

Sam Houston State University

Protection of Human Subjects Committee (PHSC/IRB)

Regular and Thesis/Dissertation 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/

Sam Houston STATE UNIVERSITY eRA Portal Streamlining Electronic Research Administration

Home

Home

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

Get Profile

Home

Login

Get Profile

SPIN

GENIUS

Get Profile Login

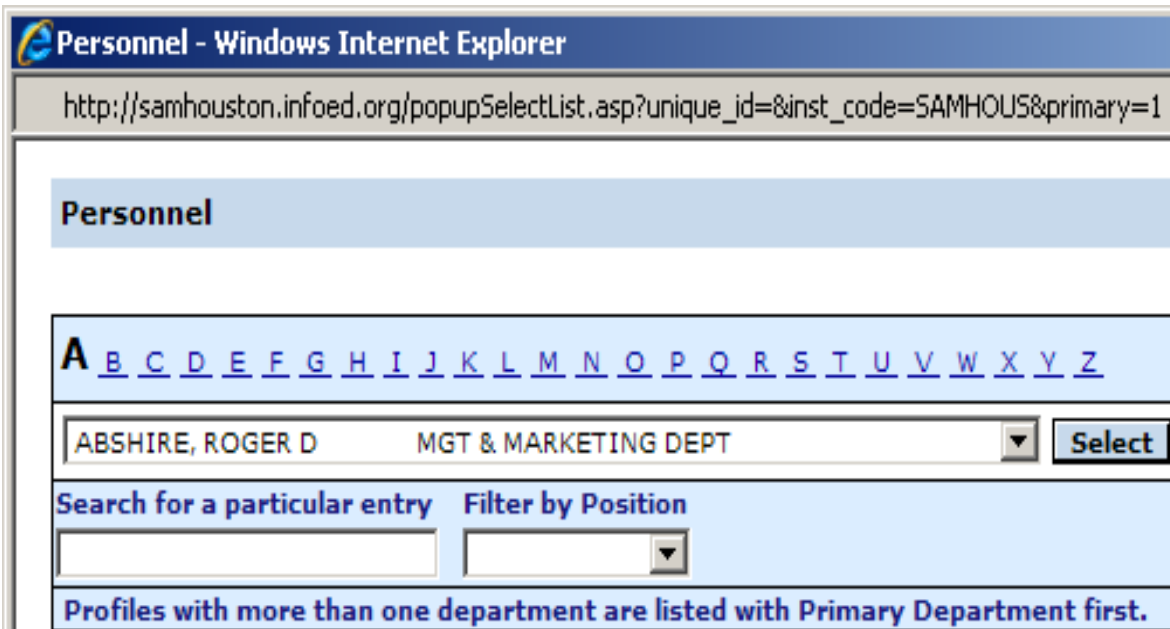
Step 1... Select your **State/Province**
Texas

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

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

Profile Not Found in List

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.



Personnel - Windows Internet Explorer

http://samhouston.infoed.org/popupSelectList.asp?unique_id=&inst_code=SAMHOUS&primary=1

Personnel


A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

ABSHIRE, ROGER D MGT & MARKETING DEPT

Search for a particular entry Filter by Position

Profiles with more than one department are listed with Primary Department first.

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



Sam Houston State University eRA Portal Streamlining Electronic

Log Out Help New Portal | Get Profile

Get Profile Login

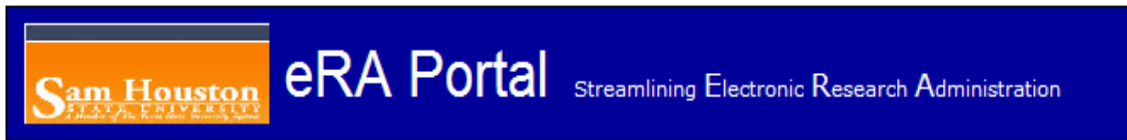
Step 1... Select your **State/Province**
Texas

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

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

Step 4... **Is this the Profile?**
- select -

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



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 and will include the User ID (SHSU login) and password. The user is then able to use this information to log onto the system.

New Faculty and Student Login

New faculty and 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.

