Sam Houston State University

Protection of Human Subjects Application

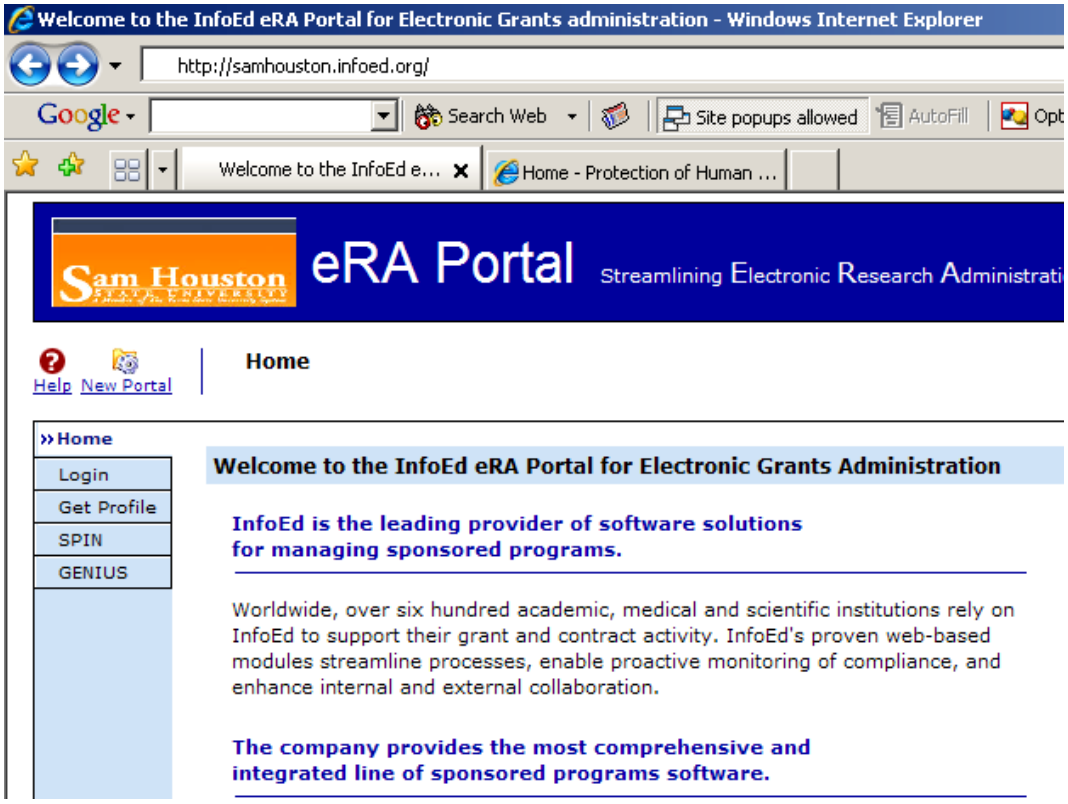
Sam Houston State University has developed a new online system for reviewing research on human subjects. This system is hosted off-campus by InfoEd, which is headquartered in Albany, New York. Unlike the previous system, this program can be accessed with either a PC or a Mac, on-campus or off. An internet connection is required, but it will even work with a dial-up modem. Beginning in the Fall, 2008, all new human subjects applications must be made with this new system. This program is more sophisticated than the previous one and captures important information that was not requested on the previous system. 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

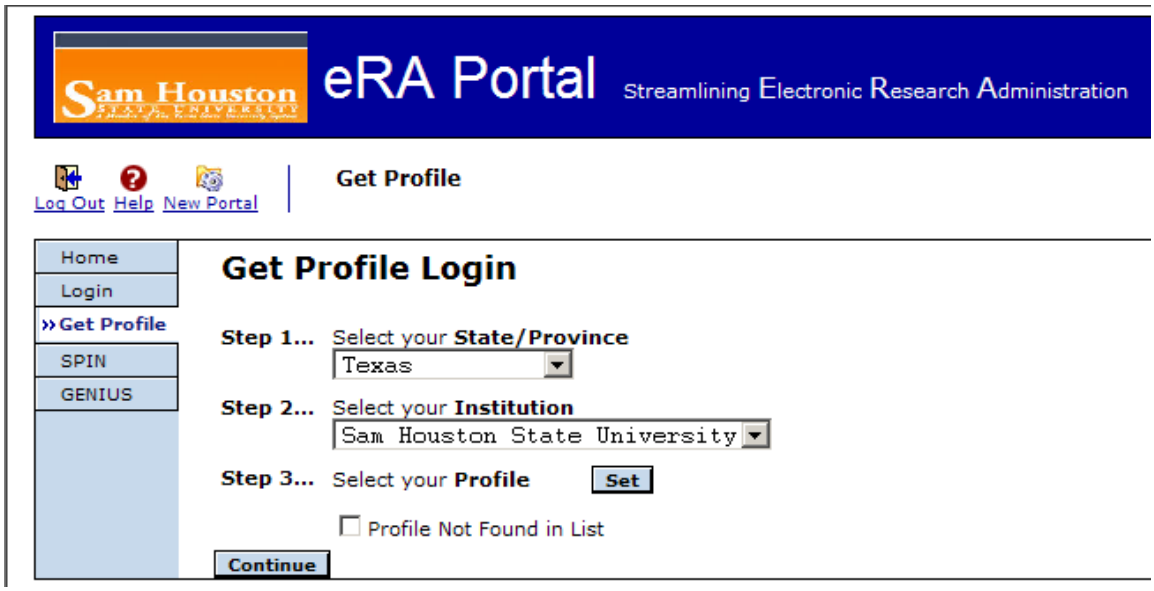
Logging into the System

On the home page are two important buttons on the left margin: **login** and **get profile**. When you use this system the very first time, you must click "get profile." You should only have to do this the first time.

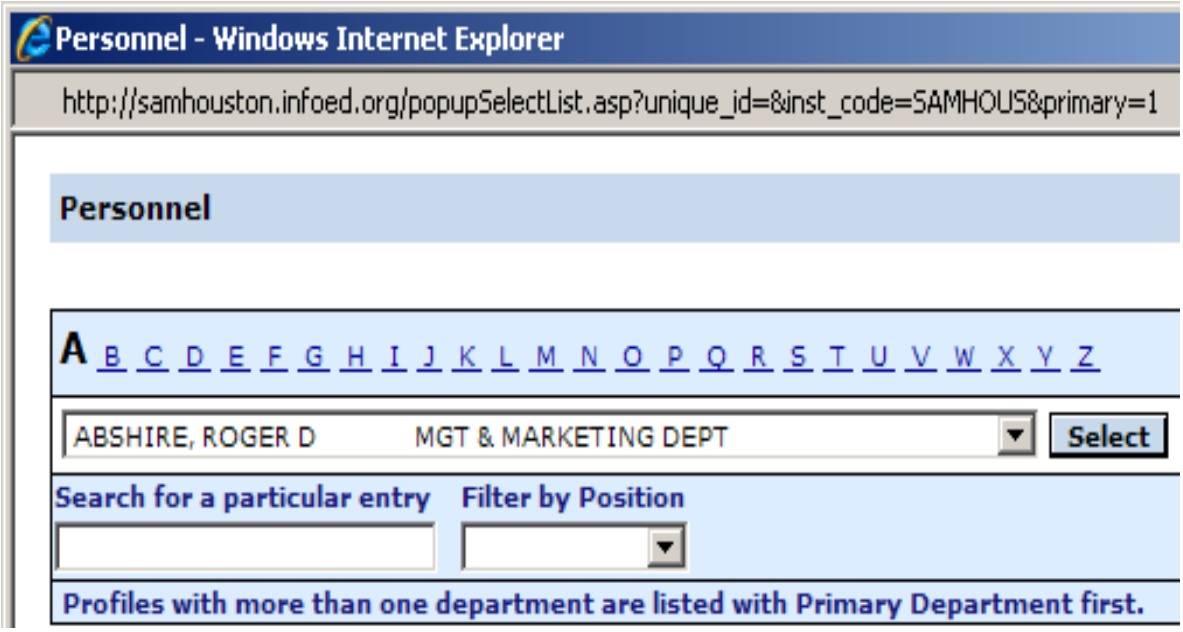


Getting a profile involves 5 steps:

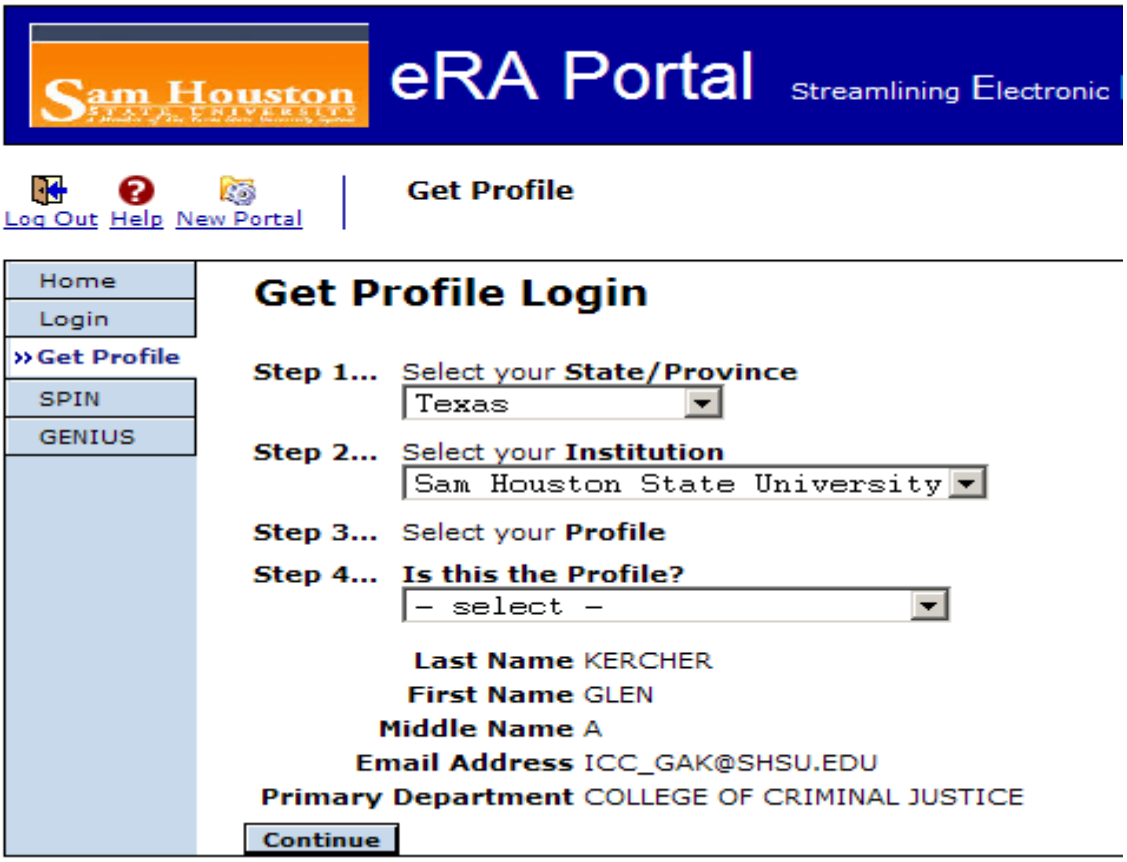
1. identify your state (TX) from the pull-down menu and continue;
2. select our university from the pull-down menu and continue;

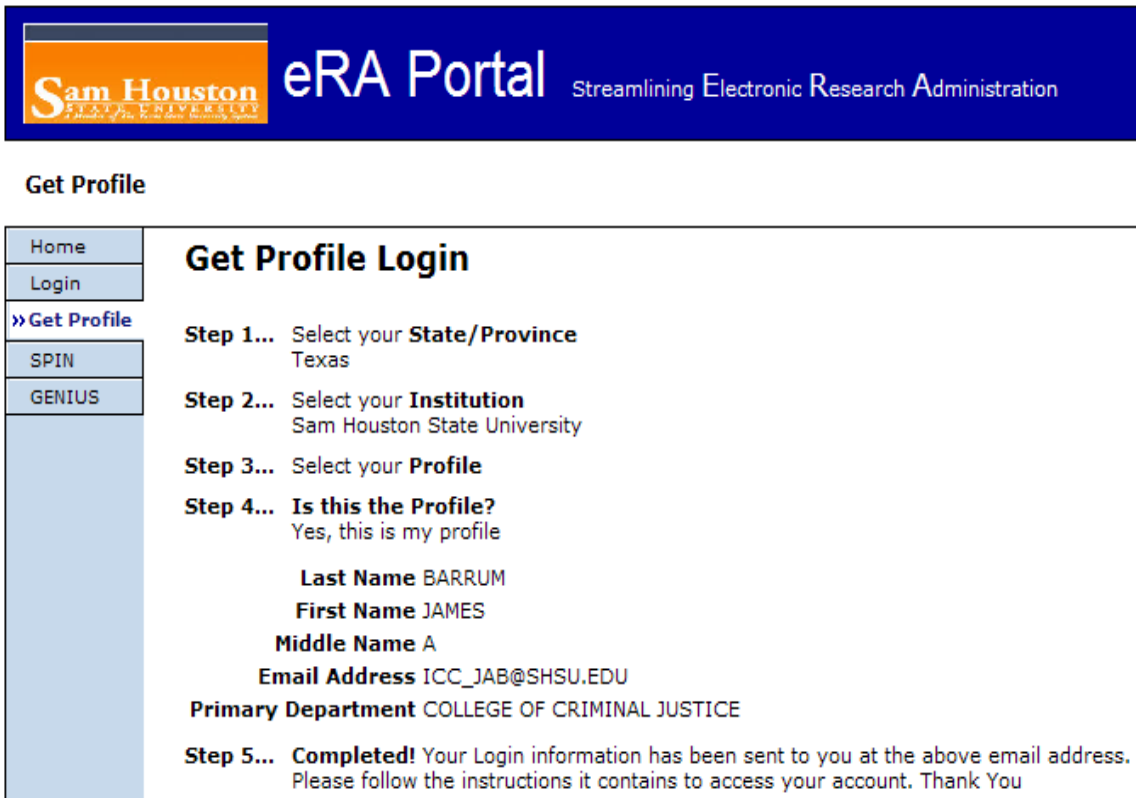


3. select your profile and continue. To select your profile, click “set” and select the first letter of your last name. From the pull-down menu select your name and click “select.” Then close that dialogue box. At this point the user’s profile should be pulled into the system from university data bases.



