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;”
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

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 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.
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.
Protection of Human Subjects

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
   - Records (e.g., medical, employment, school)
   - Internet
   - E-mail
   - Other

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 uploaded where indicated.

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

IXa. Informed Consent applies to this application
   - Yes
   - No

IX. Procedures to Obtain Informed Consent/Assent
A. Indicate all of the types of consent processes to be used in the research, and attach copies of all relevant documents to this application.
   - Written Informed Consent
   - Waiver of Informed Consent
   - Parental Permission
   - Waiver of Parental Permission
   - Waiver of Documentation of Consent
   - Assent - Written
   - Assent - Verbal
   - Waiver of Assent
   - Alteration 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 process but delegate the authority to perform these duties to others:
   - Only the PI will obtain consent
   - Only Delegates will obtain consent
   - PI, Co-PIs, and delegates will obtain consent

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, Alteration of Consent, or Waiver of Documentation**

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

A. Are you requesting a waiver of informed consent or an alteration of consent under 45 CFR 46.116 (d) for all or part of the research?

- [ ] Yes
- [ ] No

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

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

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:

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

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

☐ The only record linking the subject and the research would be a signed consent document, the principal risk or harm of the research would be a breach of confidentiality and each subject will be asked whether they want documentation linking themselves to the research, and the subject’s wishes will govern.

☐ The research involves no more than minimal risk or harm to the subject and involves no procedures for which written consent is normally required outside of the research context.

Explanation:

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

Investigator Assurance

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

*I agree with the above:

*Date Application Completed:

*Application Document Version #: 

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 access 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 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 one 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 carefully 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.

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.

The route for a **Classroom Application** is as follows.
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. The user will then be asked that the profile on the screen is his or hers; if yes, click “continue;”
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

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 access 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 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 carefully 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 being 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).