Sam Houston STATE UNIVERSITY
eRA Portal Streamlining Electronic Research Administration

Log Out Help New Portal | Get Profile

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:** 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, new faculty and 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 validated, 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.

Sam Houston STATE UNIVERSITY
A Member of The Texas State University System

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**.

Persons Not Affiliated with SHSU

PIs who are not affiliated with SHSU and who want to conduct human subjects research at Sam Houston State University must notify the ORSP (936.294.3876) and give the information necessary for that office to provide them with a profile. Once they have a validated profile, they will be able to access this online system.

Creating a New Regular or Thesis/Dissertation Application


This application is to be used by graduate students who are working on their theses, dissertations or by faculty and staff of Sam Houston State University. 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 horizontal list of letters from A to Z, with the letter 'K' highlighted. Below the letters is a dropdown menu showing the selected name: "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

Initial Application Complete

Page 1

A.

Is this project a:

Classroom Project

Regular Initial

Thesis/Dissertation

PAGES

Save
 Check In/Out
 Quest Hist
 Form Hist
 Print

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.

Once the application opens, the user is asked to identify the project as one submitted by faculty and staff, or thesis and dissertation students (pull-down box under A). Select the appropriate type and a blue hyperlink will appear below the type of application box that is highlighted **Initial Regular, or thesis/dissertation**.

NOTE: Graduate students who are conducting supervised research that is not a class requirement nor a thesis or dissertation should still use the Thesis/Dissertation Application. This is necessary in order for the route to include everyone who is required to review supervised research. Once the application is submitted, it will be forwarded to the supervising faculty member.

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

Save Check In/Out Quest Hist Form Hist Print	<p>Initial Application <input type="checkbox"/> Complete</p> <p>Page 1</p> <p>A.</p> <p>Is this project a: Regular Initial</p> <p>Please complete the regular Initial Application form. Initial Regular Application Incomplete</p>
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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 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.

Save Check In/Out Quest Hist Form Hist Print	<p>Initial Regular Application <input type="checkbox"/> Complet</p> <p>Page 1</p> <p>Office of Research and Special Programs Sam Houston State University Huntsville, TX 77341 (936) 294-3876</p> <p>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</p> <p><input type="checkbox"/> *I hereby certify that a copy of my HPPERT Certification has been sent to the ORSP (Office of Research and Special Programs)</p> <p>I. Research Title</p> <p>*Research Title: SHSU</p> <p>II. Personnel:</p> <p>A. Principal Investigator (PI):</p> <p>*Name: KERCHER, GLEN A *University Status/Title: </p> <p>*Department: *College: </p> <p>*Phone Number: *Email Address: </p> <p>B. Faculty Sponsor - required when PI is a student:</p> <p>Name: University Status/Title: </p> <p>Department: College: </p> <p>Phone Number: Email Address: </p> <p>C. Co-Investigators and any other Key Research Personnel (Co-PIs) </p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Name</th> <th style="width: 20%;">Department</th> <th style="width: 20%;">College</th> <th style="width: 20%;">Email Address</th> <th style="width: 20%;">University Status/Title</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Name	Department	College	Email Address	University Status/Title					
Name	Department	College	Email Address	University Status/Title							

documentation should be uploaded at (III.D.6). Click the plus sign, find the document to include in the application, and then select the upload button.

6.
+

If you have already received approval documents, please attach.

IV. Conflict of Interest (COI) Disclosure

All investigators involved in this research must disclose to the PHSC all real, apparent, or perceived conflicts of interest, including significant financial, professional, and institutional conflicts. The term "investigator" is defined as any person responsible for the design, conduct, or reporting of the research. This includes, but is not limited to, the Principal Investigator, Co-Investigator, and other key research personnel. Disclosure statements regarding these conflicts may also be required in the informed consent document(s).

A. Financial COI

*1. Do any investigators, or family members thereof, have a real, apparent, perceived, or potential significant financial COI associated with this study? Yes ▾

1A.
Summarize the conflict:

2. Has a management plan been developed to address the significant financial COI disclosed above? Please note: Final PHSC approval of the research cannot be provided until a management plan is in place.