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

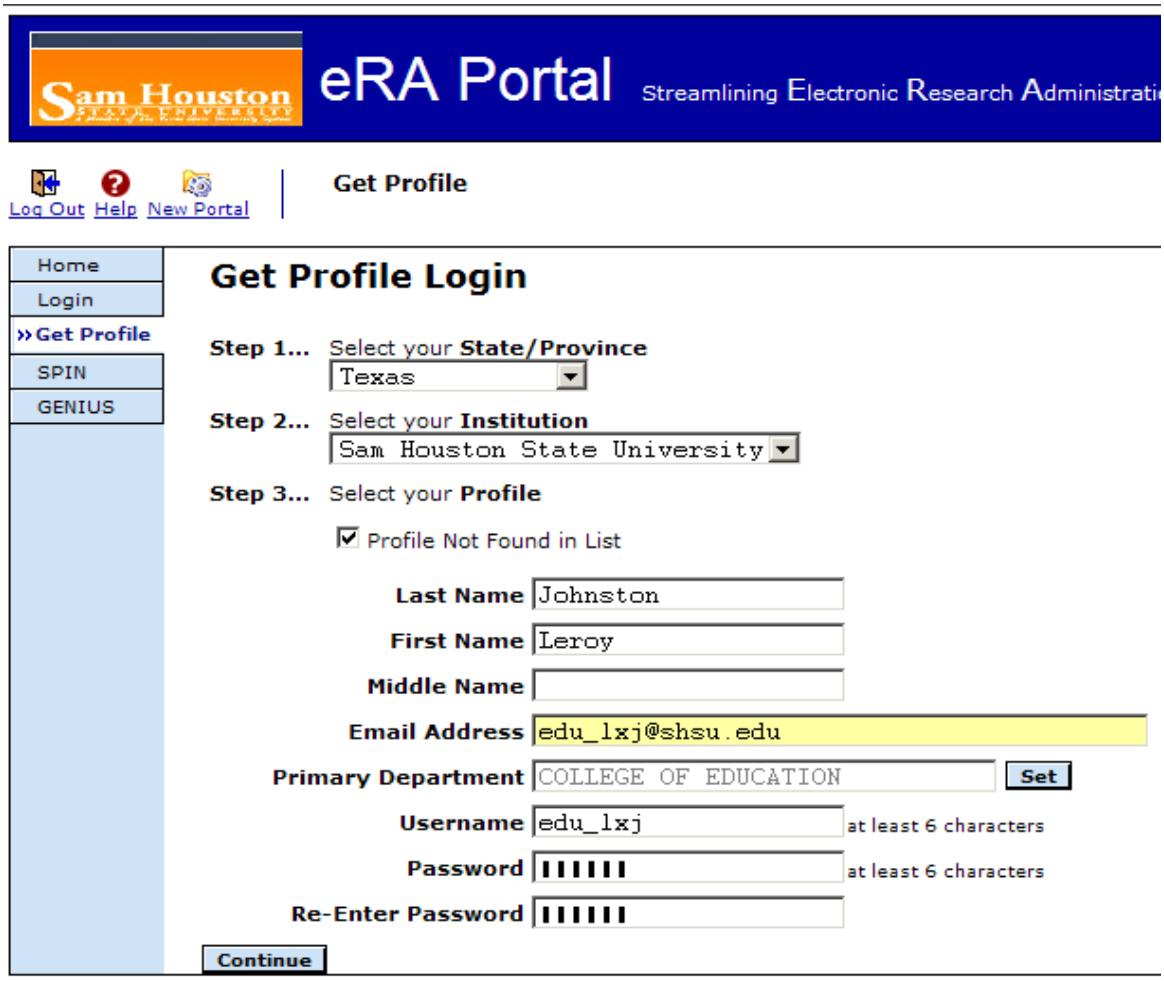

Sam Houston
eRA Portal
Streamlining Electronic
Log Out
Help
New Portal
Get Profile
Home
Login
»Get Profile
SPIN
GENIUS
Get Profile Login
Step 1... Select your State/Province
Texas
Step 2... Select your Institution
Sam Houston State University
Step 3... Select your Profile
Step 4... Is this the Profile?
– select –
Last Name KERCHER
First Name GLEN
Middle Name A
Email Address ICC_GAK@SHSU.EDU
Primary Department COLLEGE OF CRIMINAL JUSTICE
Continue


Sam Houston
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
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

5. Shortly thereafter the user's login information will be confirmed by email will include the User ID (SHSU login) and password. The user is then able to use this information to log onto the system.

New Faculty and Student Login

New faculty and students will not be able to get a profile so easily, because their information may not yet be accessible from university records. 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, SHSU email address, primary department, user ID and password. Once that information has been added, click "continue," which will take the person to step five.



However, before an email is sent to the user, the profile must be validated by the Office of Research and Special Programs. This could take several days, depending upon the availability of personnel in that office. To avoid being delayed in starting a research project, new faculty and students should be encouraged to get their profiles set before they are ready to submit an application. This recommendation is particularly important for students who will be conducting research for a class.

Using the Program

Once a profile has been set, the user can return to the InfoEd home page and click the **Login** button along the left margin (pg 2). The next screen should have the user's name printed at the top. Along the left margin are two categories: **My Human Subjects** and **My Profile**.

The My Human Subjects list is the most important for most uses with this system. Here are found links to new applications, modifications of previously submitted protocols that are under review, amendments, adverse event reporting, continuing review, final reports, and help. While scrolling down the list the user should choose the link that serves his/her intent. For example, to begin a new application, click **Create New**. If clicking that link does not take the user to the application, check to be sure there is not a popup blocker preventing access. If so, disable it.

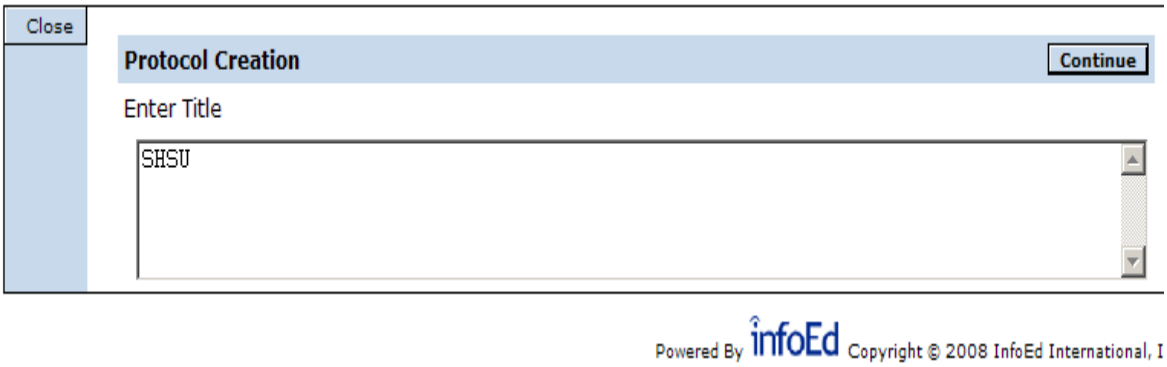
Selecting the **Show/List** link will take the user to a list of all his or her applications that are under review and have been previously approved. To make modifications to a previously submitted application that is still under review, click the **open folder icon** to the left of the protocol. Clicking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

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**.

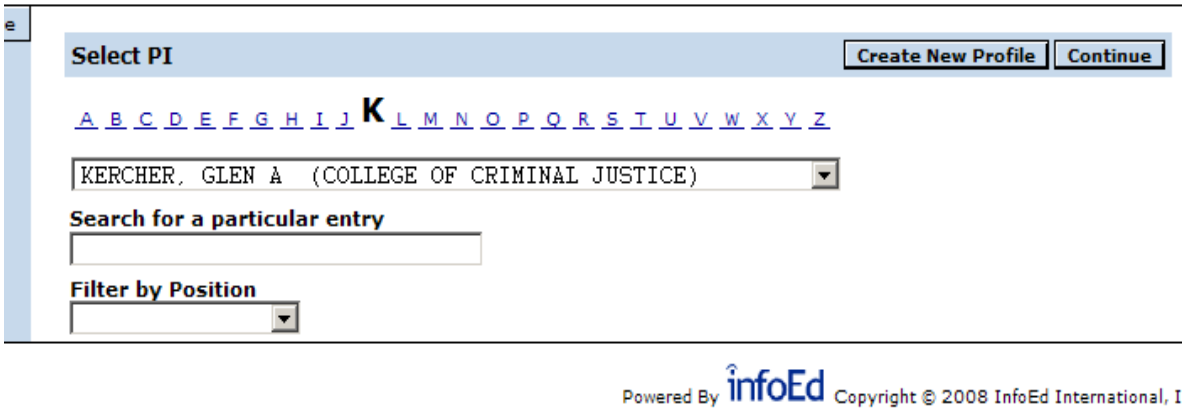
Creating a New Regular or Thesis/Dissertation Application

To submit a new application the user logs into the system, pulls down the list under My **Human Subjects**, and selects **Create New**. At the **Create** dialogue box, check

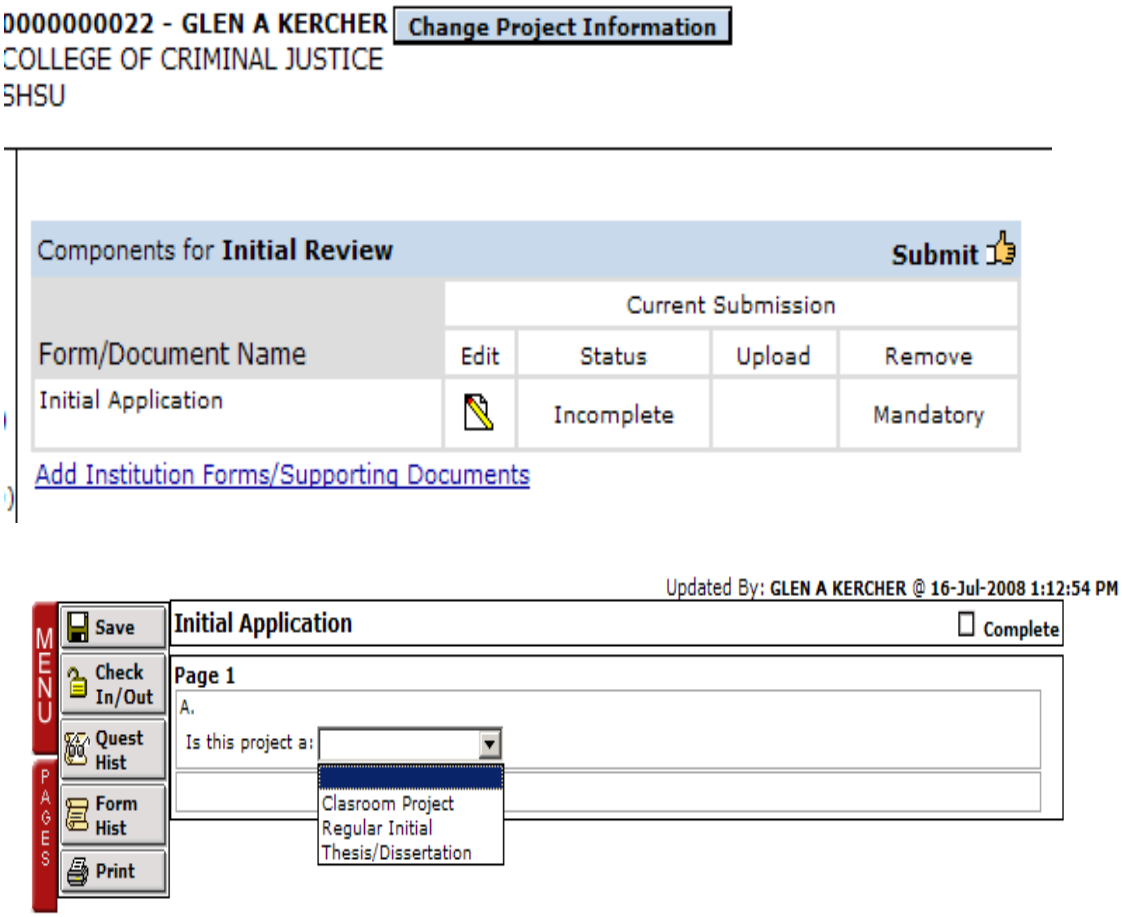
My Human Protocol and continue. Then the user will be asked to give a title to the research project and continue.



