

# IRB PRESENTATION: REGULAR/THESIS/DISSERTATION APPLICATION

BY SHARLA MILES  
OFFICE OF RESEARCH & SPONSORED PROGRAMS  
SAM HOUSTON STATE UNIVERSITY  
AUGUST 6, 2011

# STEP 1: CREATING YOUR PROFILE

- Why we are required—significance of the process?
- <http://samhouston.infoed.org/>
- **Login and Get Profile:** 2 important buttons – left margin
- Get Profile
- Getting a profile involves 5 steps:
  1. ID state (TX); click continue
  2. Select university (SHSU); click continue
  3. “Get profile” – check the box for, “Profile Not Found in List”
  4. User asked to complete: Name (under which you are registered at SHSU); SHSU email (system does not recognize some of the other carriers); primary department; and username & password; click continue
  5. Email confirmation of user’s login information—includes the user ID (SHSU login) and password.

# 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 (936.294.4875) 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.

# InfoEd Home Page

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** eRA Portal Streamlining Electronic Research Administration

Help New Portal Home

» 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.**



# eRA Portal

Streamlining Electronic Research Administration



[Log Out](#)



[Help](#)



[New Portal](#)

## 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



 [Log Out](#)  [Help](#)  [New Portal](#)

**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

**Last Name** Johnston

**First Name** Leroy

**Middle Name**

**Email Address** edu\_lxj@shsu.edu

**Primary Department** COLLEGE OF EDUCATION

**Username** edu\_lxj at least 6 characters

**Password** ■■■■■■ at least 6 characters

**Re-Enter Password** ■■■■■■



## 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**

**Step 4...** **Is this the Profile?**  
Yes, this is my profile

**Last Name** BARRUM

**First Name** JAMES

**Middle Name** A

**Email Address** ICC\_JAB@SHSU.EDU

**Primary Department** COLLEGE OF CRIMINAL JUSTICE

**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

**\*\*\*Once your Profile is created, you will be able to use the program immediately. ORSP no longer is required to manually validate profiles.\*\*\***

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

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



# eRA Portal

Streamlining Electronic Research Administration

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Home

>> Home

Login

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

Once Profile is set, Click Login and enter name and password



# eRA Portal

Streamlining Electronic Research Administration

## Login

Home

>> Login

Get Profile

SPIN

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## Login

Username

Password

Login

Click Login or hit Enter key



[Find Funding](#)



[CV Database](#)



[Log Out](#)



[Help](#)



[Portal](#)

### My Human Subjects



[Show/List](#)



[Search For](#)



[Create New](#)

4 Records Found.

### My Open Action Items

**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=

- User name appears at top of screen
- Two categories: My Human Subjects & My Profile
- See Next Slide for further instructions

