

IRB PRESENTATION: THE CLASSROOM APPLICATION

BY SHARLA MILES

OFFICE OF RESEARCH & SPONSORED PROGRAMS

SAM HOUSTON STATE UNIVERSITY

STEP 1: CREATING YOUR PROFILE

- Why we are required—significance of the process?
- <http://samhouston.infoed.org/>
- 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.

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**

Set

Profile Not Found in List

Continue

- 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

Set

Username edu_lxj at least 6 characters

Password | | | | | | | | at least 6 characters

Re-Enter Password | | | | | | | |

Continue

WARNING: The Primary Department defaults to *Research & Sponsored Programs*, so this **MUST** be changed. Profile will be temporarily suspended if the correct department is not set.

[0-9](#) [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](#)

- CAREER SERVICES
- CASHIER'S OFFICE
- CHEMISTRY DEPT
- COLLEGE OF BUSINESS ADMINISTRATIO
- COLLEGE OF CRIMINAL JUSTICE
- COLLEGE OF CRIMINAL JUSTICE
- COLLEGE OF EDUCATION
- COLLEGE OF FINE ARTS & MASS COMMUNICATIONS
- COLLEGE OF HUMANITIES & SOCIAL SCIENCES
- COLLEGE OF SCIENCES
- COMMUNICATION STUDIES
- COMPUTER SCIENCE
- COMPUTER SERVICES
- CONTINUING EDUCATION
- CONTRACTS AND GRANTS
- CORRESPONDENCE TIME SHEETS
- COUNSELING CENTER
- CURRICULUM & INSTRUCTION DEPT**

Locate

- CAREER SERVICES
- CASHIERS OFFICE
- + COLLEGE OF BUSINESS ADMINISTRATIO
- + COLLEGE OF CRIMINAL JUSTICE
- COLLEGE OF CRIMINAL JUSTICE
- COLLEGE OF EDUCATION
 - CURRICULUM & INSTRUCTION DEPT
 - ED LEAD & COUNSELING DEPT
 - HEALTH & KINESIOLOGY DEPARTMEN
 - LANG, LIT, AND SPEC POP
 - LIBRARY SCIENCE



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

Important Reminders

- All new profiles validated by InfoEd
- Email confirming Username and Password
- Encouraged to create profile early
- This recommendation is especially important for students who are conducting research for a class.
- Since profile is validated immediately after creation, you may begin using the program

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

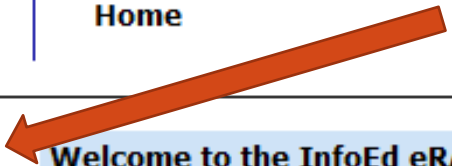
Welcome to the InfoEd e... x Home - Protection of Human ...

 **eRA Portal** Streamlining Electronic Research Administration

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

Home

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- GENIUS



Welcome to the InfoEd eRA Portal for Electronic Grants Administration

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



eRA Portal

Streamlining Electronic Research Administration

Login

Home	Login
>> Login	
Get Profile	
SPIN	
GENIUS	

Username

Password

Three red arrows are drawn on the page. One arrow points from the top right towards the Username input field. A second arrow points from the top right towards the Password input field. A third arrow points from the bottom left towards the Password input field.

