Sam Houston State University
Protection of Human Subjects Committee (PHSC/IRB)

Regular and Thesis/Dissertation Application

Welcome to the Sam Houston State University online system for reviewing research on human subjects. This system is hosted off-campus by InfoEd, which is headquartered in Albany, New York. This program can be accessed with either a PC or a Mac, on-campus or off. An internet connection is required, but it will even work with a dial-up modem (but at slower speeds). Beginning in the fall 2008 semester, all new human subjects applications must be made with this new system. This program is more sophisticated than previous procedures used at SHSU and captures important information that was not requested on the previous systems. This is an important feature because it gives the University a better audit trail for our procedures and applications and improves compliance with Federal guidelines.

The new application system is found by pasting the following URL into your browser.
http://samhouston.infoed.org

Internet Explorer is the browser that works best with this system.

An alternate method is to go to the Office of Research and Sponsored Programs website, click the link to IRB Tab, then click on the Application tab, and then click the link to InfoEd’s IRB Application System. Please note there is also a tab for Instruction Manuals and Training, if this is your first time completing an IRB application, you should download a copy of the manual that coincides with the type of application you are completing.

Logging into the System

On the home page are two important buttons on the left margin: login and get profile. When you use this system the very first time, you must click “get profile.” You should only have to do this the first time.
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. Insure that the email listed is the account you access, since all communication through InfoEd will use that email.
4. The user will then be asked that the profile on the screen is his or hers; if yes, click “continue;”
5. Shortly thereafter the user’s login information will be confirmed by email and will include the User ID (SHSU login) and password. The user is then able to use this information to log onto the system.

**New Faculty and Student Login**

New faculty and students will not be able to get a profile so easily. At the first screen of the “get profile,” check the box at the bottom, “profile not found in list” (pg 2). Then the user will be asked to fill in

- his/her name – user must use the name under which he/she is registered at SHSU,
- SHSU email address (do not enter yahoo, aol, gmail, or any other email address, as the system does not recognize some of those carriers),
- primary department,
- user ID and password.

Once that information has been added, click “continue,” which will take the person to step five.
NOTE: Before an email is sent to the new user, the profile must be validated by the Office of Research and Sponsored Programs. This could take several days, depending upon the availability of personnel in that office. If you enter a profile on a weekend, the profile will not be validated until the early part of the following week. To avoid being delayed in starting a research project, new faculty and students are encouraged to get their profiles entered weeks before they are ready to submit an application. This recommendation is particularly important for students who are conducting research for a class.

Using the Program

Once a profile has been validated, the user can return to the InfoEd home page, click Login and enter name and password along the left margin (pg 2). Then click the Login button (do not just “enter”). The next screen should have the user’s name printed at the top. Along the left margin are two categories: My Human Subjects and My Profile.

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

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

The **Search For** link will enable the user to access his or her protocols that have been closed. Opening an old application can enable the user to copy and paste from the old to a new application. This can also be accomplished by selecting **Create New** and checking **Copy from Existing Human Protocol**.
Persons Not Affiliated with SHSU

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

Creating a New Regular or Thesis/Dissertation Application

This application is to be used by graduate students who are working on their theses, dissertations or by faculty and staff of Sam Houston State University. After logging in, the Principal Investigator (PI) should go into My Human Subjects along the left margin and select Create New. At the Create dialogue box, check New Human Protocol and click continue. In the Protocol Creation box, enter the title of the research and click continue.

At the Select PI window, your name should appear in the PI box. If it is not there, click on the first letter of your last name to see if you are in the system. If so, select your name and close. If not, call the Office of Research and Sponsored Programs at X3876 for assistance. Click continue.

At the Components for Initial Review window, click the Edit icon by the Initial Application line to open an application.
To identify the application as a regular research project, select Regular Initial or Thesis/Dissertation from the drop down box beside “Is this project a:”.

At that point a blue highlighted line appears below that response which when selected, takes the user to the application itself.

NOTE: Along the left margin of the formal application is a Menu tab. When that is clicked, the PI has the option of saving the application. Saving an application periodically is a good idea, so that no information will be inadvertently deleted. Printing a copy of the completed application provides a reference for the PI and supervising faculty. It can also be sent to other participating agencies or institutions. NOTE: You can only print an application once it has been checked complete and the red pdf icon appears next to Complete. To print, simply use the Ctrl P on your keyboard.

Once the application opens, the user is asked to identify the project as one submitted by faculty and staff, or thesis and dissertation students (pull-down box under A). Select the appropriate type and a blue hyperlink will appear below the type of application box that is highlighted Initial Regular, or thesis/dissertation.
NOTE: Graduate students who are conducting supervised research that is not a class requirement nor a thesis or dissertation should still use the Thesis/Dissertation Application. This is necessary in order for the route to include everyone who is required to review supervised research. Once the application is submitted, it will be forwarded to the supervising faculty member.