The next dialogue box asks the user to select the primary investigator (PI). If the user's name does not appear there, try looking under the first letter of the last name and select from the list. Then continue.

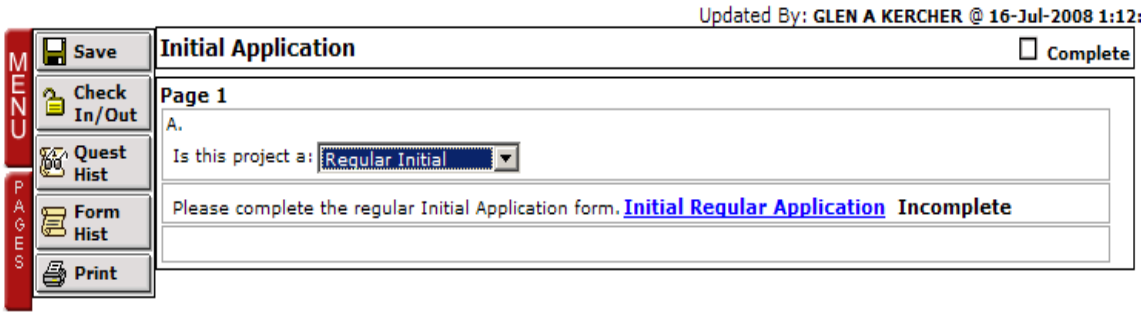


At the **Components for Initial Review** dialogue box, click the **Edit** button to the left of the new application. That will open the **Initial Application** program.

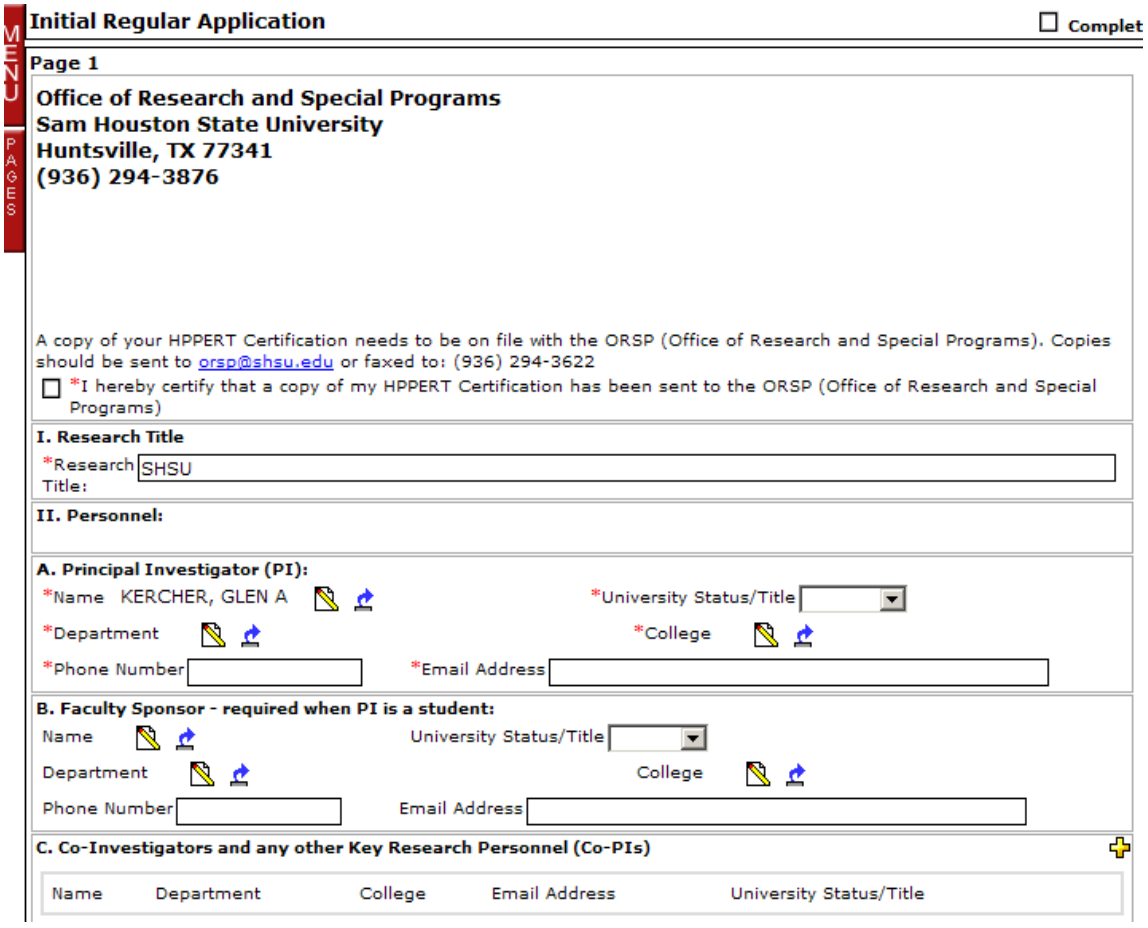


Please note: Along the left margin of the formal application is a **Menu** tab. When that is clicked, the PI has the option of saving the application and printing it. **Saving** an application periodically is a good idea, so that no information will be inadvertently deleted. **Printing** a copy of the completed application provides a reference for the PI and supervising faculty. It can also be sent to other participating agencies or institutions.

The user is asked to identify the project as one submitted by faculty and staff, thesis and doctoral students, and classroom applications. Select the appropriate type and a blue line will appear below the type of application box that is highlighted **Initial Regular, thesis/dissertation, or Classroom Application.**



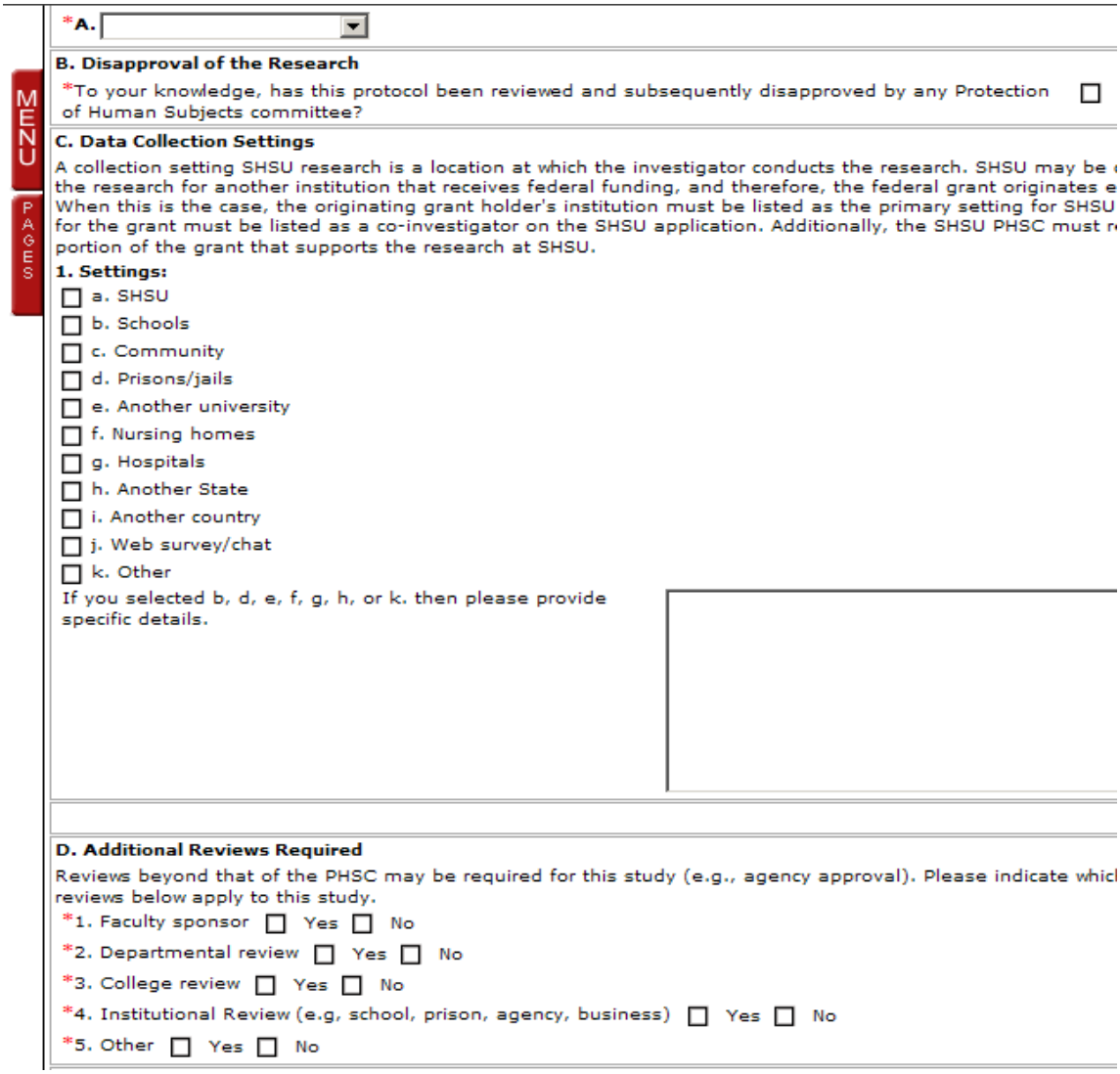
Clicking that link will take the user to page one of the application.



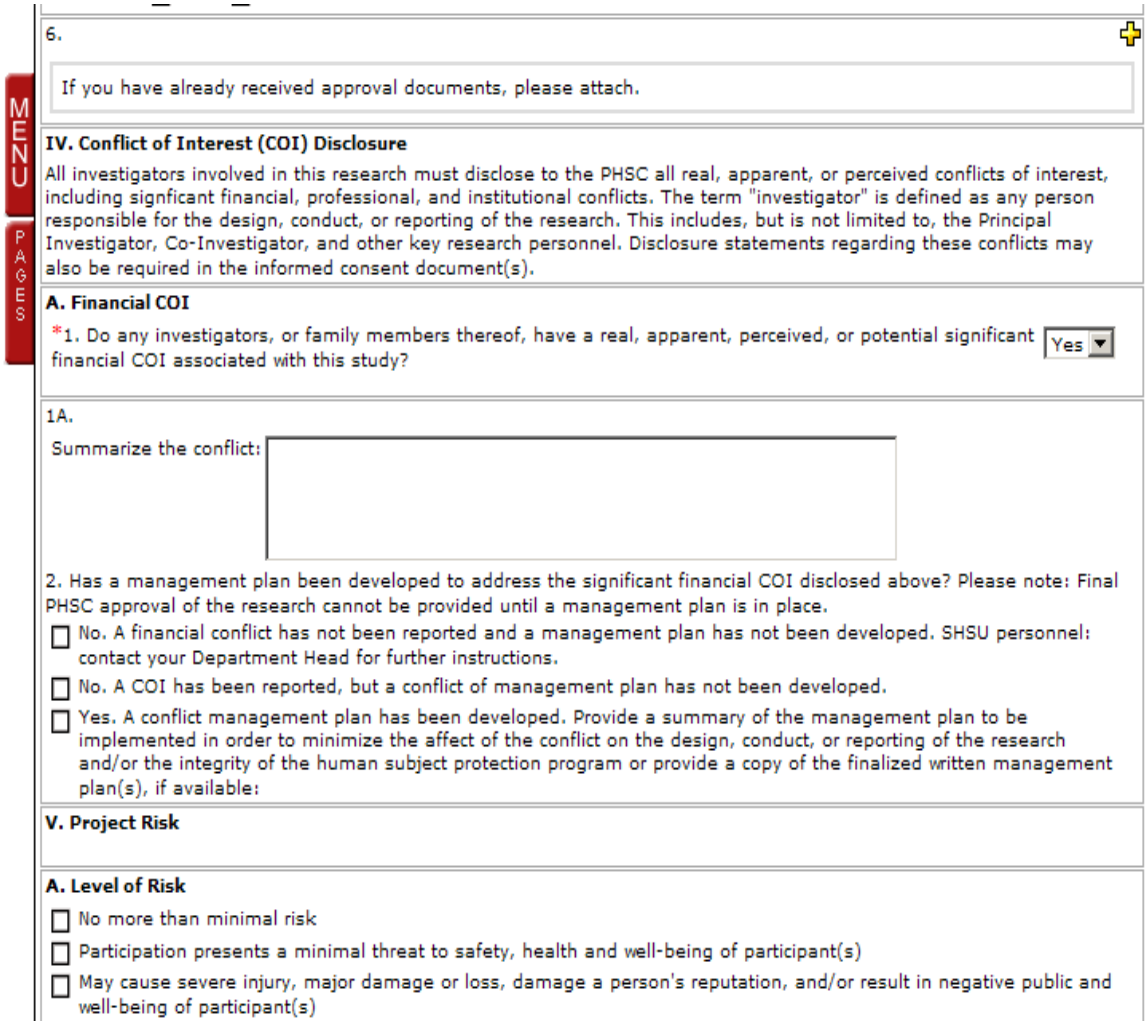
The user's name should appear on the application automatically, but the department, college, status/title, phone number and email address have to be typed into the application. That information does not pull from your profile in this version of the software. Thesis and dissertation applications as well as classroom applications require

the user to specify the faculty sponsor and contact information. Co-investigators should be listed for all 3 types of applications.