Enter username and password; click Login or simply press Enter on keyboard



Log Out Help Portal

My Human Subjects



Show/List







Search For



Create New

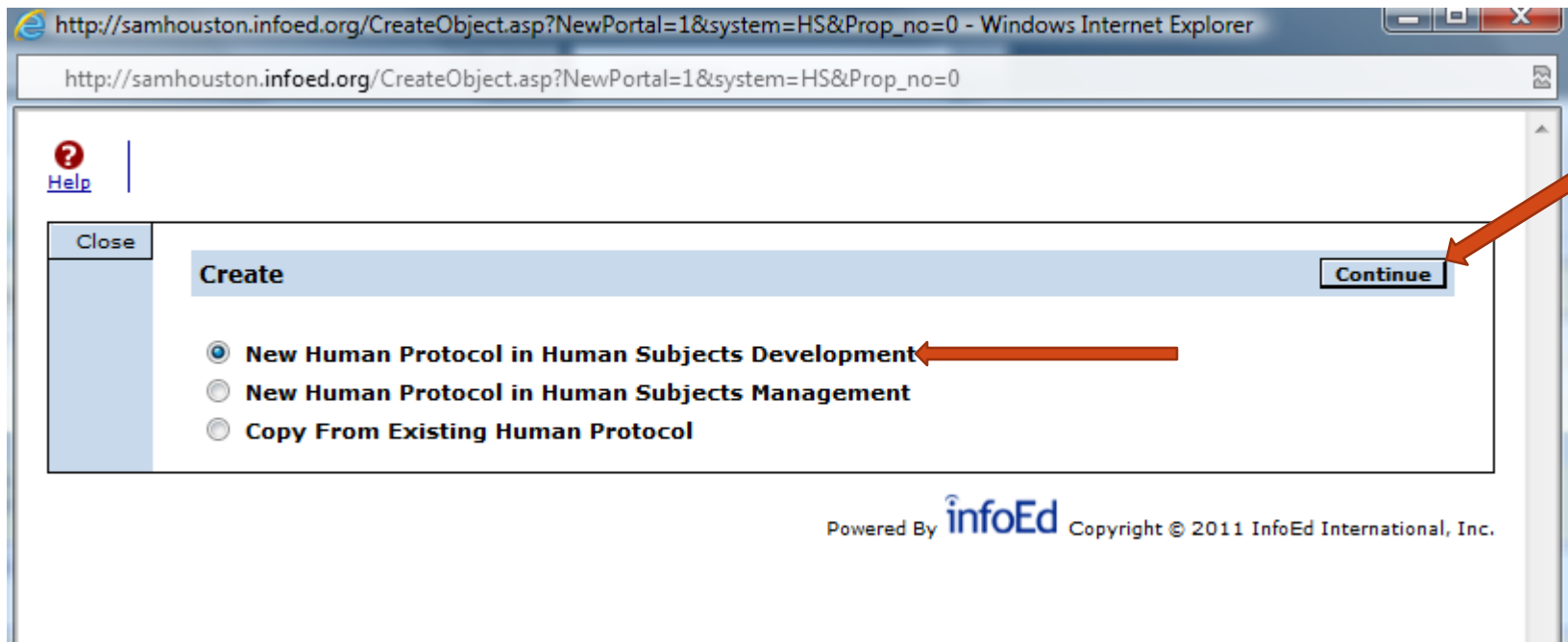
4 Records Found.

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
- My Human Subjects

My Profile




At the Create dialogue box, selection defaults to the **New Human Protocol** option, so click **Continue**.

Close


Protocol Creation

Enter Title

Continue



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

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e

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](#)

Search for a particular entry

Filter by Position

At the **Select PI** window, your name should appear in the PI box, so again all you do here is click **Continue**.

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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

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

[Add Institution Forms/Supporting Documents](#)

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IMPORTANT: At the Components for Initial Review window—Uploading attachments—click on [Add Institution Forms/Supporting Documents](#)

Upload



Upload

Close



Upload new document

Name



Location

Browse...



Category

Folder

Document ID

Document Version Number

Document Version Date

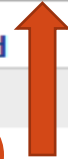
- Survey
- Advertising
- Marketing Material
- Protocol
- Letter of Support
- Consent Forms
- Form Letter
- Misc Documents
- Science/Abstract
- Application Form
- Conflict of Interest Statement



Add Initial Review Components

Add

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



Add Components - Windows Internet Explorer
http://samhouston.infoed.org/Protocol/popUpGetAddComponent.asp?ObjectID=195E4F4F-9DFB-4393-B74C-36E347D6003F&RP=1&SCW=1

Please click 'Close' to complete the upload of your documents.

Upload

Would you like to upload a new **document** **version of an existing document**

Upload new document

Name

Location

Category

Folder

Document ID

Document Version Number

Document Version Date

Add Initial Review Components

Form Name	Type	Add
Assent Form	Conditional Use	<input type="checkbox"/>
Consent Form	Conditional Use	<input type="checkbox"/>

Done Internet 100%

Protocol 2011-07-029

- Submissions (1)
 - Initial Review (1)
 - Initial Review**
 - Amendment (0)
 - Adverse Event (0)
 - Protocol Deviations (0)
 - Final Report (0)
 - Linkages (0)
 - Management
 - Attachments (2)
 - Communications (0)
 - Contacts
 - Access

Components for Initial Review

Submit

Current Submission

Form/Document Name	Edit	Status	Upload	Remove
IRB Application <i>Application Form</i>		Completed		Mandatory
Miles Cover Letter <i>Misc Documents</i>		Completed		

[Add Institution Forms/Supporting Documents](#)



Protocol 2011-07-029

- Submissions (1)
 - Initial Review (1)
 - Initial Review

Components for Initial Review

Submit 

Form/Document Name

IRB Application
Application Form[Add Institution Forms/Supporting Documents](#)

Edit



Status

Incomplete

Upload

Remove

Mandatory

Current Submission

Back at the Components for Initial Review window, click the Edit icon by the Initial Application to open and get started.