**My Profile**

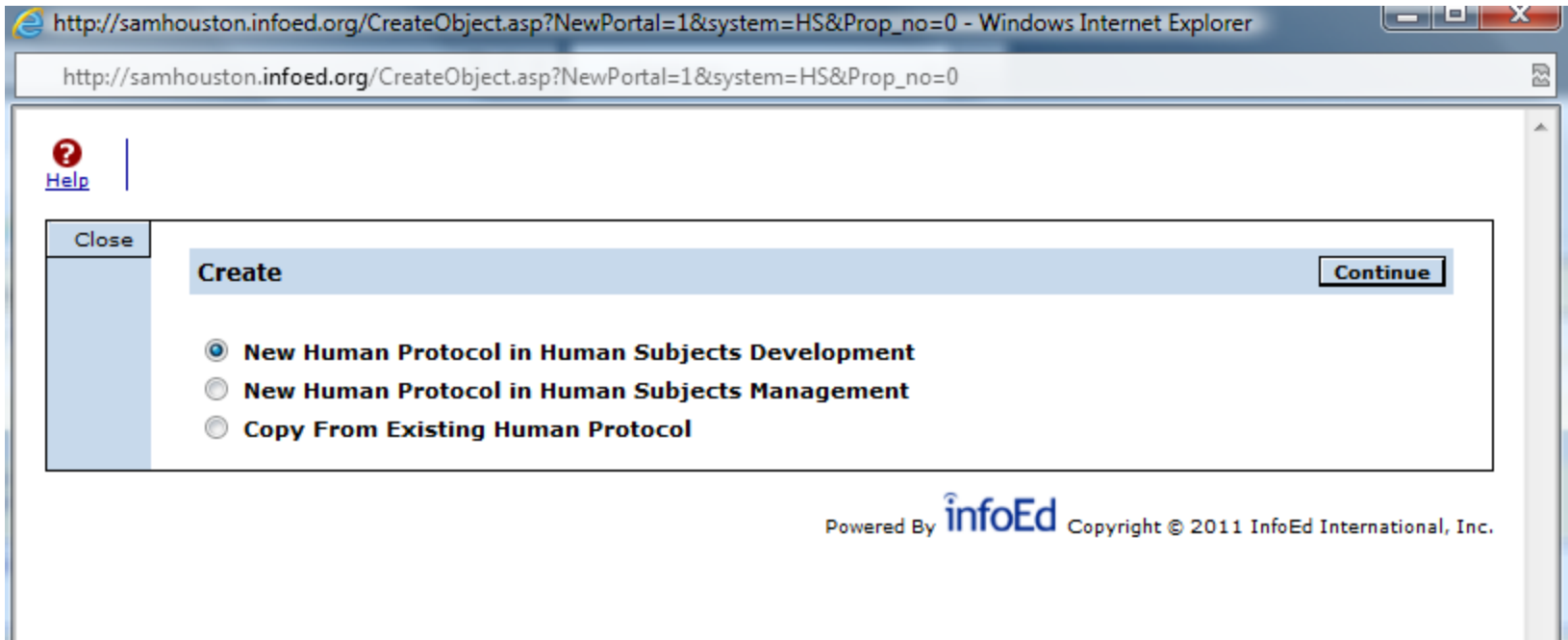
The **My Human Subjects** list is the most important for most uses with this system. Here are found links to new applications, modifications of previously submitted protocols that are under review, amendments, adverse event reporting, continuing review, final reports, and help. While scrolling down the 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 Regular Initial 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**.


Close

### Protocol Creation

Continue

Enter Title

In the **Protocol Creation** box, enter the title of the research and click **continue**.


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### Select PI

Create New Profile Continue

[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](#)

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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 X4875 for assistance. Click **continue**.

Submission General - Windows Internet Explorer  
 http://samhouston.infoed.org/compliancenet/ui/DevSubmission.aspx?ProjId=16BCC214-94E5-436A-8D1C-B18046E41A5D&objectid=195E4F4F-9DFB-4393-B74C-36E347D6003F

Done Back Save Forward Help Access Show | 2011-2012 IRB Presentation PowerPoint  
 Sharla G Miles - RESEARCH & SPONSORED PROGRAMS

Protocol  
 2011-07-029  
 Change Project Information

Protocol 2011-07-029  
 Submissions (1)  
 Initial Review (1)  
 Initial Review

**Components for Initial Review** Submit

Form/Document Name	Current Submission			
	Edit	Status	Upload	Remove
IRB Application Application Form		Incomplete		Mandatory

[Add Institution Forms/Supporting Documents](#)

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

Uploading attachments—click on [Add Institution Forms/Supporting Documents](#)

Initial Application  Complete

Page 1

A.

Is this project a:

- Classroom Project
- Regular Initial
- Thesis/Dissertation

Save

Check In/Out

Quest Hist

Form Hist

Print

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”:

Formal application appears below

Menu







Save

Check In/Out

Print

See Next Slide  
for further  
information

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. 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.