Settings III.C.1. Under settings the PI may choose as many as apply. Additional information must be provided for every location other than SHSU.



Additional Reviews, III.D.1-5. Select all that apply. If approval to conduct the research has been granted by the agency or institution, that documentation should be uploaded at III.D.6.

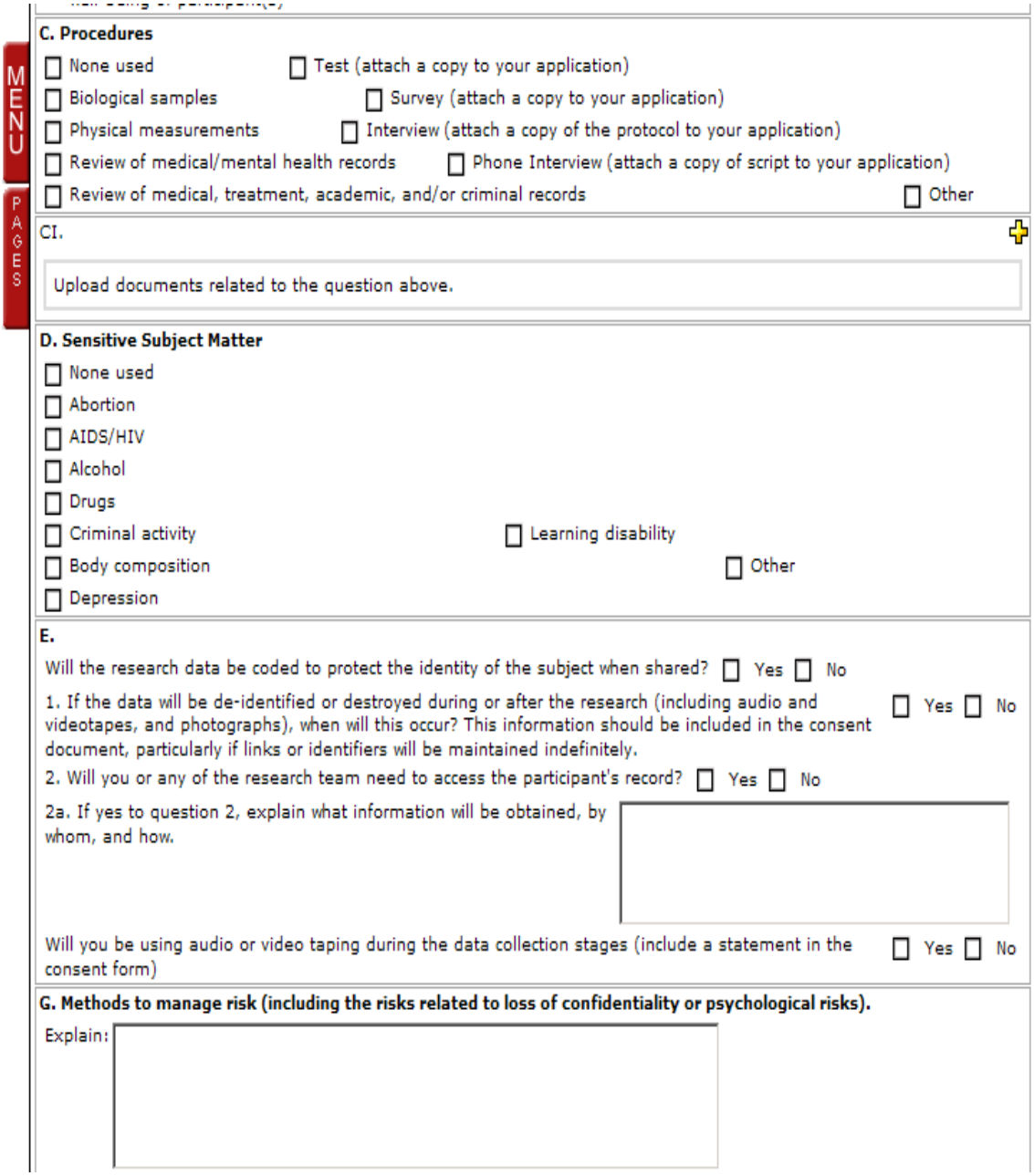


Click the plus sign and then click the upload button and attach the documentation.

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.

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.

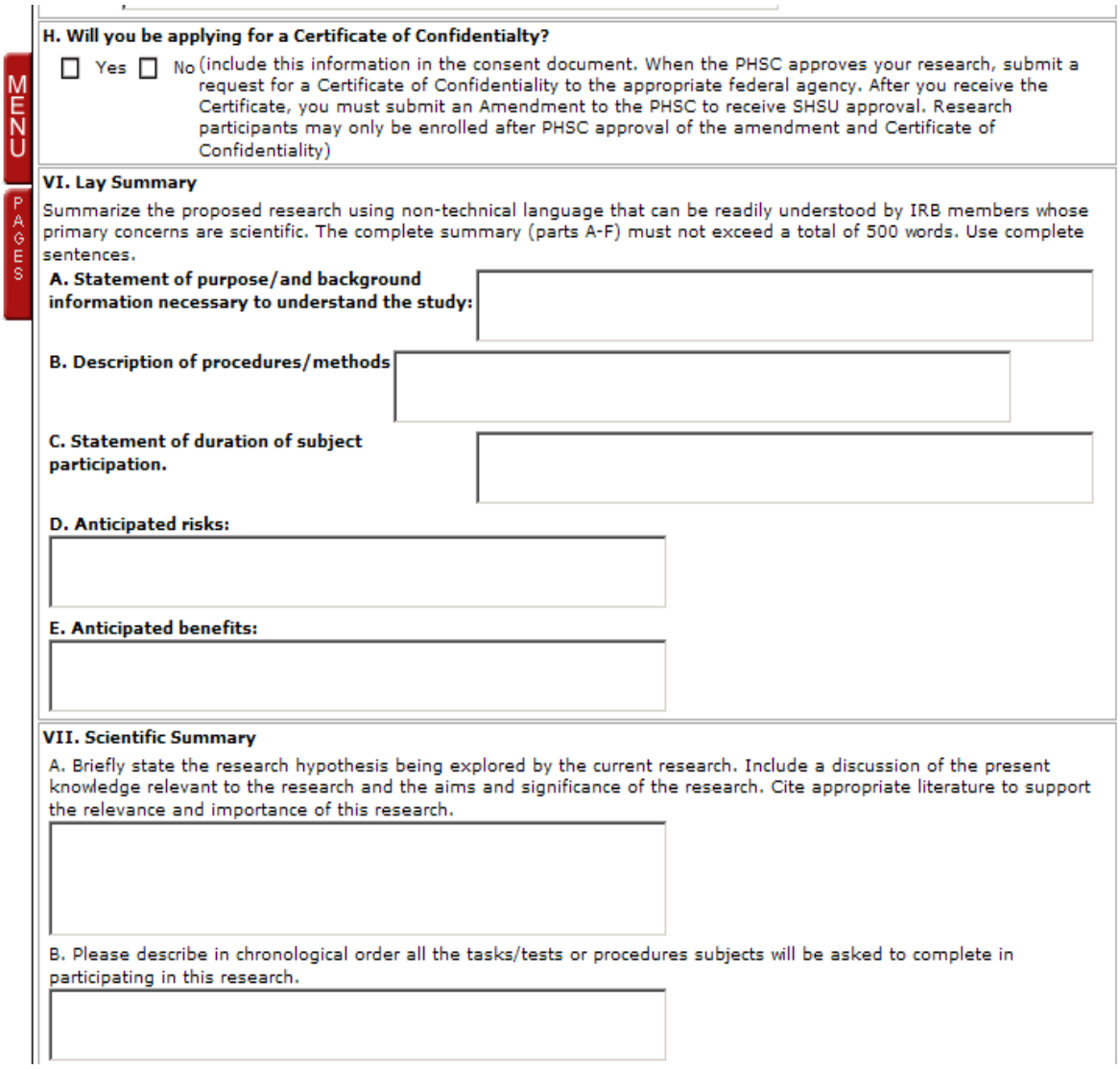


Sensitive Subject Matter, V.C. Choose all that apply.

Protecting Anonymity and Confidentiality, V.D. Answer each question.

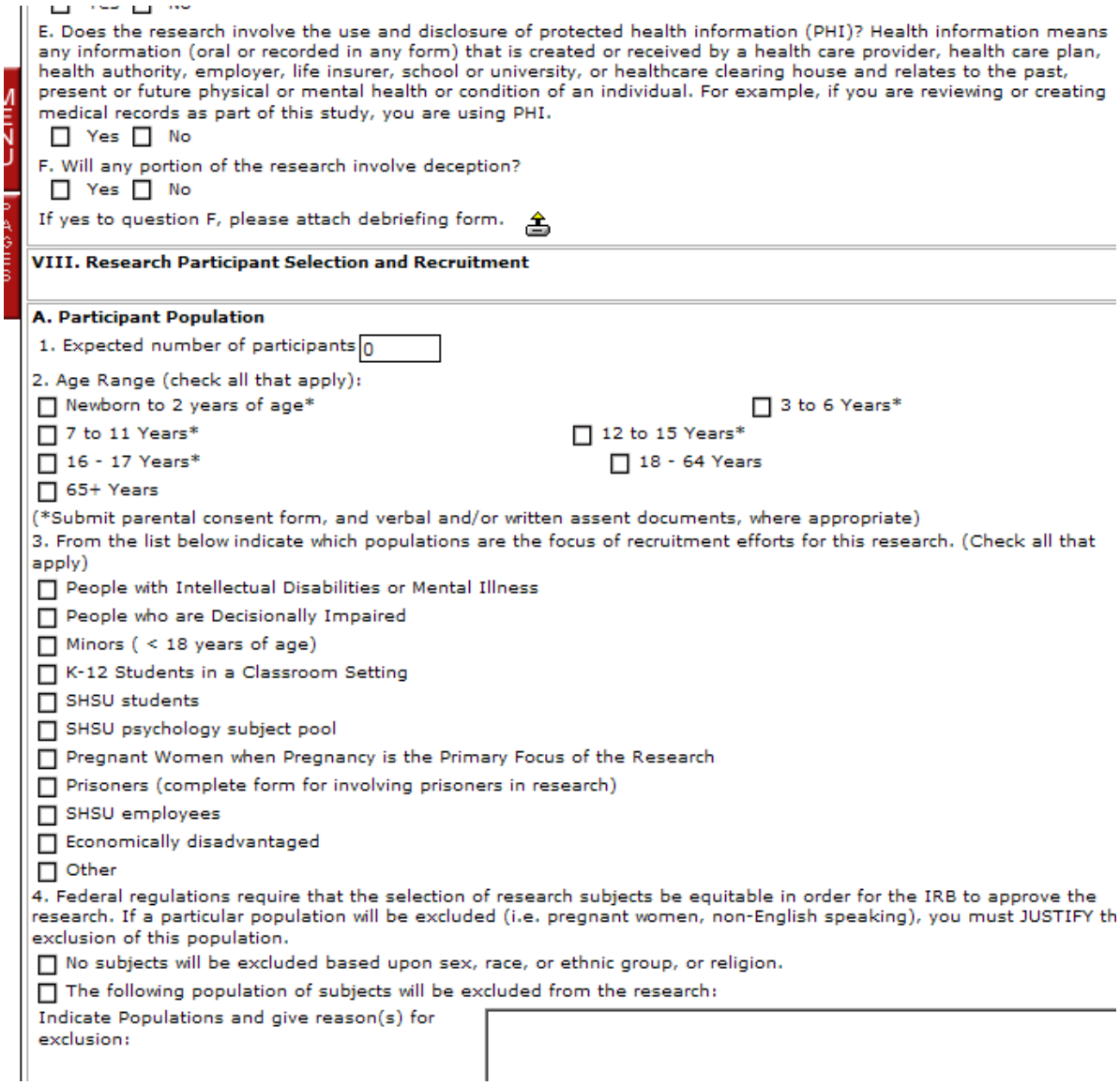
Managing Risk, V.E. This is a very important consideration and should be thought through carefully before submitting the application.