Clicking that link will take the user to page one of the application. At the top of the application the user is asked to indicate whether the required HPPERT training has been completed. If the training has been completed, a copy of the certificate must either be faxed to 936.294.3622 or emailed to trishaallen@shsu.edu. If the HPPERT training has not been completed, the PI and all Co-PIs must take the course through the National Institute of Health at: http://phrp.nihtraining.com/users/login.php. Users of the training must first register in that system. Once the training is completed, print a copy of the certificate and send a copy to either of the above addresses. Please do not attach a copy of the certificate to 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 the PI’s profile in this version of the software. The system may not eventually consider the application as complete until the PI’s information is also added to Section II B Faculty Sponsor. Thesis and dissertation applications require the user to specify the faculty sponsor and contact information. Co-investigators should be listed for all types of applications. The contact information (including email address) for the supervising faculty and co-PIs must be imputed manually. To insure proper routing, check this information for accuracy.

**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) Questions 1-5 in Section D must be answered. 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, find the document to include in the application, and then select the upload button.

IV. Conflict of Interest (COI) Disclosure

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

A. Financial COI

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

   - Yes
   - No

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

   - No. A financial conflict has not been reported and a management plan has not been developed. SHSU personnel contact your Department Head for further instructions.
   - No. A COI has been reported, but a conflict of management plan has not been developed.
   - Yes. A conflict management plan has been developed. Provide a summary of the management plan to be implemented in order to minimize the effect of the conflict on the design, conduct, or reporting of the research and/or the integrity of the human subject protection program or provide a copy of the finalized written management plan(s), if available.

V. Project Risk

A. Level of Risk

   - No more than minimal risk
   - Participation presents a minimal threat to safety, health and well-being of participant(s)
   - May cause severe injury, major damage or loss, damage a person’s reputation, and/or result in negative public and well-being of participant(s)

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

Level of Risk (V A) The PI should select of the level of risk to participants in terms of physical, emotional, legal, and reputation issues. The PHSC will review this to determine if there is agreement about risk.

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

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

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

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

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

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

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

**Lay Summary (V I)** Under sections A through E, the PI is asked to summarize the research project in *lay* terms, so that persons unfamiliar about the area of investigation can determine what is being proposed. Please note that in the Scientific Summary of VII, more detailed information is requested about the study.
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.
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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.
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Records (VIII C) This addresses needing to access records about participants outside the University. Appropriate documentation for cooperation/permission from the custodian of the records should be uploaded where indicated.

Obtaining Participant Consent (IX) There are different kinds of consent documents: adult signed consent, adult unsigned consent/cover letter, signed parental consent, signed assent (participants between the ages of 12-17), and waiver of assent. Check the appropriate types and upload those documents into the application.

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

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

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

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

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practically 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:

- [ ] 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:

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. When returning to an application started earlier, do not start a new application for the same project. Go to My Human Subjects and click Show/List to find the application. To open the application, click the “folder” under Actions, this will open to the Submissions page, and then click the folder under Open, this will open to the Components for Initial Review page, and there you will the Edit icon beside the Initial Application.

If everything has been completed and documents uploaded, check the Complete box in the upper right hand corner of the application. If information needs to be added, the user will get an error message that lists where the missing data are. Once the system accepts a protocol as complete, the user must wait for the system to accept it. Follow the progress bar at the bottom of the screen. When it is accepted, a pdf icon will appear next to the complete button at the top of the application. Then the user can close that screen.

The next dialogue box that appears will be the very Initial Application page of the application. There is a complete button here too that must be checked. When the system accepts it, another pdf icon will appear next to the complete box. When that appears, close that screen, and the user will be taken to...
the Components for Initial Review screen. The application and accompanying documents are listed here and can be reviewed. The PI may edit the submission by clicking the icon.

If the Complete box and the red pdf icon do not appear, the application may not be readable. Attempt to check the document back in by clicking the Check In/Out button in the red Menu tab on the left side of the screen. This may need to be done a couple of times until a message indicates that the user has ownership of the application. At that point, check the “Complete” box again. If that does not work, send an email request to Trisha Allen (trishaallen@shsu.edu) describing the difficulty encountered. When sending an email, the user should be sure to include his/her complete name and, if possible, the application number. Sometime afterward, the PI will receive an email containing information about the status of the application.

Accessing other documents and forms, such as consent/assent forms, click the blue hyperlink highlighted in the dialogue box below (Add Institution/Supporting Documents). Then select whichever forms are relevant to the application. The consent form templates are available here.
Uploading other documents; give a name to the document being uploaded and select where it is located on the user’s computer. Then choose the appropriate category. Then click Upload. Word document to be uploaded must be saved at Word 2003 (doc), not Word 2007 (docx). Pdf documents can be uploaded.