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:

- Classroom Project
- Regular Initial
- Thesis/Dissertation

Save
Check In/Out
Table of Contents
Quest Hist
Form Hist
Print

To identify the application as a classroom research project, select **Classroom Project** from the drop down box beside “Is this project a”:

Formal application appears below

Menu
Save
Check In/Out
Print

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

Classroom Application

I. Ethics Certification (CITI)

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.

I hereby certify that a copy of my Ethics Certification (CITI) has been sent to the ORSP.

At the top of **Page 2** of the application the user is asked to confirm 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

*Research Title:



2011-2012 IRB Presentation PowerPoint



III. Personnel

A. Principal Investigator (PI)

*Name Miles, Sharla G  

*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
------	------------	---------	---------------	-------------------------

- 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)
- ****Reminder: when making revisions, reinserting faculty sponsor name in Personnel section****
- 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

Personnel - Windows Internet Explorer
http://samhouston.infoed.org/popupselectlist.asp?LETTER=S&unique_id=&ParentField=A1BB7545-5222-43E7-9348-FE82FCB3F422&DataTypeDesc=Personne

Personnel Close

[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](#)

Sabbagh-Barrett, Jamie	COMMUNICATION STUDIES	Select
STRAWSER, JEFFERY W	ACCOUNTING DEPT	
STRETCHER, ROBERT H	GENERAL BUSINESS & FINANCE	
STRICKLAND, SUSAN D	NEWTON GRESHAM LIBRARY	
STRICKLER, EVA C	RESEARCH & SPONSORED PROGRAMS	
Stroud, Caroline Hamilton	PSYCHOLOGY/PHILOSOPHY	
STROUD, STEPHANIE S	COLLEGE OF CRIMINAL JUSTICE	
STUCKEY, KELLY G	ED LEAD & COUNSELING DEPT	
STUTTS, KYLE J	AGRIC & INDUSTRIAL SCIENCES	
Stutts, Neil	COLLEGE OF HUMANITIES & SOCIAL SCIENCES	
Suarez, Monica Lynn	ED LEAD & COUNSELING DEPT	
Subjack, Jeanne Marie	COLLEGE OF CRIMINAL JUSTICE	
SULLIVAN, LAURA L	GENERAL BUSINESS & FINANCE	
SULLIVAN, LESLIE A	FINANCIAL AID	
SULLIVAN, NICOLE L	SCHOOL OF MUSIC	
SULLIVAN, SAMUEL L	CURRICULUM & INSTRUCTION DEPT	
Swaminathan, Ana	COLLEGE OF CRIMINAL JUSTICE	
Swanson, Brooke Kannesha	MASS COMMUNICATION	
SWARTHOUT, MARY B	MATHEMATICS & STATISTICS	
SWARTHOUT, STEPHANIE L	HUMAN RESOURCES DEPARTMENT	
Sweat II, Morris Ray	MASS COMMUNICATION	
Swedberg, Alicia Pharr	LANG, LIT, AND SPEC POP	
Sweeney, Dee Ann McMahon	ED LEAD & COUNSELING DEPT	
Sweeney, Jason Michael	HISTORY DEPT	
SWEENEY, LINDA S	ACCOUNTING DEPT	
Sweeney, Nicole Megan	Sam Houston State University	
SWEETEN, MARY K	FINANCIAL AID	
SWICEGOOD, PHILIP R	LANG, LIT, AND SPEC POP	
SWICEGOOD, SARAH B	LANG, LIT, AND SPEC POP	
Swindell, Samuel Van Saun	COLLEGE OF CRIMINAL JUSTICE	
Szymczak, Tracy Michelle	LANG, LIT, AND SPEC POP	

Done Internet 100%

Departments

Select Close

Select department from list:

[0-9](#) [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](#)

- CAREER SERVICES
- CASHIER'S OFFICE
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- COLLEGE OF CRIMINAL JUSTICE
- COLLEGE OF EDUCATION
- COLLEGE OF FINE ARTS & MASS COMMUNICATIONS
- COLLEGE OF HUMANITIES & SOCIAL SCIENCES
- COLLEGE OF SCIENCES
- COMMUNICATION STUDIES
- COMPUTER SCIENCE
- COMPUTER SERVICES
- CONTINUING EDUCATION
- CONTRACTS AND GRANTS
- CORRESPONDENCE TIME SHEETS
- COUNSELING CENTER
- CURRICULUM & INSTRUCTION DEPT**