Lay Summary, V.I. Under sections A through E, the PI is asked to summarize the research project in lay terms. Please note that in the Scientific Summary of VII, more detailed information is requested about the study.



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.



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 0

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 th exclusion of this population.

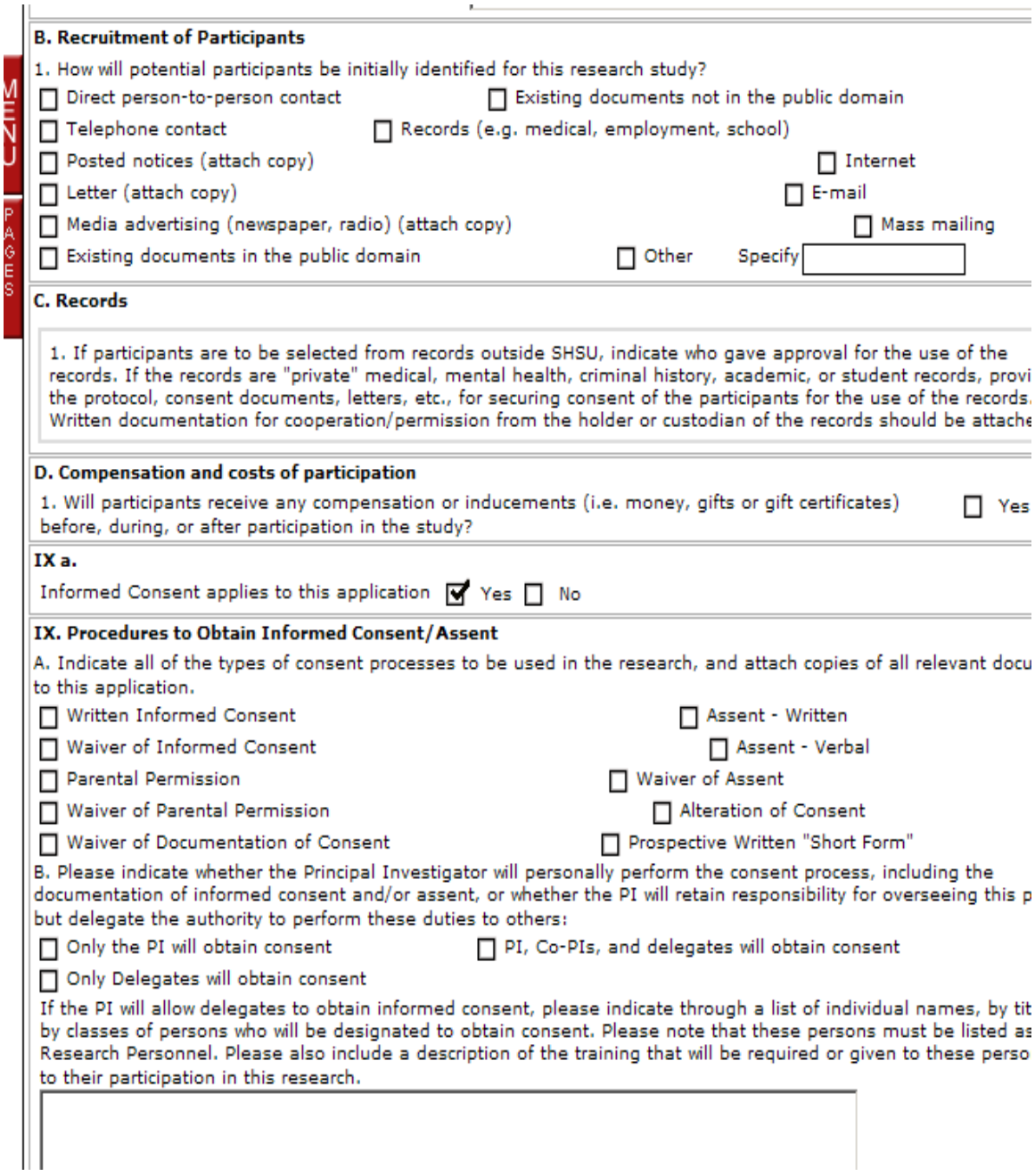
☐ No subjects will be excluded based upon sex, race, or ethnic group, or religion.

☐ 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.



B. Recruitment of Participants

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

- ☐ Direct person-to-person contact
- ☐ Existing documents not in the public domain
- ☐ Telephone contact
- ☐ Records (e.g. medical, employment, school)
- ☐ Posted notices (attach copy)
- ☐ Internet
- ☐ Letter (attach copy)
- ☐ E-mail
- ☐ Media advertising (newspaper, radio) (attach copy)
- ☐ Mass mailing
- ☐ Existing documents in the public domain
- ☐ Other Specify

C. Records

1. If participants are to be selected from records outside SHSU, indicate who gave approval for the use of the records. If the records are "private" medical, mental health, criminal history, academic, or student records, provi 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 attache

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

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 docu to this application.

- ☐ Written Informed Consent
- ☐ Assent - Written
- ☐ Waiver of Informed Consent
- ☐ Assent - Verbal
- ☐ Parental Permission
- ☐ Waiver of Assent
- ☐ Waiver of Parental Permission
- ☐ Alteration of Consent
- ☐ Waiver of Documentation of Consent
- ☐ 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 p but delegate the authority to perform these duties to others:

- ☐ Only the PI will obtain consent
- ☐ PI, Co-PIs, and delegates will obtain consent
- ☐ Only Delegates will obtain consent

If the PI will allow delegates to obtain informed consent, please indicate through a list of individual names, by tit 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 perso 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, 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.

X. Request for Waiver of Consent, Alternation 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:

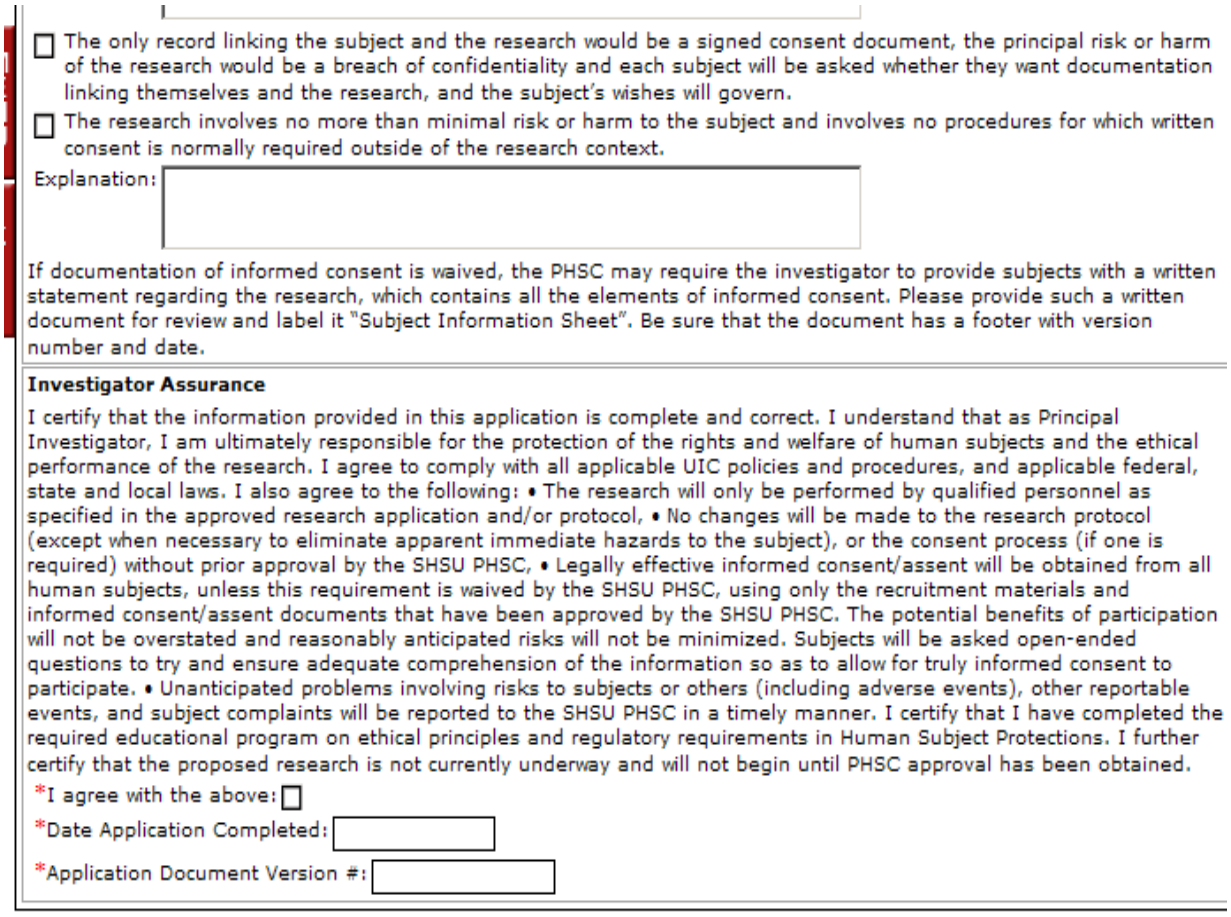
Explanation:

☐ 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.



A new submission is always identified as **Version** 1. The **date of submission** is not necessarily the date you click "completed." That should be added just before submitting it. Checking the **Complete** button on the application takes the user to the **Components for Initial Review** screen. If the application is marked as completed, it may be submitted by clicking the icon on the right side. Before doing that the user should edit the protocol, add the submission date, and **complete** it again.

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.

Be sure to save the application, even if more information is needed to **Complete** it. If everything has been completed and documents uploaded, check the **Complete** box

in the upper right at the beginning of the application. If there are things in the application that need to be addressed, the PI will be notified. Once those matters have been addressed, the PI should again check the **Complete** box.

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 and the status of each. To add to a protocol, click the **open folder** icon, and the submission dialogue box will appear. Open the application to be taken to the application.

Creating a New Classroom Application

After logging in, the student should go into **My Human Subjects** along the left margin and select **Create New**. If the next dialogue box does not open, check to see if a popup blocker is preventing assess to this part of the program and disable it. At the **Create** dialogue box, check **New Human Protocol** and click **continue**. In the **Protocol Creation** box, enter the **title** of the research and click **continue**. At the **Select PI** window, your name should appear in the PI box. If it is not there, click on the first letter of the 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 Special Programs at X3876 for assistance. Click **continue**.

At the **Components for Initial Review** window, click the **Edit** icon by the Initial Application line to open an application. Identify the application as a classroom research project. At that point a blue highlighted line appears below that response which when selected, takes the user to the application itself.

Please 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 and printing it. **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.

The user's name should pull into the application automatically. The user must type in their department, college, status/title, phone number and email address Students must specify the faculty sponsor and that person's contact information. Co-investigators should be listed at II.C. By clicking the plus sign the user can add co-PIs.

Settings, III.1. the PI may choose as many as apply. Additional information must be provided for every location other than SHSU.

Additional Reviews, IV. Select all that apply. If approval to conduct the research has been granted by the agency or institution, that documentation should be uploaded at IV.3.

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.

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

Sensitive Subject Matter, V.D. Choose all that apply.

Protecting Anonymity and Confidentiality, V.E. Answer each question.

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

Audio or Video Taping, V.G. Yes or no.

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 your project plans. This will usually mean typing more than one line.

Protected Health Information, VII E. This refers to recording or sharing protected health information (PHI). This is an issue that is regulated by federal law (HIPAA) and must be careful considered. Additional documentation is required when a study collects or distributes PHI.

Deception. If deception is used, a debriefing document should be uploaded where indicated.

Research Participant Selection and Recruitment, VIII. Check all that apply. The user will be prompted at the **Components of Initial Review** dialogue box to upload any and all forms of consent that are indicated by the application.

