="checkbox"/>
Cover Letter	Conditional Use	<input type="checkbox"/>

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.

Components for Initial Review		Submit 		
		Current Submission		
Form/Document Name	Edit	Status	Upload	Remove
Initial Application		Completed		Mandatory
Consent Form(s) <i>Consent Forms</i>		Completed		

[Add Institution Forms/Supporting Documents](#)

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.

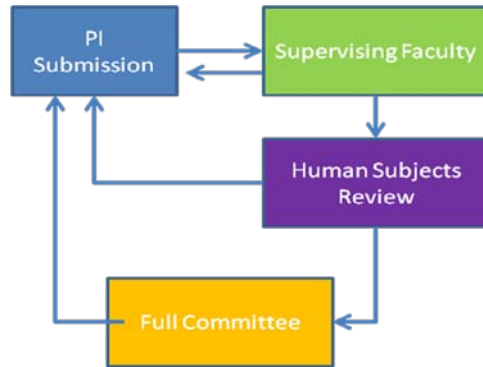
Your supervising faculty instructor will not be able to access your application to make changes for you.

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

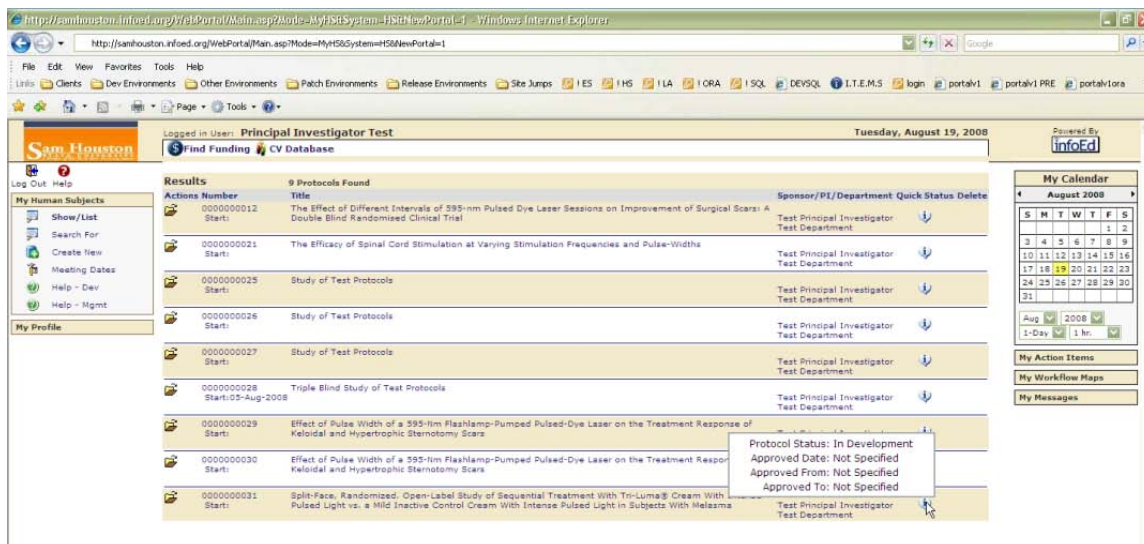
If the user is submitting a revised edition, type 2 in the version box. The version needs to be changed only if the initial submission is returned for modifications.

Routing an Application.