No. A financial conflict has not been reported and a management plan has not been developed. SHSU personnel: contact your Department Head for further instructions.

No. A COI has been reported, but a conflict of management plan has not been developed.

Yes. A conflict management plan has been developed. Provide a summary of the management plan to be implemented in order to minimize the affect of the conflict on the design, conduct, or reporting of the research and/or the integrity of the human subject protection program or provide a copy of the finalized written management plan(s), if available:

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)

Conflict of Interest (IV) Select Yes or No from the pull-down menu.

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 this to determine if there is agreement about risk.

Procedures (V B) Check the types of procedures that will be used in the research. More than one procedure may be checked. The PI is then prompted to upload documents related to those procedures. By clicking the plus sign again, additional uploads are allowed.

PAGE 3
 C
 D
 E
 G

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 of the protocol 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

CI. +

Upload documents related to the question above.

D. Sensitive Subject Matter

None used
 Abortion
 AIDS/HIV
 Alcohol
 Drugs
 Criminal activity Learning disability
 Body composition Other
 Depression

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.

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

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

Explain:

Sensitive Subject Matter (V C) Choose all that apply.

Protecting Anonymity and Confidentiality (V D) Answer each question.

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

Lay Summary (V I) Under sections A through E, the PI is asked to summarize the research project in *lay* terms, so that persons unfamiliar about the area of investigation can determine what is being proposed. Please note that in the Scientific Summary of VII, more detailed information is requested about the study.

MEM
PAGE
S

H. Will you be applying for a Certificate of Confidentiality?
 Yes No (include this information in the consent document. When the PHSC approves your research, submit a request for a Certificate of Confidentiality to the appropriate federal agency. After you receive the Certificate, you must submit an Amendment to the PHSC to receive SHSU approval. Research participants may only be enrolled after PHSC approval of the amendment and Certificate of Confidentiality)

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 risks:

E. Anticipated benefits:

VII. Scientific Summary

A. Briefly state the research hypothesis being explored by the current research. Include a discussion of the present knowledge relevant to the research and the aims and significance of the research. Cite appropriate literature to support the relevance and importance of this research.

B. Please describe in chronological order all the tasks/tests or procedures subjects will be asked to complete in participating in this research.

Scientific Summary (VII) This section asks for more a broader research context, including hypotheses, state of knowledge, and related research from the literature.

Protected Health Information (VII E) This inquires about 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.

SHSU

Yes No

E. Does the research involve the use and disclosure of protected health information (PHI)? Health information means any information (oral or recorded in any form) that is created or received by a health care provider, health care plan, health authority, employer, life insurer, school or university, or healthcare clearing house and relates to the past, present or future physical or mental health or condition of an individual. For example, if you are reviewing or creating medical records as part of this study, you are using PHI.

Yes No

F. Will any portion of the research involve deception?

Yes No

If yes to question F, please attach debriefing form.

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*

3 to 6 Years*

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

4. Federal regulations require that the selection of research subjects be equitable in order for the IRB to approve the research. If a particular population will be excluded (i.e. pregnant women, non-English speaking), you must JUSTIFY the exclusion of this population.

No subjects will be excluded based upon sex, race, or ethnic group, or religion.

The following population of subjects will be excluded from the research:

Indicate Populations and give reason(s) for exclusion:

Use of Deception (VII F) If deception is used, a debriefing document should be uploaded where indicated.

Research Participant Selection and Recruitment (VIII) Check all that apply.

CSMS
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B. Recruitment of Participants

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

<input type="checkbox"/> Direct person-to-person contact	<input type="checkbox"/> Existing documents not in the public domain
<input type="checkbox"/> Telephone contact	<input type="checkbox"/> Records (e.g. medical, employment, school)
<input type="checkbox"/> Posted notices (attach copy)	<input type="checkbox"/> Internet
<input type="checkbox"/> Letter (attach copy)	<input type="checkbox"/> E-mail
<input type="checkbox"/> Media advertising (newspaper, radio) (attach copy)	<input type="checkbox"/> Mass mailing
<input type="checkbox"/> Existing documents in the public domain	<input type="checkbox"/> Other Specify <input style="width: 100px;" type="text"/>

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.