Accessing Records, VIII. C. When intending to **access records** about participants outside the University, appropriate documentation for cooperation/permission from the custodian of the records should be uploaded. Clicking on the plus sign will provide an icon for uploading the necessary documentation.

Obtaining Participant Consent, IX. There are different kinds of consent: adult participant signed consent, signed parental consent, and signed assent (usually for children 12-17). Check the appropriate types and upload those documents into the application.

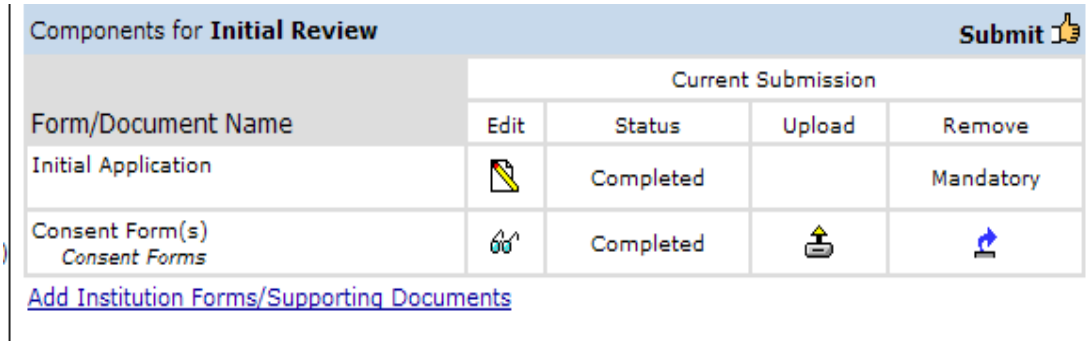
Waiver of Consent, Alteration of Consent, or Waiver of Documentation, X. Check the appropriate justification for the request.

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

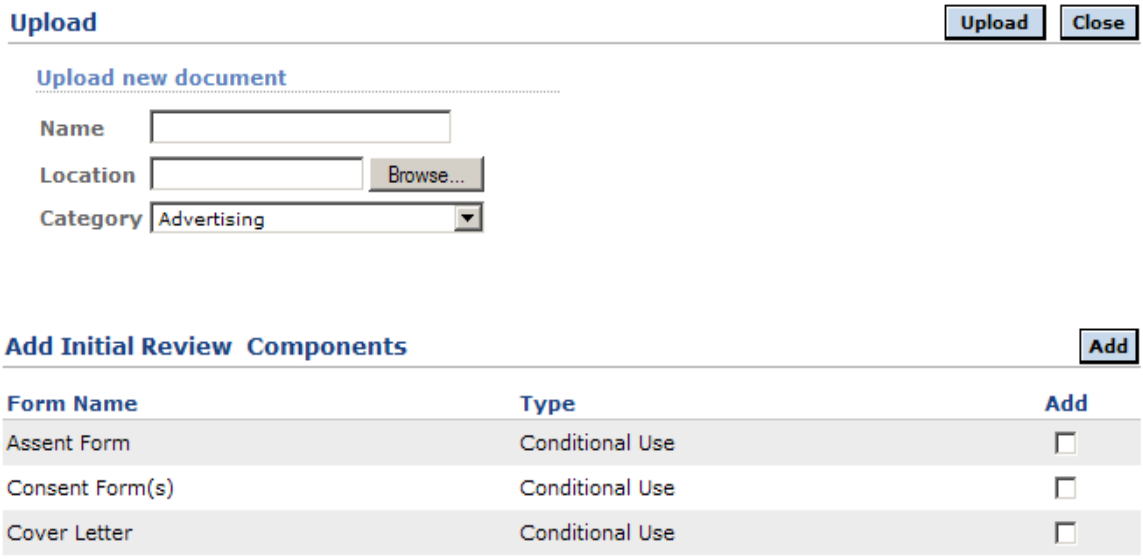
Be sure to save the application even if more information is needed to **Complete** it. If everything has been completed and documents uploaded, check the **Complete** box in the upper right at the beginning of the application. If there are things in the application that need to be addressed, the PI will be notified. Once those matters are addressed, the PI should again check the **Complete** box.

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 and the status of each. To add to a protocol, click the **open folder** icon, and the submission dialogue box will appear. Open the application to be taken to the application.

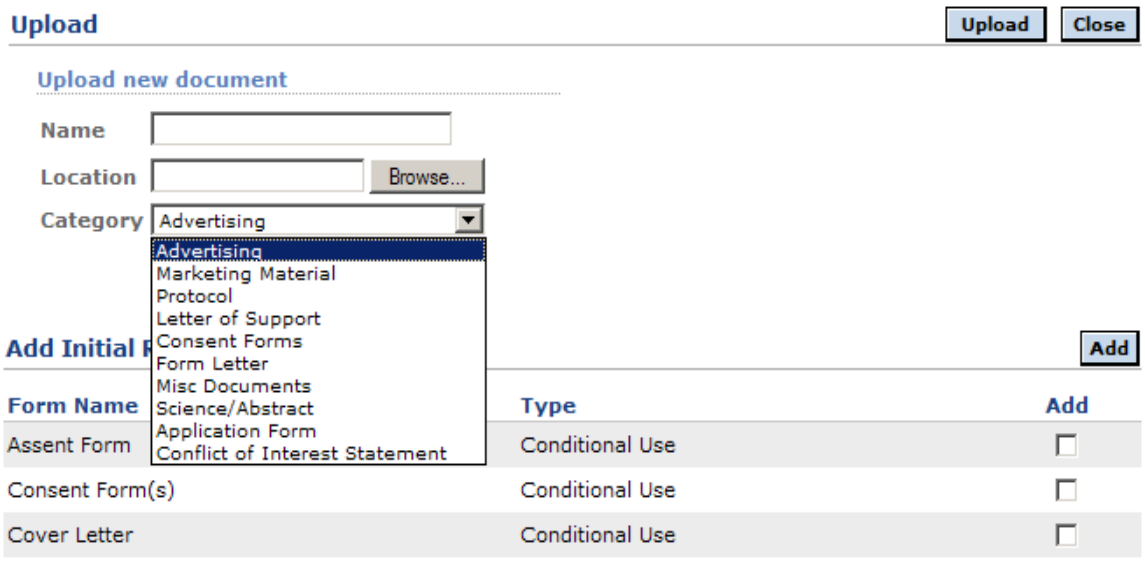
After completing the application the user will be taken to the **Components for Initial Review** screen which shows the current submission and status of the application. You may edit the submission by clicking the icon.



To access other documents and forms, click the link above. Then select (check **Add**) whichever forms are relevant to the application.



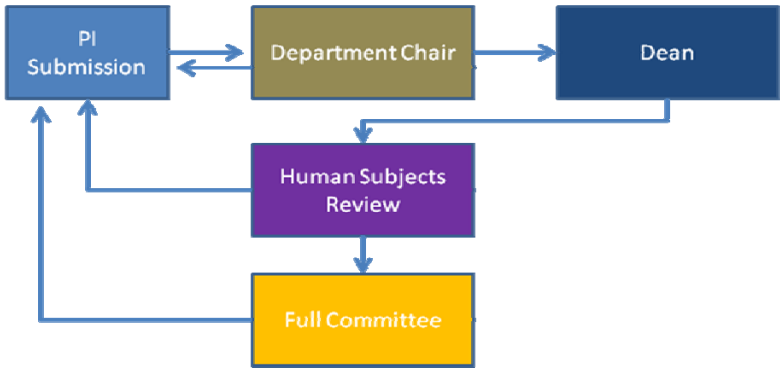
To upload other documents, give a name to the document begin uploaded and select where it is located on the user's computer. Then choose the appropriate category. Then click **Upload**.



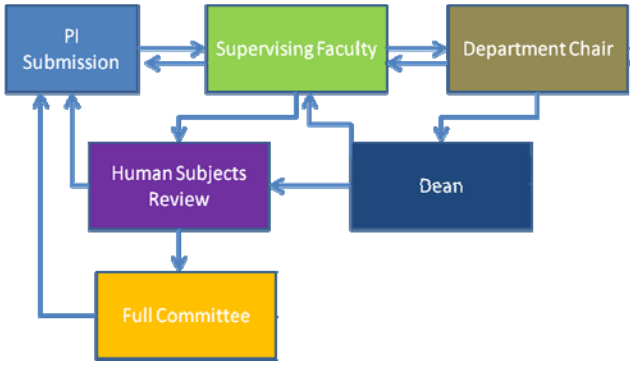
When the **Components for Initial Review** screen indicates that the application and other documents are complete, save the application and click the **Submit** button in the upper right corner. That will send the application to the first reviewer.

Routing an Application.

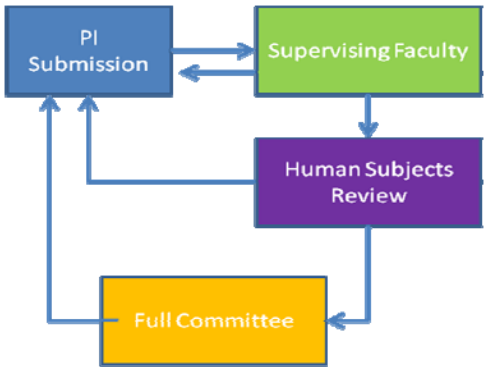
Once a **Regular Application** is submitted, it will follow the route illustrated below.



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



The route for a **Classroom Application** is as follows.



A user can check on the status of an application by logging into the system, opening **My Human Subjects**, and clicking **Show/List**. Holding the cursor over the **Quick Status** icon will show where the protocol is in the routing.

Sam Houston State University

Protection of Human Subjects Application

Classroom Research

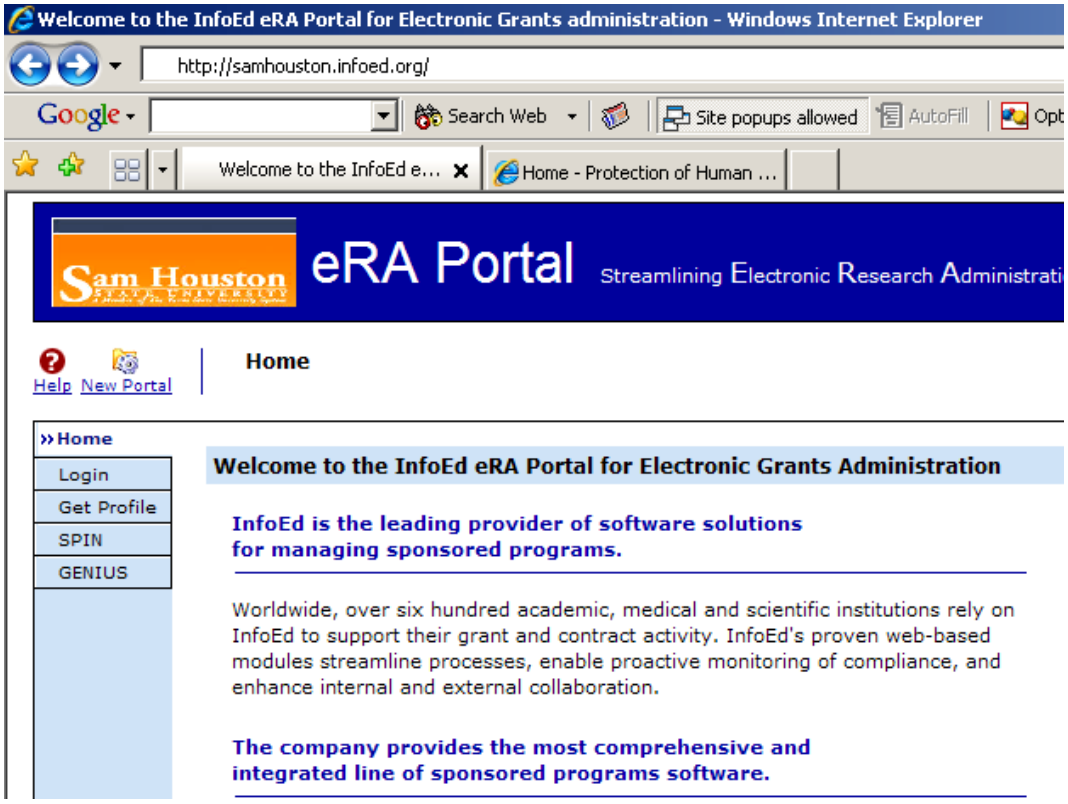
Sam Houston State University has developed a new online system for reviewing research on human subjects. This system is hosted off-campus by InfoEd, which is headquartered in Albany, New York. Unlike the previous system, this program can be accessed with either a PC or a Mac, on-campus or off. An internet connection is required, but it will even work with a dial-up modem. Beginning in the Fall, 2008, all new human subjects applications must be made with this new system. This program is more sophisticated than the previous one and captures important information that was not requested on the previous system. 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