Locate

- CAREER SERVICES
- CASHIERS OFFICE
- + COLLEGE OF BUSINESS ADMINISTRATIO
- + COLLEGE OF CRIMINAL JUSTICE
- COLLEGE OF CRIMINAL JUSTICE
- COLLEGE OF EDUCATION
- CURRICULUM & INSTRUCTION DEPT



- Save
- Check In/Out
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- Print

D. Disapproval of the Research

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

▼
Yes
No

E. 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 | |

F. 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
- *2. Institutional Review (e.g, school, prison, agency, business)
- *3. Have you already received approval documents?

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

D. Disapproval of the Research
*To your knowledge, has this protocol been reviewed and subsequently disapproved by any Protection of Human Subjects Committee (PHSC)? No ▾

E. 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 checked="" 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 checked="" type="checkbox"/> k. Other
<input type="checkbox"/> f. Nursing homes	

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

F. 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 ▾

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

*3. Have you already received approval documents? Yes ▾

4. Approval Documents: +

Attach approval documents here:

Additional Reviews (F) - 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, a *signed letter of support (on the district letterhead) from the school or district must be attached to the application.*

-  Save
-  Check In/Out
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-  Form Hist
-  Print

IV. 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)
 - participant(s)

- C. Procedures**
- | | |
|---|--|
| <ul style="list-style-type: none"> <input type="checkbox"/> None used <input type="checkbox"/> Biological samples <input type="checkbox"/> Physical measurements <input type="checkbox"/> Review of medical/mental health records <input type="checkbox"/> Review of medical, treatment, academic, and/or criminal records <input type="checkbox"/> Psychological Inventory (attach a copy to your application) | <ul style="list-style-type: none"> <input type="checkbox"/> Test (attach a copy to your application) <input type="checkbox"/> Survey (attach a copy to your application) <input type="checkbox"/> Interview (attach a copy to your application) <input type="checkbox"/> Phone Interview (attach a copy of script to your application) <input type="checkbox"/> Other |
|---|--|

- D. Sensitive Subject Matter**
- | | |
|--|--|
| <ul style="list-style-type: none"> <input type="checkbox"/> None used <input type="checkbox"/> Abortion <input type="checkbox"/> AIDS/HIV <input type="checkbox"/> Alcohol <input type="checkbox"/> Drugs | <ul style="list-style-type: none"> <input type="checkbox"/> Criminal activity <input type="checkbox"/> Body composition <input type="checkbox"/> Depression <input type="checkbox"/> Learning disability <input type="checkbox"/> Other |
|--|--|

- E. Maintaining Confidentiality**
- Will the research data be coded to protect the identity of the subject when shared?
1. Will the data be de-identified or destroyed during or after the research (including audio and videotapes, and photographs)?
This information should be included in the consent document, particularly if links or identifiers will be maintained indefinitely.
2. Will you or any of the research team need to access the participant's record?

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)

- Save
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IV. 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

<input type="checkbox"/> None used	<input type="checkbox"/> Test (attach a copy to your application)
<input type="checkbox"/> Biological samples	<input checked="" 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 of script to your application)
<input type="checkbox"/> Review of medical, treatment, academic, and/or criminal records	<input type="checkbox"/> Other
<input type="checkbox"/> Psychological Inventory (attach a copy to your application)	

D. Sensitive Subject Matter

<input checked="" 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

E. Maintaining Confidentiality

Will the research data be coded to protect the identity of the subject when shared?

1. Will the data be de-identified or destroyed during or after the research (including audio and videotapes, and photographs)? This information should be included in the consent document, particularly if links or identifiers will be maintained indefinitely.

2. Will you or any of the research team need to access the participant's record?

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

Explain:

This MUST be completed!!!

G. Will you be using audio or video taping during the data collection stages (include a statement in the consent form)



V. 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-D) 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:

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.