<b>MENU</b> <b>PAGES</b>	 Save	<b>IRB Application</b> <input type="checkbox"/> Complete
	 Check In/Out	<b>Page 1</b>
	 Table of Contents	<b>Contact Information</b>
	 Quest Hist	Office of Research and Sponsored Programs Sam Houston State University Huntsville, TX 77341 (936) 294-4875
	 Form Hist	<b>Type of Application</b>
	 Print	Is this project a: <input type="text" value="Thesis/Dissertation"/>
	<b>Page 3</b>	<b>Initial Regular Application</b>
		<b>I. Ethics Certification (CITI)</b>
		A copy of your CITI Certification needs to be on file with the Office of Research and Sponsored Programs (ORSP). A copy of this certificate will be emailed automatically to Sharla Miles upon completion of the training.
		<input type="checkbox"/> *I hereby certify that a copy of my CITI Certification has been sent to the ORSP.

- The application is the same for the Regular Initial option, which is only for Faculty use.
- At the top of **Page 3** 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 me. A copy of this certificate **does not** have to be attached to the application.



## II. Research Title



\*Reserach Title:

2011-2012 Thesis/Dissertation and Regular Initial PowerPoint Presentation

## III. Personnel:



### A. Principal Investigator (PI)

\*Name [Miles, Sharla G](#)  

\*Department  

\*Phone Number \_\_\_\_\_



\*University Status/Title

\*College  

\*Email Address \_\_\_\_\_



### B. Faculty Sponsor - required when PI is a student:

Name [Miles, Sharla G](#)  

Department  

Phone Number \_\_\_\_\_

University Status/Title



College  



Email Address \_\_\_\_\_

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

Name	Department	College	Email Address	University Status/Title
------	------------	---------	---------------	-------------------------



### B. Faculty Sponsor - required when PI is a student:

Name  

Department  

Phone Number \_\_\_\_\_

University Status/Title

College  

Email Address \_\_\_\_\_

- User's name and title auto-populates within application
- Students must remove their name from faculty sponsor (B) using the blue arrow (compare both B sections)
- To choose Department/College, click on the Edit icon (paper & pencil symbol)
- User must type in their contact information
- Select student from menu for University status
- Do the same for your Faculty Sponsor

#### IV. Research Funding

\*A. The funding status of my project is:

Funded  
Not Funded  
Pending Grant Proposal

#### B. Disapproval of the Research

\*To your knowledge, has this protocol been reviewed and subsequently disapproved by any Protection of Human Subjects Committee (PHSC)?

No ▼

#### C. 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 grant 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 on 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.

##### 1. Settings:

- |  |   |
|--|---|
| <input type="checkbox"/> a. SHSU               | <input type="checkbox"/> g. Hospitals       |
| <input type="checkbox"/> b. Schools            | <input type="checkbox"/> h. Another State   |
| <input type="checkbox"/> c. Community          | <input type="checkbox"/> i. Another country |
| <input type="checkbox"/> d. Prisons/jails      | <input type="checkbox"/> j. Web survey/chat |
| <input type="checkbox"/> e. Another university | <input type="checkbox"/> k. Other           |
| <input type="checkbox"/> f. Nursing homes      |   |

Research Funding (IV A) – The PI may select the funding status of their project

Disapproval of Research (IV B) – Informs the IRB if this application has been reviewed previously

Settings (IV C 1) - The PI may choose as many as apply. Additional information must be provided for every location other than SHSU

#### D. Additional Review 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
- \*2. Departmental review
- \*3. College review (Chair and Dean)
- \*4. Institutional review (e.g., school, prison, agency, business)
- \*5. Other
- 6. Have you already received approval documents from other agencies (e.g., other schools aside from SHSU, prison, agency, business)?

**Additional Reviews (IV D)** - 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 F 4. 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.

## V. 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).

### 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. If yes, please 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 integrity of the human subject protection program or provide a copy of the finalized written management plan(s), if available.