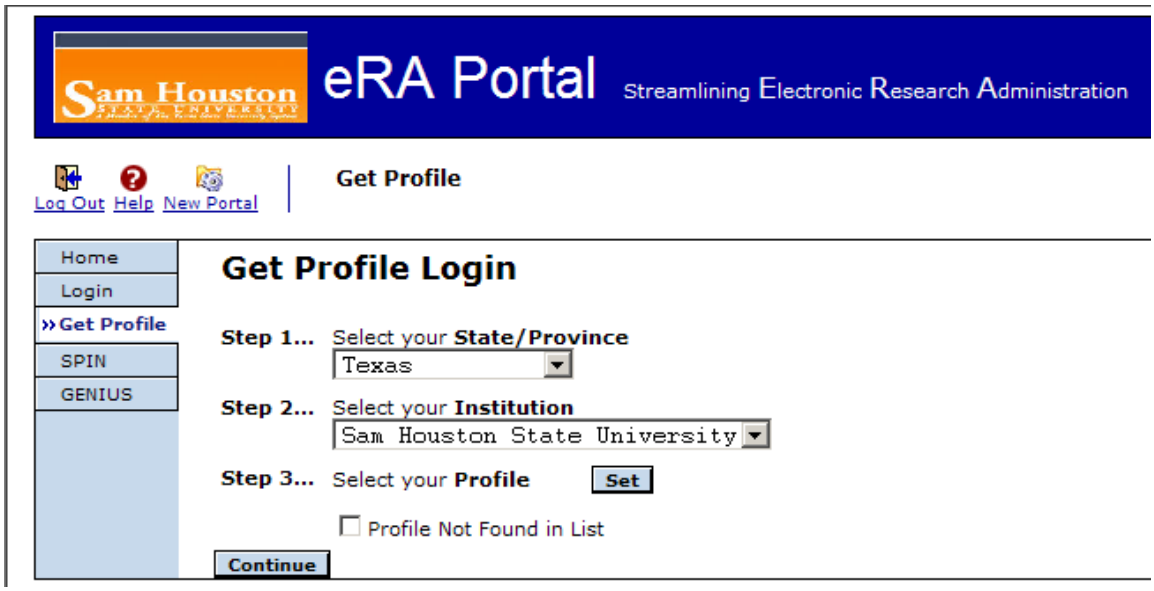
Logging into the System

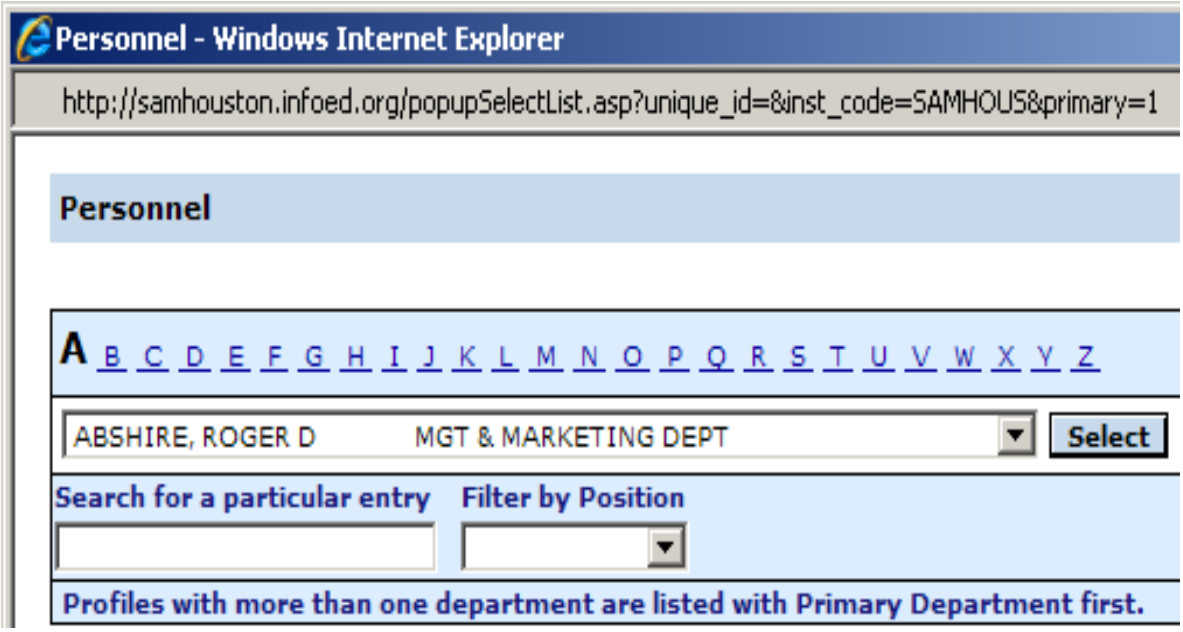
On the home page are two important buttons on the left margin: **login** and **get profile**. When you use this system the very first time, you must click “get profile.” You should only have to do this the first time.



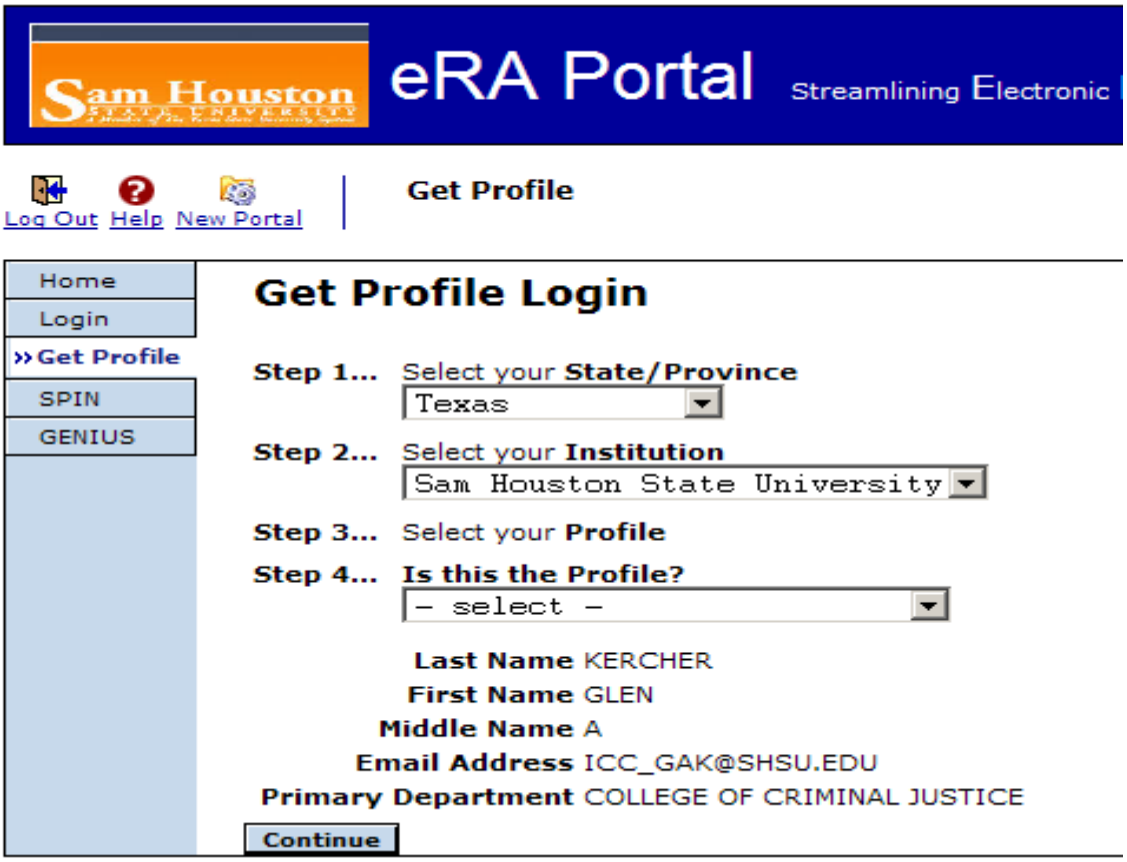
Getting a profile involves 5 steps:

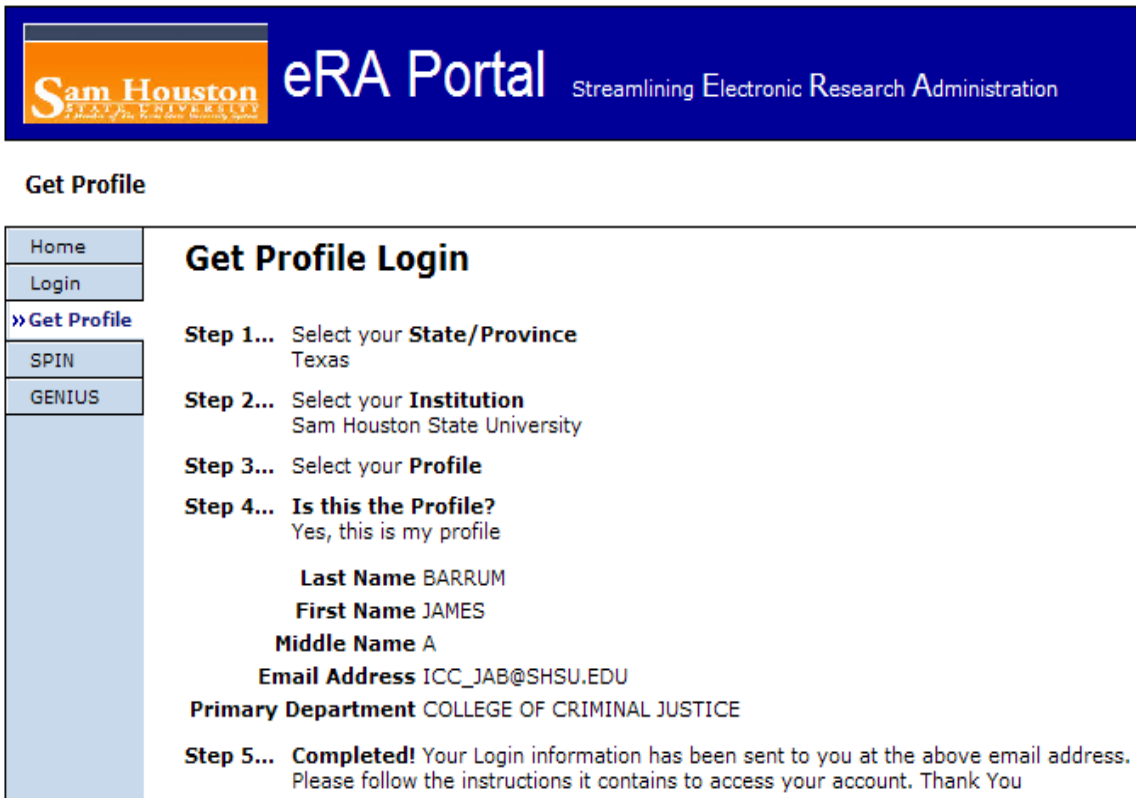
1. identify your state (TX) from the pull-down menu and continue;
2. select our university from the pull-down menu and continue;



3. select your profile and continue. To select your profile, click “set” and select the first letter of your last name. From the pull-down menu select your name and click “select.” Then close that dialogue box. At this point the user’s profile should be pulled into the system from university data bases.
4. 