- Save
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VI. Research Participant Selection and Recruitment

A. Participant Population

1. Expected number of participants 150

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

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

*****This is ONLY a Sample!!!*****

B. Recruitment of Participants

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

- Direct person-to-person contact
- Telephone contact
- Posted notices (attach copy)
- Letter (attach copy)
- Media advertising (newspaper, radio) (attach copy)
- Existing documents in the public domain
- Existing documents not in the public domain
- Internet
- E-mail
- Mass mailing
- 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

VII. 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"/> Participant signed Informed Consent | <input type="checkbox"/> Assent - Written |
| <input type="checkbox"/> Waiver of Informed Consent | <input type="checkbox"/> Waiver of Assent |
| <input type="checkbox"/> Parental Permission | <input type="checkbox"/> Prospective Written "Short Form" |
| <input type="checkbox"/> Waiver of Parental Permission | |
| <input checked="" type="checkbox"/> Cover Letter | |

******This is ONLY a Sample!!!!**

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

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: 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: 31-Jul-2011

- Save
- Check In/Out
- Table of Contents
- Quest Hist
- Form Hist

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: Classroom Project

- 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**
 - Amendment (0)
 - Adverse Event (0)
 - Protocol Deviations (0)
 - Final Report (0)
- Linkages (0)
- Management
- Attachments (1)
- Communications (0)
- Contacts
- Access

Components for Initial Review

Submit

Current Submission

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

[Add Institution Forms/Supporting Documents](#)

Once Complete is checked, the system completes its conversion of application to pdf; app. Disappears/refreshes Components window; click Submit

Protocol - Windows Internet Explorer
http://samhouston.infoed.org/Protocol/SubmissionLogin.asp?ObjectID=195E4F4F-9DFB-4393-B74C-36E347D6003F

Certification Close

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

Accepted Declined

Objectid=195E4F4F-9DFB-4393-B74C-36E347D6003F

Protocol
2011-07-029

Change Project Information

Submit

Current Submission

	Upload	Remove
ed		Mandatory

Protocol - Windows Internet Explorer
http://samhouston.infoed.org/Protocol/SubmissionLogin.asp?ObjectID=195E4F4F-9DFB-4393-B74C-36E347D6003F

Certification Close

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 Continue

Electronic signature

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Submit - Windows Internet Explorer

http://samhouston.infoed.org/messaging/Submit.asp?ObjectID=195E4F4F-9DFB-4393-B74C-36E347D6003F&DUUniq

Protocol **2011-07-029 - Sharla G Miles "2011-2012 IRB Presentation PowerPoint" (In Development)**

[Refresh Route](#) [Route Path - IRB Application-Classroom](#) [Add New Person to Review Path](#) **Submit**

Step 1 **Add Supervising Faculty** Sharla G Miles

Step 2 **Post-Route Screening** Sharla G Miles

Change Project Information

Submit

Current Submission

	Upload	Remove
ed		Mandatory

Communications (0)
Contacts
Access

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

- Protocol 2011-07-029**
- 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	View	Status	Upload	Remove
IRB Application <i>Application Form</i>		Completed		Mandatory

Routing Progress

2011-07-029 - Sharla G Miles "2011-2012 IRB Presentation PowerPoint"

Route Name	Route Type	Step Number/Name	Who	Notified	Decision Insert
IRB Application-Classroom	Final Review	Step 1 - Add Supervising Faculty	Sharla G Miles	31-Jul-2011 11:22:13 PM	
IRB Application-Classroom	Final Review	Step 2 - Post-Route Screening	Sharla G Miles		

No comments have been recorded yet

You can tell this has been submitted, because (1) no Submit “thumbs-up” symbol and (2) the Routing Progress appears below matrix table

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



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

Components for Initial Review

Submit

Form/Document Name
IRB Application Application Form

Current Submission			
Edit	Status	Upload	Remove
	Completed		Mandatory

Add Institution Forms/Supporting Documents

IRB Application- Classroom	Final Review	Step 1 - Add Supervising Faculty	Sharla G Miles	31-Jul-2011 11:22:13 PM	DisApproved - Changes Required	
IRB Application- Classroom	Final Review	Returned for revisions	Sharla G Miles	02-Aug-2011 6:02:18 AM	Informed -	
IRB Application- Classroom	Final Review	Step 1 - Add Supervising Faculty	Sharla G Miles			
IRB Application- Classroom	Final Review	Step 2 - Post-Route Screening	Sharla G Miles			

Comments

Sharla G Miles "The Lay Summary does not fall in line with the focus of your research title. Please revise and resubmit your application. Thanks."

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 Menu: 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 **ONCE** on **Check In/Out**—this will **grant you ownership to the form**

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** as before (refer to **slide #32**)

Components for Initial Review Submit

Current Submission

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

[Add Institution Form/Supporting Documents](#)