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



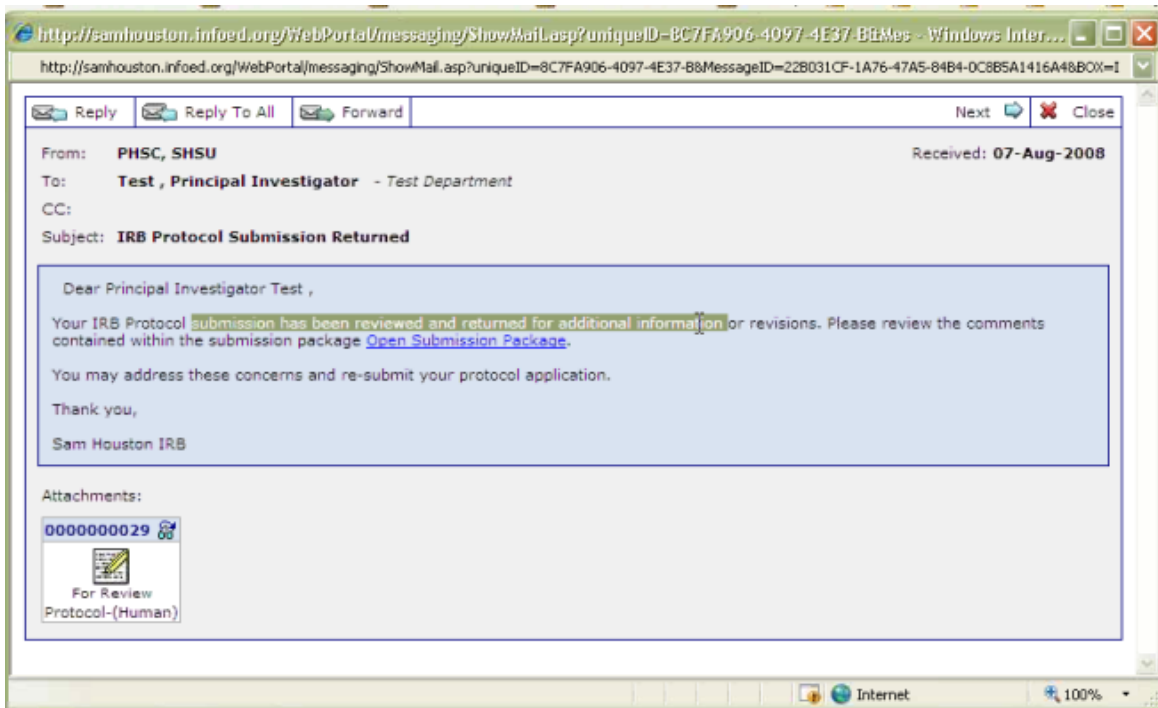
A user can check on the status of an application by logging into the system, opening **My Human Subjects**, and clicking **Show/List**. Opening the folder to the application will bring up the Submission folder. The status of the application will be listed here. If the status says “In Development,” then 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.



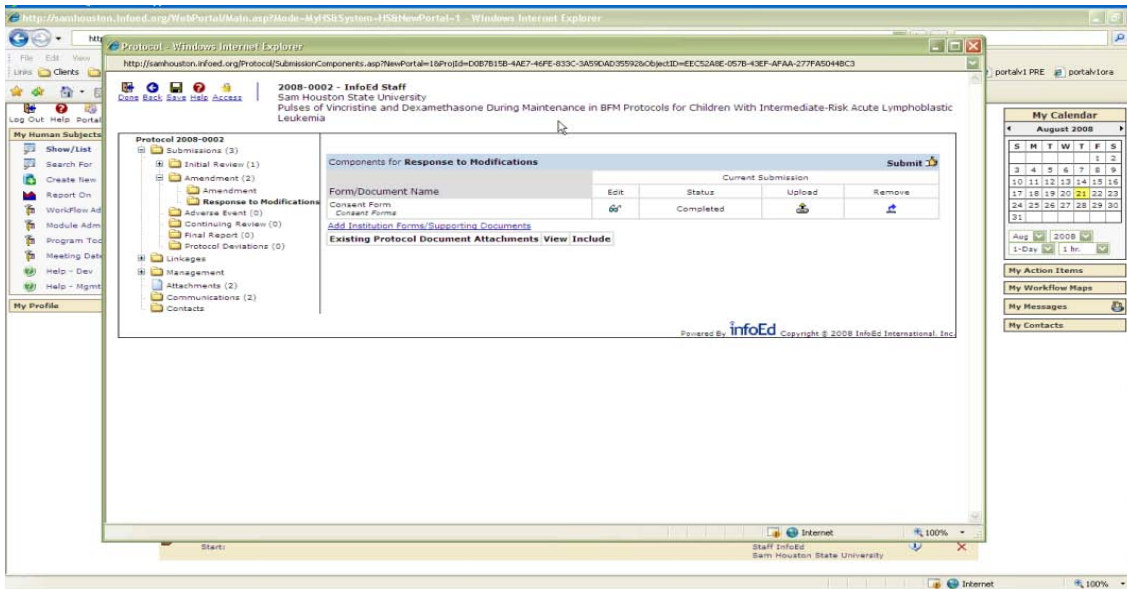
If a PI wishes to delete an application, they should email the Office of Research and Sponsored Programs PHSC coordinator, Sharla Miles (sharla_miles@shsu.edu) with the application # and a brief explanation as to why the application needs to be deleted.