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

**Yes - summary**

**Management Plan Choices**

## VI. 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)  
Participation may cause severe injury, major damage or loss, damage a person's reputation, and/or result in negative publicity and well-being of participant(s)
- well-being of participant(s)

### B. Likelihood that something will go wrong

- Unlikely to occur
- May occur in time
- Probably will occur in time
- Likely to occur immediately or in a short period of time and expected to occur frequently

### C. Procedures

- |   |  |
|---|--|
| <input type="checkbox"/> None used  | <input type="checkbox"/> Test (attach a copy to your application)            |
| <input type="checkbox"/> Biological samples   | <input type="checkbox"/> Survey (attach a copy to your application)          |
| <input type="checkbox"/> Physical measurements  | <input type="checkbox"/> Interview (attach a copy to your application)       |
| <input type="checkbox"/> Review of medical/mental health records                        | <input type="checkbox"/> Phone Interview (attach a copy to your application) |
| <input type="checkbox"/> Review of medical treatment, academic, and/or criminal records | <input type="checkbox"/> Other   |

### D. Sensitive Subject Matter

- |                                    |  |
|------------------------------------|--|
| <input type="checkbox"/> None used | <input type="checkbox"/> Criminal activity   |
| <input type="checkbox"/> Abortion  | <input type="checkbox"/> Body composition    |
| <input type="checkbox"/> AIDS/HIV  | <input type="checkbox"/> Depression          |
| <input type="checkbox"/> Alcohol   | <input type="checkbox"/> Learning disability |
| <input type="checkbox"/> Drugs     | <input type="checkbox"/> Other               |

See Next Slide for  
further instructions

### E. Maintaining Confidentiality

- \*1. Will the research be coded to protect the identity of the subject when shared?
2. If the data will be de-identified or destroyed during or after the research (including audiotapes, videotapes, and photographs), when will this occur? Note: This information should be included in the consent document, particularly if links or identifiers will be maintained indefinitely.

3. Will you or your research team need access to participants' records?
4. Will you be using audio or video taping during the data collection stages (include a statement in the consent form)?

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

Explain:

- G. Will you be applying for a Certificate of Confidentiality? (please include a statement in the consent form)

**Level of Risk (VI 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 (VI 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 (VI D)** - Choose all that apply.

**Maintaining Confidentiality (VI E)** - Answer each question.

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

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

## VII. 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:

Lay Summary (VII) - Under sections A through E, 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.

### VIII. 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.

C. If the research will require blood draws, bone marrow biopsy samples, other biopsies, or the collection of other tissues, etc., performed solely because of participation in the research, please indicate the exact months and frequency with which sample will be taken.

D. Will any biological samples be stored, even temporarily, as a result of this research?

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.

F. Will any portion of the research involve deception?

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

**Protected Health Information (VIII 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 carefully considered. Additional documentation is required when a study collects or distributes PHI.

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

## IX. Research Participant Selection and Recruitment

### A. Participant Population

\*1. Expected number of participants \_\_\_\_\_

2. Age range (check all that apply):

- |   |   |
|---|---|
| <input type="checkbox"/> Newborn to 2 years of age* | <input type="checkbox"/> 3 to 6 years of age*   |
| <input type="checkbox"/> 7 to 11 years of age*      | <input type="checkbox"/> 12 to 15 years of age* |
| <input type="checkbox"/> 16 to 17 years of age*     | <input type="checkbox"/> 18 to 64 years of age  |
| <input type="checkbox"/> 65+ years of age           |   |

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, ethnic group, or religion
- The following population of subjects will be excluded from the research:

See Next Slide for  
further instructions

### 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"/> Mass mailing                                       | <input type="checkbox"/> E-mail                                      |
| <input type="checkbox"/> Media advertising (newspaper, radio) (attach copy) | <input type="checkbox"/> Letter (attach copy)                        |
| <input type="checkbox"/> Other  | If Other, please 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

### 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?

**Research Participant Selection and Recruitment (IX A & B)** - 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 (IX 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.

**Compensation and Costs of Participation (IX D)** – If PI would like to offer incentives for participation in the project, they should indicate here.