D. Compensation and costs of participation

1. Will participants receive any compensation or inducements (i.e. money, gifts or gift certificates) before, during, or after participation in the study? Yes No

IX a.

Informed Consent applies to this application Yes No

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.

<input type="checkbox"/> Written Informed Consent	<input type="checkbox"/> Assent - Written
<input type="checkbox"/> Waiver of Informed Consent	<input type="checkbox"/> Assent - Verbal
<input type="checkbox"/> Parental Permission	<input type="checkbox"/> Waiver of Assent
<input type="checkbox"/> Waiver of Parental Permission	<input type="checkbox"/> Alteration of Consent
<input type="checkbox"/> Waiver of Documentation of Consent	<input type="checkbox"/> Prospective Written "Short Form"

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:

<input type="checkbox"/> Only the PI will obtain consent	<input type="checkbox"/> PI, Co-PIs, and delegates will obtain consent
<input type="checkbox"/> Only Delegates will obtain consent	

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

Records (VIII C) This addresses needing to **access records** about participants outside the University. Appropriate documentation for cooperation/permission from the custodian of the records should be uploaded where indicated.

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. Provide justification for any exceptions to the

X. Request for Waiver of Consent, Alteration of Consent, or Waiver of Documentation

The PHSC may (1) approve a consent process that does not include, or alters, some or all of the elements of informed consent, or (2) the PHSC may waive the requirement to obtain written consent (called a waiver of documentation), or (3) the PHSC may waive the requirement to obtain informed consent entirely. In order to make these determinations, the PHSC must ensure that the Federal requirements for each waiver/alteration criterion are met and justified for the specific research protocol.

A. Are you requesting a waiver of informed consent or an alteration of consent under 45 CFR 46.116 (d) for all or part of the research? Yes No

45 CFR 46.116(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

1a

Are you requesting a:

- Waiver for all of the research Waiver for recruitment purposes An alteration of consent

Please provide a justification for your request:

B. Are you requesting a waiver of documentation of informed consent under 45 CFR 46.117 (c)? Yes No

45 CFR 46.117(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

If YES, please indicate which of the following justifications is being used to request a waiver of documentation and then provide protocol specific justification for the waiver under either criteria:

Explanation:

- The only record linking the subject and the research would be a signed consent document, the principal risk or harm of the research would be a breach of confidentiality and each subject will be asked whether they want documentation linking themselves and the research, and the subject's wishes will govern.
- The research involves no more than minimal risk or harm to the subject and involves no procedures for which written consent is normally required outside of the research context.

Explanation:

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

- The only record linking the subject and the research would be a signed consent document, the principal risk or harm of the research would be a breach of confidentiality and each subject will be asked whether they want documentation linking themselves and the research, and the subject's wishes will govern.
- The research involves no more than minimal risk or harm to the subject and involves no procedures for which written consent is normally required outside of the research context.

Explanation:

If documentation of informed consent is waived, the PHSC may require the investigator to provide subjects with a written statement regarding the research, which contains all the elements of informed consent. Please provide such a written document for review and label it "Subject Information Sheet". Be sure that the document has a footer with version number and date.

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:

*Application Document Version #:

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 Initial Application 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) Consent Forms		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.

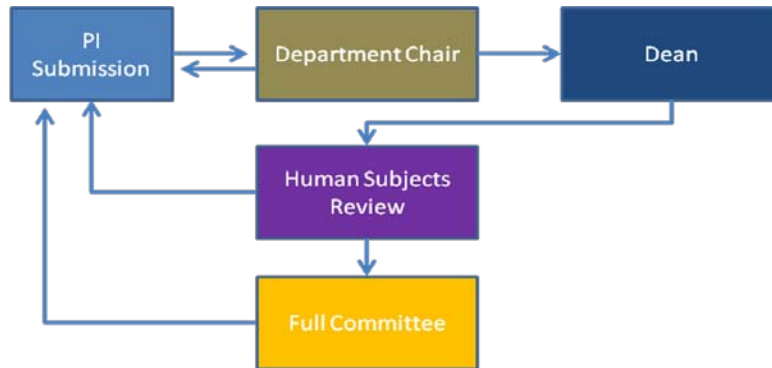
Your supervising faculty instructor will not be able to access your application to make changes for you.