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

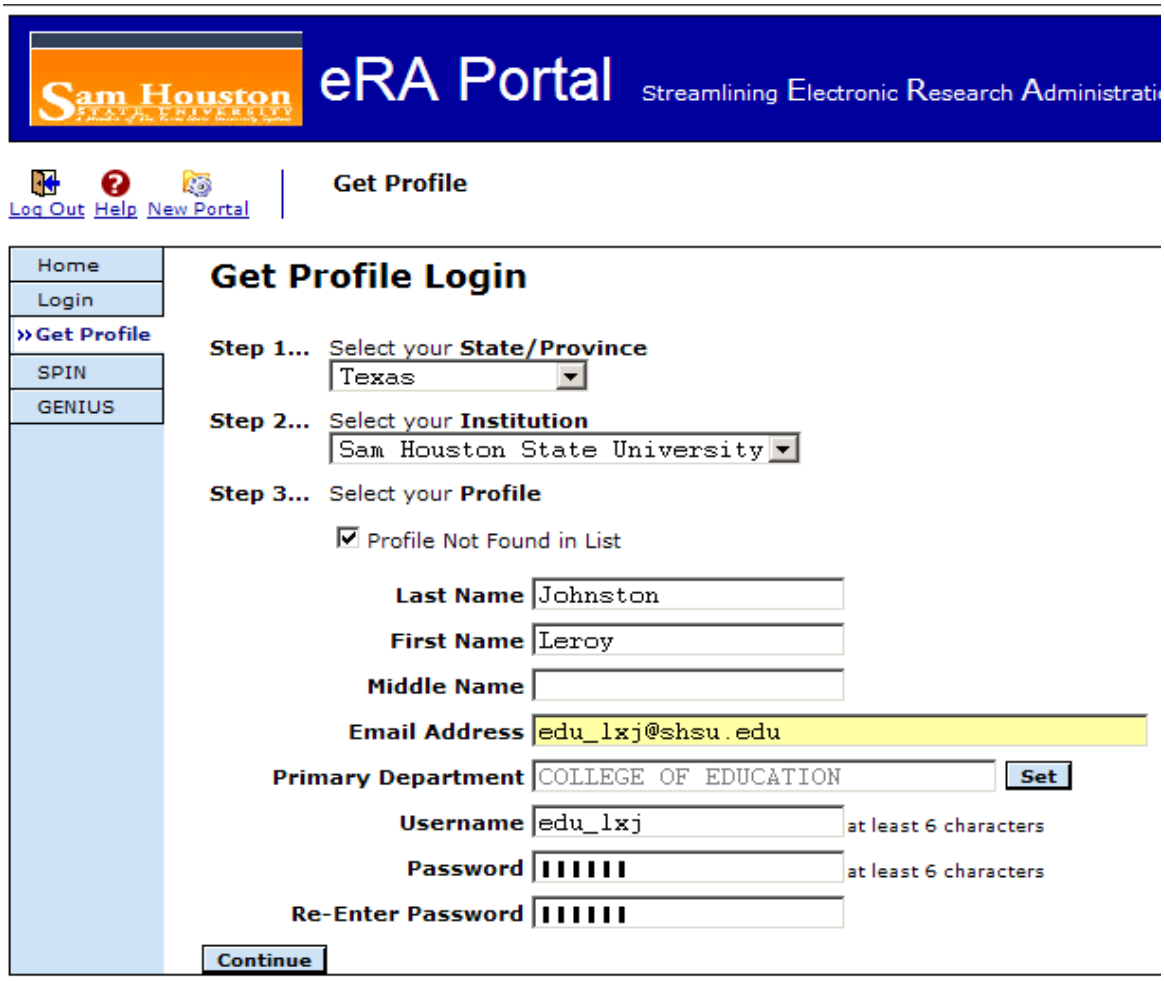

Sam Houston
eRA Portal
Streamlining Electronic
Log Out
Help
New Portal
Get Profile
Home
Login
»Get Profile
SPIN
GENIUS
Get Profile Login
Step 1... Select your State/Province
Texas
Step 2... Select your Institution
Sam Houston State University
Step 3... Select your Profile
Step 4... Is this the Profile?
– select –
Last Name KERCHER
First Name GLEN
Middle Name A
Email Address ICC_GAK@SHSU.EDU
Primary Department COLLEGE OF CRIMINAL JUSTICE
Continue


Sam Houston
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
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

6. Shortly thereafter the user's login information will be confirmed by email will include the User ID (SHSU login) and password. The user is then able to use this information to log onto the system.

New Faculty and Student Login

New faculty and students will not be able to get a profile so easily, because their information may not yet be accessible from university records. 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, SHSU email address, primary department, user ID and password. Once that information has been added, click "continue," which will take the person to step five.



However, before an email is sent to the user, the profile must be validated by the Office of Research and Special Programs. This could take several days, depending upon the availability of personnel in that office. To avoid being delayed in starting a research project, new faculty and students should be encouraged to get their profiles set before they are ready to submit an application. This recommendation is particularly important for students who will be conducting research for a class.

Using the Program

Once a profile has been set, the user can return to the InfoEd home page and click the **Login** button along the left margin (pg 2). The next screen should have the user's name printed at the top. Along the left margin are two categories: **My Human Subjects** and **My Profile**.

The My Human Subjects list is the most important for most uses with this system. Here are found links to new applications, modifications of previously submitted protocols that are under review, amendments, adverse event reporting, continuing review, final reports, and help. While scrolling down the list the user should choose the link that serves his/her intent. For example, to begin a new application, click **Create New**. If clicking that link does not take the user to the application, check to be sure there is not a popup blocker preventing access. If so, disable it.

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

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

Creating a New Classroom Application

After logging in, the student should go into **My Human Subjects** along the left margin and select **Create New**. If the next dialogue box does not open, check to see if a

popup blocker is preventing assess to this part of the program and disable it. At the **Create** dialogue box, check **New Human Protocol** and click **continue**. In the **Protocol Creation** box, enter the **title** of the research and click **continue**. At the **Select PI** window, your name should appear in the PI box. If it is not there, click on the first letter of the 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 Special Programs at X3876 for assistance. Click **continue**.

At the **Components for Initial Review** window, click the **Edit** icon by the Initial Application line to open an application. Identify the application as a classroom research project. At that point a blue highlighted line appears below that response which when selected, takes the user to the application itself.

Please 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 and printing it. **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.

The user's name should pull into the application automatically. The user must type in their department, college, status/title, phone number and email address Students must specify the faculty sponsor and that person's contact information. Co-investigators should be listed at II.C. By clicking the plus sign the user can add co-PIs.

Settings, III.1. the PI may choose as many as apply. Additional information must be provided for every location other than SHSU.

Additional Reviews, IV. Select all that apply. If approval to conduct the research has been granted by the agency or institution, that documentation should be uploaded at IV.3.

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.

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

Sensitive Subject Matter, V.D. Choose all that apply.

Protecting Anonymity and Confidentiality, V.E. Answer each question.

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

Audio or Video Taping, V.G. Yes or no.

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 your project plans. This will usually mean typing more than one line.

Protected Health Information, VII E. This refers to recording or sharing protected health information (PHI). This is an issue that is regulated by federal law (HIPAA) and must be careful considered. Additional documentation is required when a study collects or distributes PHI.

Deception. If deception is used, a debriefing document should be uploaded where indicated.

Research Participant Selection and Recruitment, VIII. Check all that apply. The user will be prompted at the **Components of Initial Review** dialogue box to upload any and all forms of consent that are indicated by the application.

Accessing Records, VIII. C. When intending to **access records** about participants outside the University, appropriate documentation for cooperation/permission from the custodian of the records should be uploaded. Clicking on the plus sign will provide an icon for uploading the necessary documentation.

Obtaining Participant Consent, IX. There are different kinds of consent: adult participant signed consent, signed parental consent, and signed assent (usually for children 12-17). Check the appropriate types and upload those documents into the application.

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

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

Be sure to save the application even if more information is needed to **Complete** it. If everything has been completed and documents uploaded, check the **Complete** box in the upper right at the beginning of the application. If there are things in the application that need to be addressed, the PI will be notified. Once those matters are addressed, the PI should again check the **Complete** box.

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 and the status of each. To add to a protocol, click the **open folder** icon, and the submission dialogue box will appear. Open the application to be taken to the application.

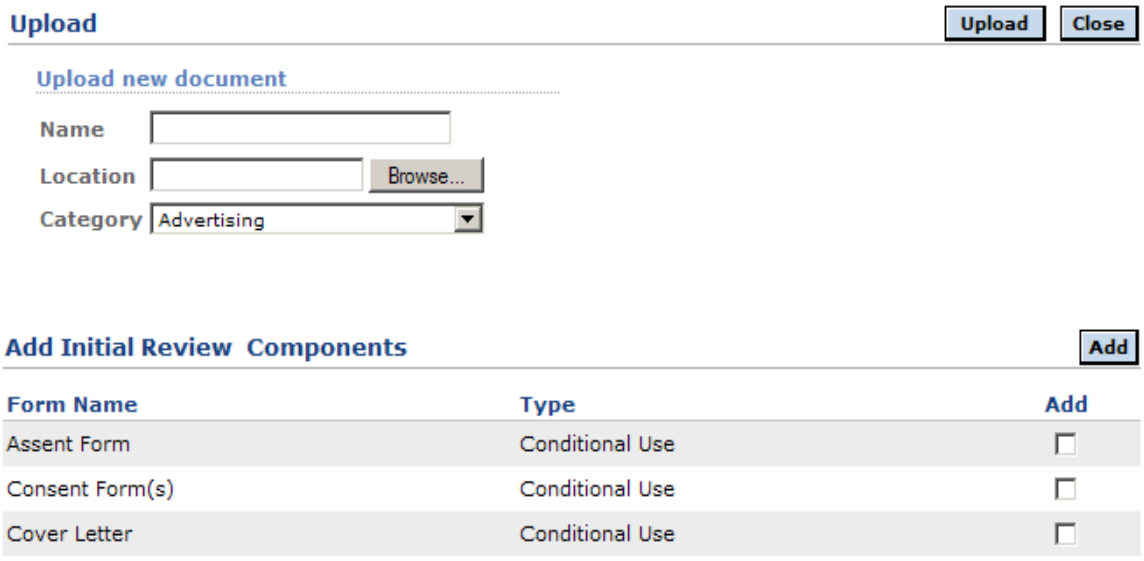
After completing the application the user will be taken to the **Components for Initial Review** screen which shows the current submission and status of the application. You may edit the submission by clicking the icon.

Components for **Initial Review** **Submit**

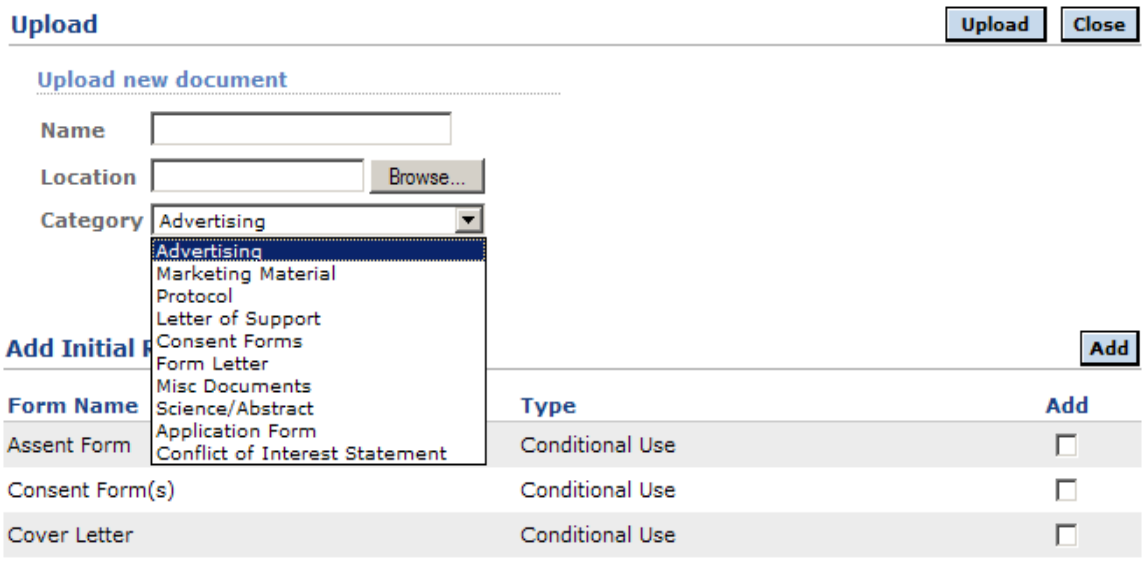
	Current Submission			
Form/Document Name	Edit	Status	Upload	Remove
Initial Application		Completed		Mandatory
Consent Form(s) *Consent Forms*		Completed		

Add Institution Forms/Supporting Documents

To access other documents and forms, click the link above. Then select (check **Add**) whichever forms are relevant to the application.



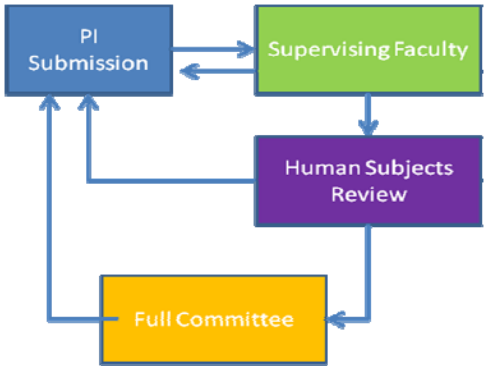
To upload other documents, give a name to the document begin uploaded and select where it is located on the user's computer. Then choose the appropriate category. Then click **Upload**.



When the **Components for Initial Review** screen indicates that the application and other documents are complete, save the application and click the **Submit** button in the upper right corner. That will send the application to the first reviewer.

Routing an Application.

Once a **Classroom Application** is submitted, it follows the route illustrated below.



A user can check on the status of an application by logging into the system, opening **My Human Subjects**, and clicking **Show/List**. Holding the cursor over the **Quick Status** icon will show where the protocol is in the routing.

1. Notification from people on the route requesting modifications, decision of the human subjects review (modification required, questions, or approved).