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.



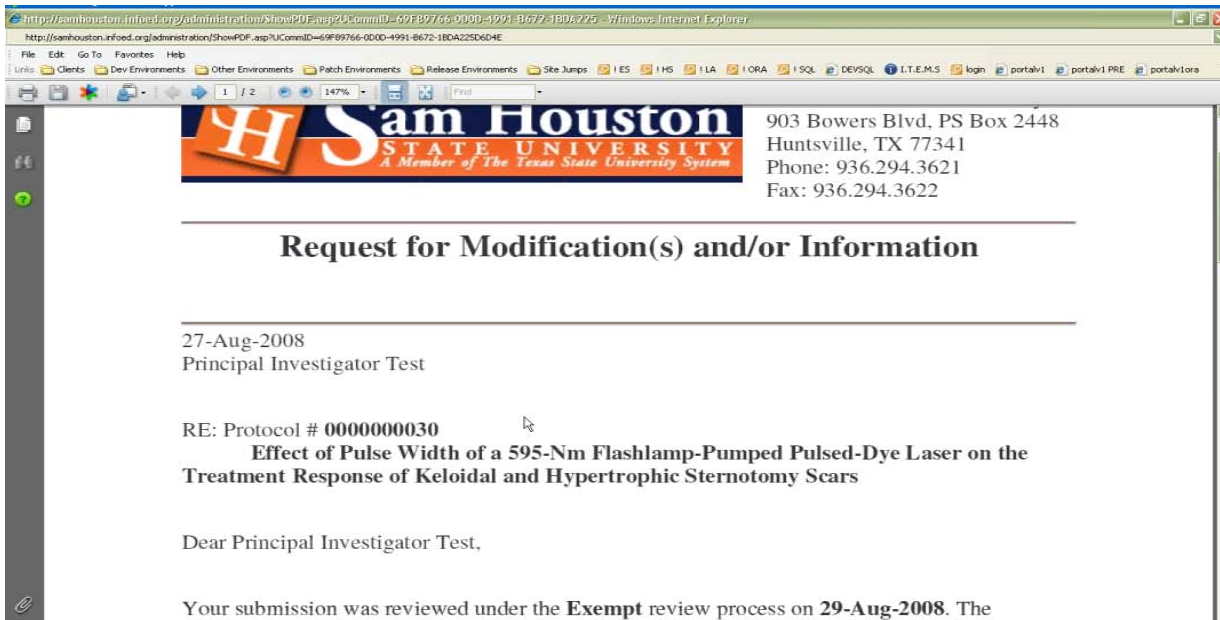
To find out what modification are requested, the PI should

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.

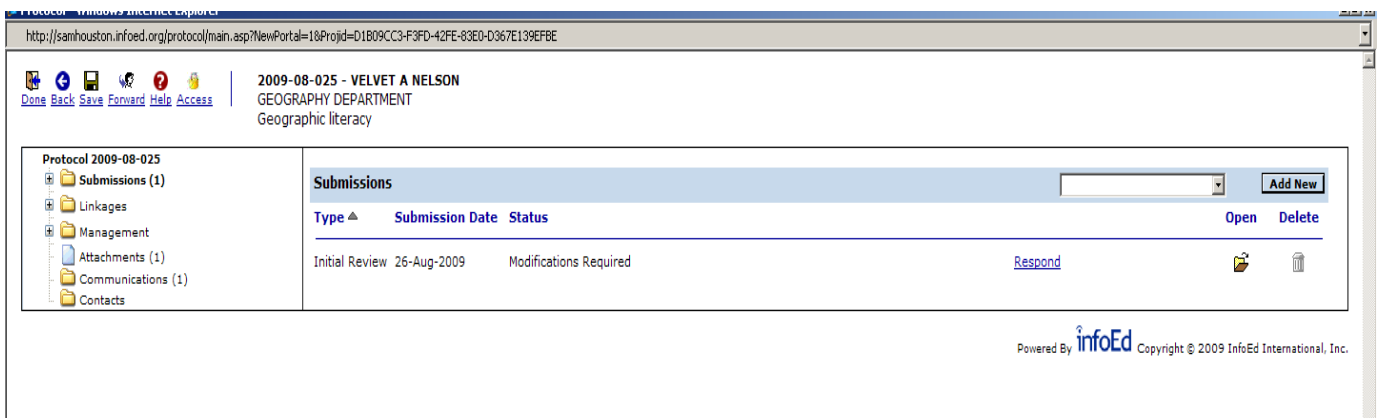
The revised protocol will be sent through the routing process again.