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

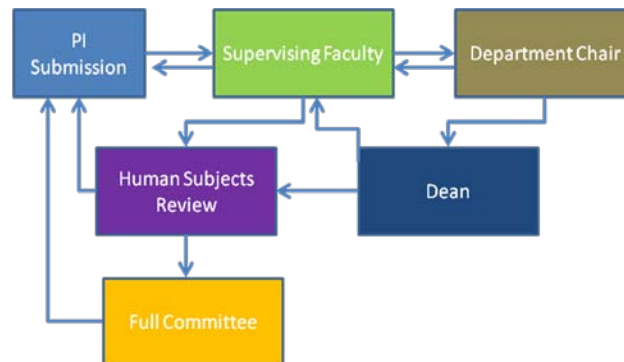
If the user is submitting a revised edition, type 2 in the version box. The version needs to be changed only if the initial submission is returned for modifications.

Routing an Application.

Once a **Regular Application** is submitted, it will follow the route illustrated below.



The route for the **Thesis/dissertation Application** is similar but adds a review by the supervising faculty member.



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.

Logged in User: Principal Investigator Test Tuesday, August 19, 2008

Find Funding CV Database

Results: 9 Protocols Found

Actions	Number	Title	Sponsor/PI/Department	Quick Status	Delete
	000000012	The Effect of Different Intervals of 595-nm Pulsed Dye Laser Sessions on Improvement of Surgical Scars: A Double Blind Randomized Clinical Trial	Test Principal Investigator Test Department		
	000000021	The Efficacy of Spinal Cord Stimulation at Varying Stimulation Frequencies and Pulse-Widths	Test Principal Investigator Test Department		
	000000025	Study of Test Protocols	Test Principal Investigator Test Department		
	000000026	Study of Test Protocols	Test Principal Investigator Test Department		
	000000027	Study of Test Protocols	Test Principal Investigator Test Department		
	000000028	Triple Blind Study of Test Protocols	Test Principal Investigator Test Department		
	000000029	Effect of Pulse Width of a 595-lm Flashlamp-Pumped Pulsed-Dye Laser on the Treatment Response of Keloidal and Hypertrophic Sternotomy Scars	Test Principal Investigator Test Department		
	000000030	Effect of Pulse Width of a 595-lm Flashlamp-Pumped Pulsed-Dye Laser on the Treatment Response of Keloidal and Hypertrophic Sternotomy Scars	Test Principal Investigator Test Department		
	000000031	Split-Face, Randomized, Open-Label Study of Sequential Treatment With Tri-Luma® Cream With Pulsed Light vs. a Mild Inactive Control Cream With Intense Pulsed Light in Subjects With Melasma	Test Principal Investigator Test Department		

Protocol Status: In Development
Approved Date: Not Specified
Approved From: Not Specified
Approved To: Not Specified

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.

Reply Reply To All Forward Next Close

From: PHSC, SHSU Received: 07-Aug-2008

To: Test, Principal Investigator - Test Department

CC:

Subject: IRB Protocol Submission Returned

Dear Principal Investigator Test,

Your IRB Protocol [submission](#) has been reviewed and returned for additional information or revisions. Please review the comments contained within the submission package [Open Submission Package](#).

You may address these concerns and re-submit your protocol application.