**X. Informed Consent**

Informed Consent applies to this application  Yes

**X. 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"/> Cover Letter                  | <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 |  |

Obtaining Participant Consent (X) 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.

### XI. 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.

**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.

**\*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?**

**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.

**\*B. Are you requesting a waiver of documentation of informed consent under 45 CFR 46.117 (c)?**

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 subjects' 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.

**Waiver of Consent, Alteration of Consent, or Waiver of Documentation (XI) Check the appropriate justification for the request. Provide justification for any exceptions to the IRB**

### **XII. 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; and 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 #: \_\_\_\_\_

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

Complete

Page Number	Question
3	Phone Number
3	Email Address
3	College
3	University Status/Title

Is this project a:

...ville, TX 77341 (936) 294-4875

When checking the Complete box, if a mandatory question is left unanswered, you will receive an error message like the one above indicating the unanswered question.

\*I hereby certify that a copy of my CITI Certification has been sent to the ORSP.


**II. Research Title**  
 \*Reserach Title:

**III. Personnel:**  
**A. Principal Investigator (PI)**  
 \*Name     
 \*Department     
 \*Phone Number

**B. Faculty Sponsor - required w**  
 Name     
 Department     
 Phone Number

Address

Message from webpage

 Sorry completing form is not allowed with incomplete mandatory fields.  
 Missing Values for:  
 Department  
 College  
 Phone Number  
 Email Address  
 University Status/Title



Page 1

**Contact Information**

Office of Research and Sponsored Programs Sam Houston State University Huntsville, TX 77341 (936) 294-4875

**Type of Application**

Is this project a:

**Components for Initial Review**

Submit

Current Submission

Form/Document Name
IRB Application <i>Application Form</i>

Edit	Status	Upload	Remove
	Completed		Mandatory

[Add Institution Forms/Supporting Documents](#)

Once the system completes its conversion of application to pdf, app. disappears; refreshes Components window; Click Submit (“thumbs-up” icon)

http://samhouston.infoed.org/Protocol/SubmissionLogin.asp?ObjectID=B65BF435-FEF1-4D79-943...

http://samhouston.infoed.org/Protocol/SubmissionLogin.asp?ObjectID=B65BF435-FEF1-4D79-943D-42A8EF313329

### Certification

I certify that the information provided in this application for for admission, and in any attachments hereto is true and complete.

Accepted    Declined

Username  Password

**Electronic signature**

100%

...C&ObjectID=B65BF435-FEF1-4D79-943D-42A8EF313329

Protocol
2011-08-013

Current Submission

Status	Upload	Remove
Completed		Mandatory

Submit - Windows Internet Explorer provided by Yahoo!

http://samhouston.infoed.org/messaging/Submit.asp?ObjectID=B65BF435-FEF1-4D79-943D-42A8EF313329&DUniq

Protocol **2011-08-013** - **Sharla G Miles** "2011-2012 Thesis/Dissertation and Regular Initial PowerPoint Presentation" (In Development)

[Refresh Route](#)   [Add New Person to Review Path](#)  

Route Path - **IRB App-Thesis/Dissertation**

Step 1	<b>Add Supervising Faculty</b>	Sharla G Miles
Step 4	<b>Post-Route Screening</b>	Sharla G Miles

100%

**DO NOT** add new person to review path; click the gray Submit button; click DONE and then logout of Infoed

- Protocol 2011-08-013
  - Submissions (1)
    - Initial Review (1)
      - Initial Review**
      - Amendment (0)
      - Adverse Event (0)
      - Protocol Deviations (0)
      - Final Report (0)
    - Linkages (0)
    - Management
    - Attachments (1)
    - Communications (0)
    - Contacts
    - Access

**Components for Initial Review**

Current Submission

Form/Document Name	Edit	Status	Upload	Remove
IRB Application <i>Application Form</i>		Completed		Mandatory

[Add Institution Forms/Supporting Documents](#)