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.



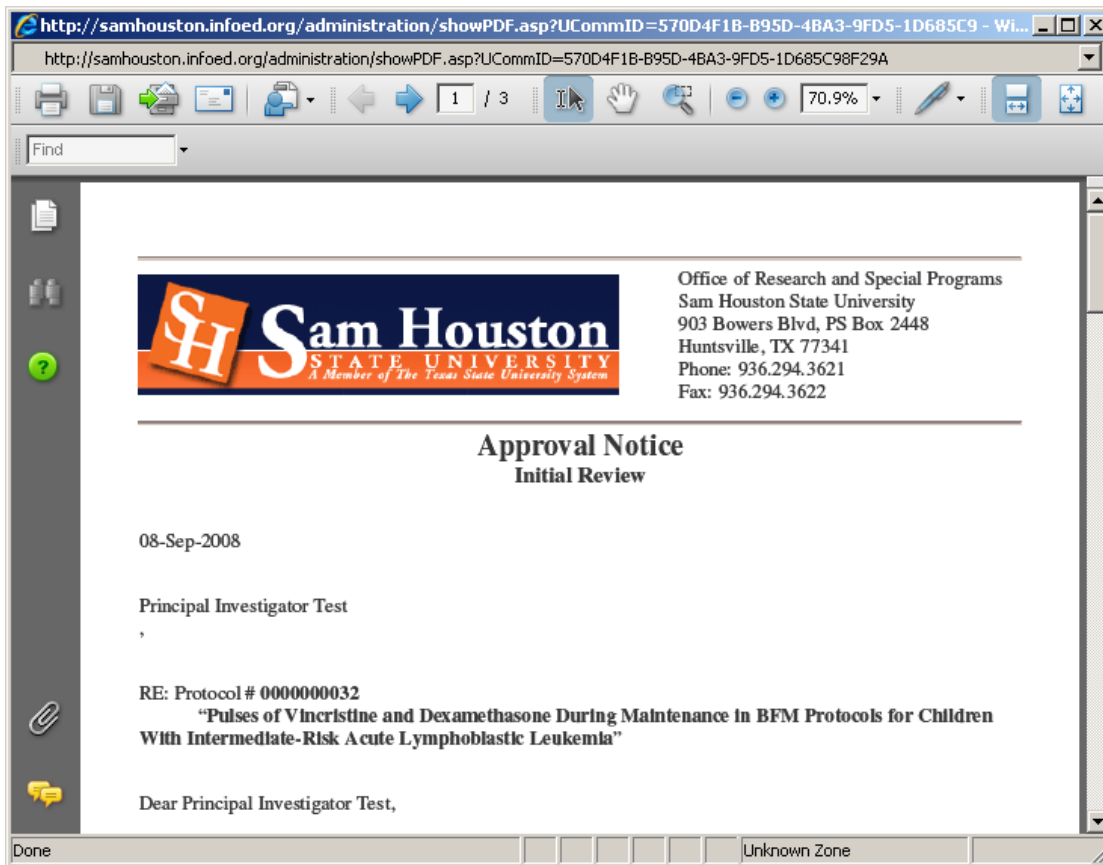
When opening the applications, the **Submissions** screen appears which will have at least 2 lines, Initial Review and Request for Modifications. Click the blue hyperlink **Respond** on the latter line and the user will be taken to the application itself to make changes.



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.*