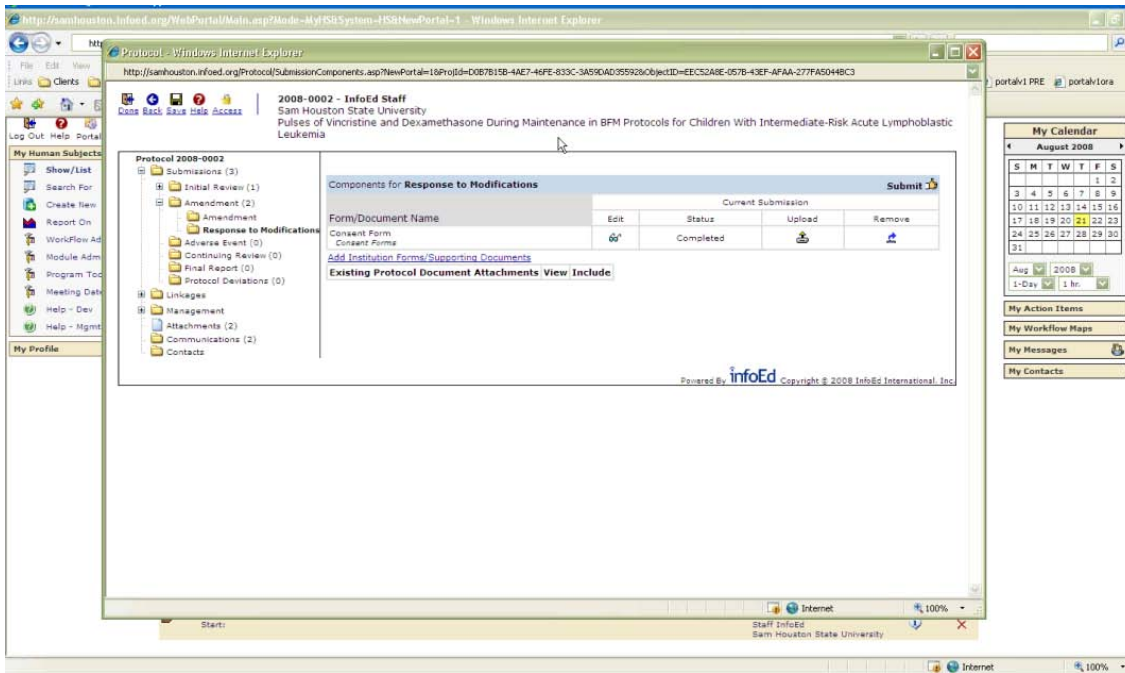
Thank you,

Sam Houston IRB

Attachments:

000000029 For Review Protocol-(Human)

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.



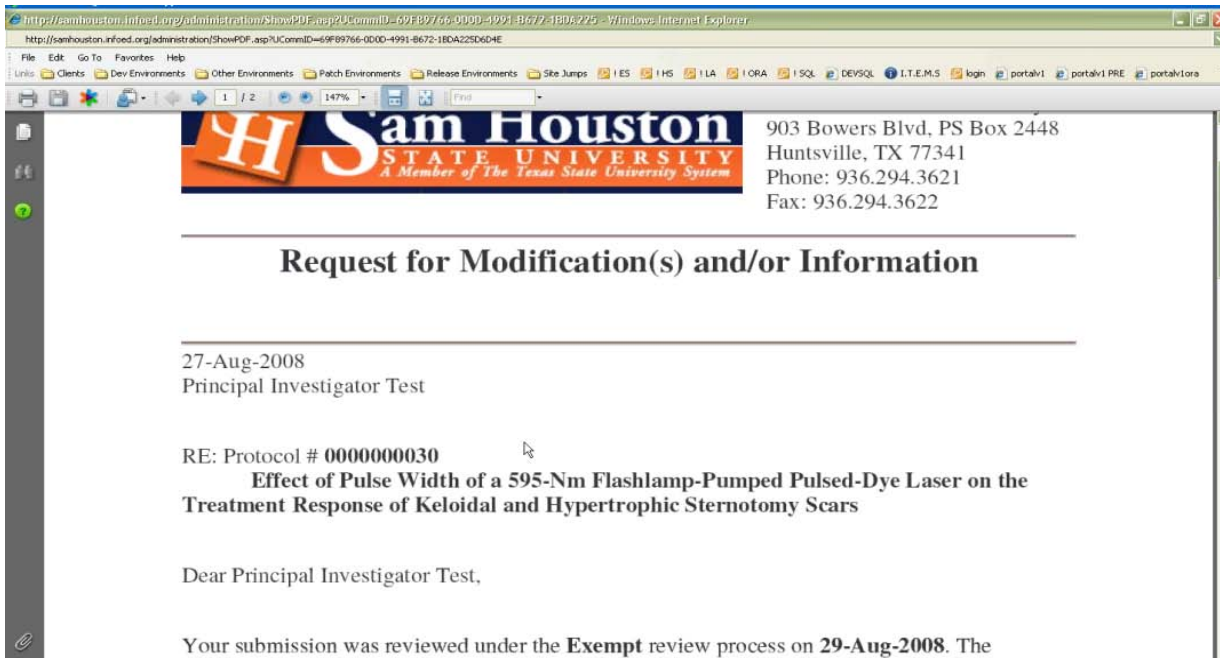
To find out what modification are requested, the PI should