Routing Progress						
2011-08-013 - Sharla G Miles "2011-2012 Thesis/Dissertation and Regular Initial PowerPoint Presentation"						
Route Name	Route Type	Step Number/Name	Who	Notified	Decision	Insert
IRB App- Thesis/Dissertation Review	Final	Step 1 - Add Supervising Faculty	Sharla G Miles	07-Aug-2011 6:33:05 PM		
IRB App- Thesis/Dissertation Review	Final	Step 4 - Post-Route Screening	Sharla G Miles			

*No comments have been recorded yet*

You know application is submitted because (1) no Submit “thumbs-up” symbol and (2) the Routing Progress appears below matrix table

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.

---

**From:** sharla\_miles@shsu.edu [mailto:sharla\_miles@shsu.edu]  
**Sent:** Tuesday, August 02, 2011 6:02 AM  
**To:** Miles, Sharla; Miles, Sharla  
**Subject:** IRB Protocol Submission Returned

Dear Sharla G Miles ,

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

**Click on the link in your email to open the protocol**

- Protocol 2011-08-013
- Submissions (1)
- Linkages (0)
- Management
- Attachments (1)
- Communications (0)
- Contacts
- Access

**DO NOT CLICK ON RESPOND**

**Submissions** Add New

Type	Submitted on	Status	Approved From	Approved To	Review Date	Open	Delete
Initial Review	07-Aug-2011	Modifications Required <a href="#">Respond</a>					

Path to get to your application: samhouston.infoed.org>My Human Subjects>Show/List>Open folder (Actions column)>Submissions window appears

If you take this path, you will “tree out” the Submissions folder on the left-hand side under the Protocol number (see below) and click on the second Initial Review option

**Components for Initial Review**

Submit

Form/Document Name
IRB Application Application Form

[Add Institution Forms/Supporting Documents](#)

Current Submission			
Edit	Status	Upload	Remove
	Completed		Mandatory

ROUTE NAME Step number / name WHO ROUTED DECISION



Click on Edit icon (paper & pencil) to open application

Components for Initial Review

Submit

Form/Document Name
IRB Application Application Form

Edit	Status	Upload	Remove
	Completed		Mandatory


[Add Institution Forms/Supporting Documents](#)

Route Name	Type	Step Number / Name	Who	Noticed	Received
IRB App- Thesis/Dissertation Review	Final	Step 1 - Add Supervising Faculty	Sharla G Miles	07-Aug-2011 6:33:05 PM	DisApproved - Changes Required
IRB App- Thesis/Dissertation Review	Final	Returned for revisions	Sharla G Miles	07-Aug-2011 6:40:37 PM	Informed -
IRB App- Thesis/Dissertation Review	Final	Step 1 - Add Supervising Faculty	Sharla G Miles		
IRB App- Thesis/Dissertation Review	Final	Step 4 - Post-Route Screening	Sharla G Miles		

**Comments**

Sharla G Miles "Your application is not complete. All questions must be answered. Please complete your application and re-submit. Thank you. ~Sharla"

**NOTE: In the routing progress box below the matrix table, there is a comments section containing all requested revisions to the protocol. Please follow these instructions in your revisions.**

**IRB Application**  Complete 

**Page 1**

**Contact Information**  
Office of Research and Sponsored Programs Sam Houston State University Huntsville, TX 77341 (936) 294-4875

**Type of Application**  
Is this project a:

**Page 2**

**Navigation:** Save, Check In/Out, Table of Contents, Quest Hist, Form Hist, Print

### Uncheck Complete Box

If the system will not allow you to uncheck the Complete box, click the Check In/Out button ONE time.

Edit application as requested


Save

### Check Complete Box



There will be a few minutes delay while Infoed is preparing the pdf file

Your application disappears and your Submissions window is refreshed

Click Submit

**Components for Initial Review** Submit 

Current Submission

Form/Document Name	Edit	Status	Upload	Remove
IRB Application Application Form		Completed		Mandatory

[Add Testimonial Forms/Supporting Documents](#)