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,
8. Re-submit the application.

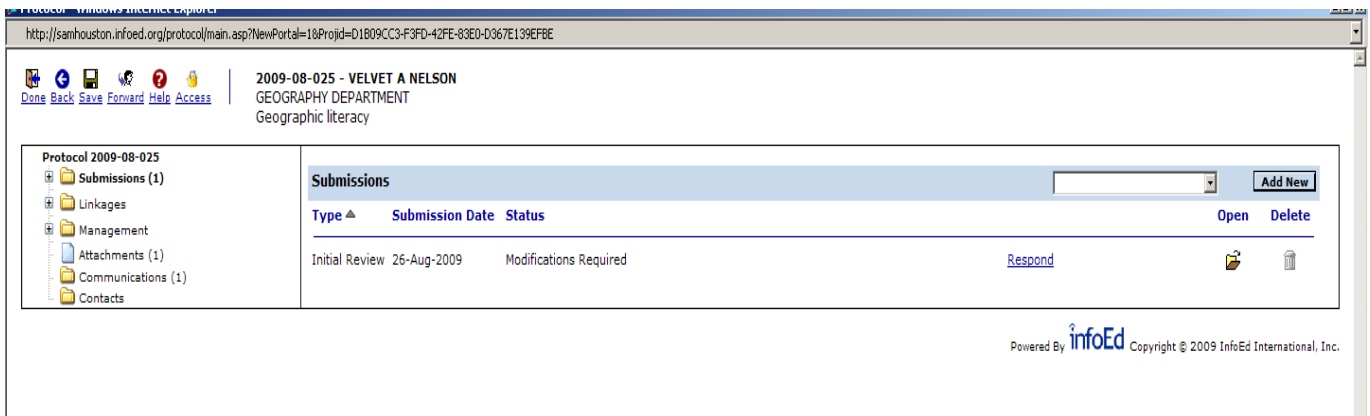
The revised protocol will be sent through the routing process again.

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.



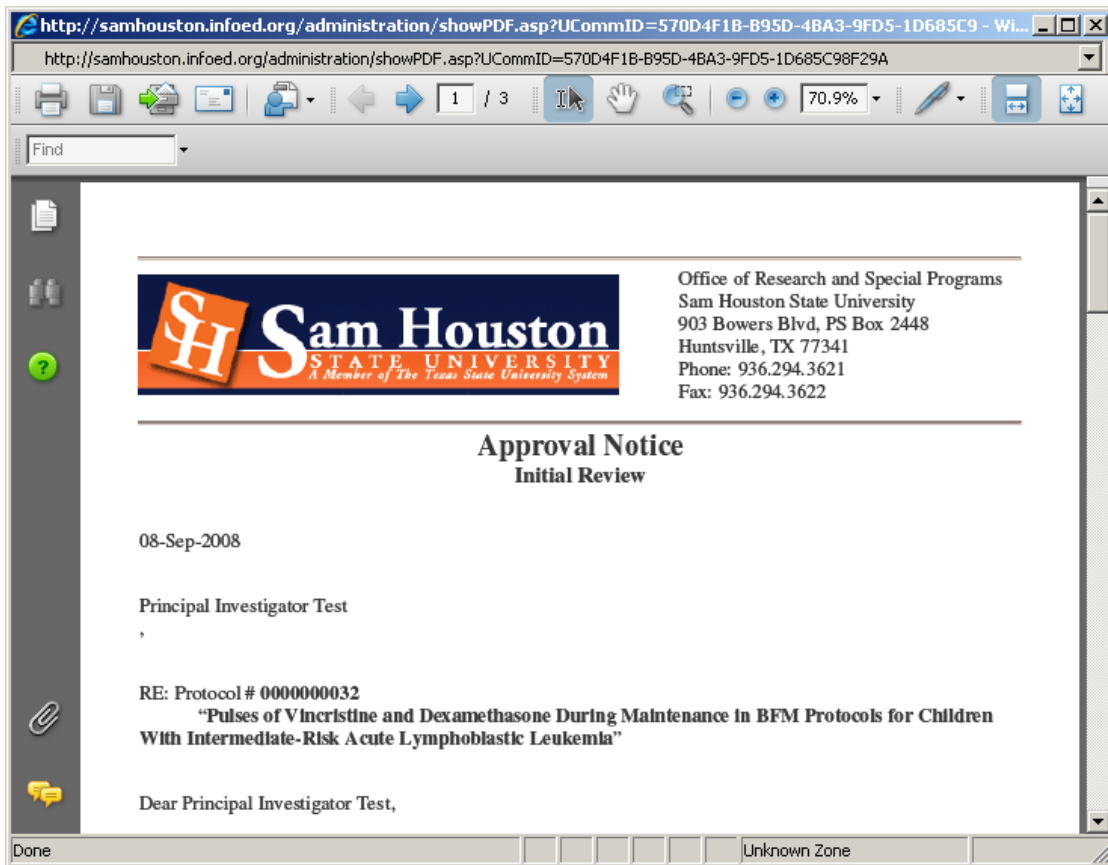
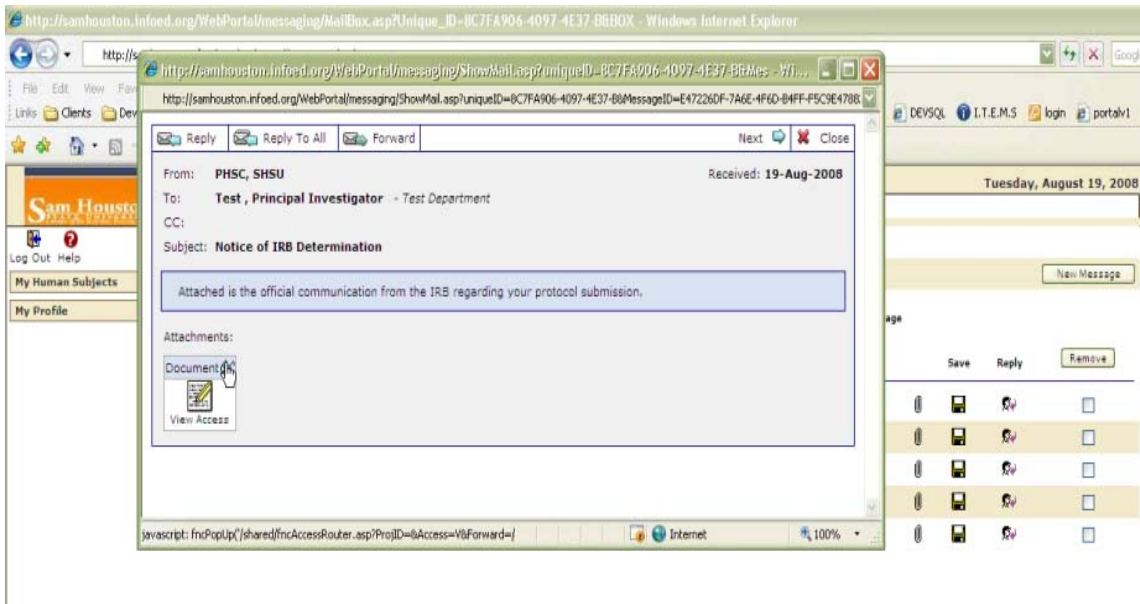
When opening the applications, the **Submissions** screen appears which will have at least 2 lines, Initial Review and Request for Modifications. Click the blue hyperlink **Respond** on the latter line and the user will be taken to the application itself to make changes.



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. Approval 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.*