Before submitting an application the user should be sure that all necessary documents are attached to the application (e.g., surveys, interview protocols, consent forms and letters of cooperation). Letters of cooperation must be signed by the person having the authority to grant permission, and the document should be on the official letterhead of that agency.

Once the PI is ready to submit the application, click the Submit button (thumbs up icon). After that the PI will be asked to accept a certification that the information is correct and will be asked for login credentials, the user must then click on a gray Continue button and then a gray Submit button. Once that is done, the user should click Done (upper left hand corner) and then log out of InfoEd.

To return to an application that was either started or submitted earlier, login and choose the My Human Subjects tab on the left. Clicking Show/List takes the user a list of his or her protocols. To add to a protocol, click the Open folder icon, and the submission dialogue box will appear. Open the folder to be taken to the application. To make changes it is necessary to uncheck the Complete box on the application. When finished with the revisions, click the Complete boxes again and wait for the red pdf icon to appear and then close out of the application screens. At the Components for Initial Review screen, click the Submit button. Before leaving the system, click Done and then log out of the system.

If a student has not received any feedback from Ms. Allen in the ORSP or from the supervising faculty member, he/she should contact either person to insure the application was submitted properly.

Your supervising faculty instructor will not be able to access your application to make changes for you.
A new submission is always identified as **Version 1**. The **date of submission** is not necessarily the date when the PI checked “completed.”

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

**Routing an Application.**

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

![Routing Diagram of a Regular Application](image)

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

![Routing Diagram of a Thesis/Dissertation Application](image)

A user can check on the status of an application by logging into the system, opening **My Human Subjects**, and clicking **Show/List**. Opening the folder to the application will bring up the Submission folder. The status of the application will be listed here. If the status says “In Development,” then the application has not been submitted correctly or it has been returned for changes and/or corrections. Always remember to click **done** (upper left hand corner of the screen) when the application has been closed again. Then log out of the system.
If a PI wishes to delete an application, they should email the Office of Research and Sponsored Programs PHSC coordinator, Trisha Allen (trishaallen@shsu.edu) with the application # and a brief explanation as to why the application needs to be deleted.

**Review Results**

At any point in the review routing (i.e., supervising faculty, department chair, dean, PHSC), the PI may be asked for modifications. When those are required, an email will alert the user to log into the system to find out what is being requested.

Click the **Open Submission Package**, and the user will be asked to log into the system. When that is done, the user is taken to the **Components of Initial Review** dialogue box.
To find out what modification are requested, the PI should

1. Open the initial application,
2. Read the reviewer comments,
3. Open the application itself,
4. Un-click the Completed box in the upper right hand corner,
5. Make the modifications,
6. Re-click the Completed box,
7. Save the changes made to the application,
8. Re-submit the application.

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

A PI will not automatically be alerted about comments reviewers have made or the current status of his or her application. The PI is only notified when changes are required and when a protocol has been approved by the PHSC. In the latter case a decision form will be sent to the PI (with notification). Do not begin collecting data for a project involving human participants until the protocol has been officially approved by the SHSU PHSC. No one other than the PHSC has the authority to give you permission to start data collection.

A PI may also receive a Modifications Letter resulting from a review by the PHSC (pdf format). Respond to those modifications in the same way as above.
When opening the applications, the **Submissions** screen appears which will have at least 2 lines, Initial Review and Request for Modifications. Click the blue hyperlink **Respond** on the latter line and the user will be taken to the application itself to make changes.

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**Approved Research**

When a protocol has been approved by the PHSC, the PI will receive a letter by email that so states (pdf format). After opening it, save the letter, so that appropriate documentation can be given when requested by faculty or participating agencies. Approval for research studies are only good for one year. If the study extends beyond that period, an Amendment must be completed.

**NOTE:** Research should not begin before receiving this approval letter.
Approval Notice
Initial Review

08-Sep-2008

Principal Investigator: Test

RE: Protocol # 0000000032
“Pulses of Vincristine and Dexamethasone During Maintenance in BFM Protocols for Children With Intermediate-Risk Acute Lymphoblastic Leukemia”

Dear Principal Investigator Test,
Amendments, Adverse Events, Continuing Review, Final Report

Once a protocol has been approved, the PI may want to amend it, but will not be able to change the already approved protocol. Changes are made through amendments. A PI may want to report an adverse event, ask for approval to continue the research past the time limit set in the approval letter, and submit a final report when the research is completed. To do these things, log into InfoEd and open the My Human Subjects tab. Click Show List and select the protocol you wish to address. After opening it check along the right side of the dialogue box and select submissions. There are found links to these three documents. Open the document you need, complete it, save it and submit. These submitted documents go directly to the Chair of the PHSC for review.

NOTE: Amendments, Adverse Event, Continuing Review, and Final Report documents should only be used after an application has been approved by the PHSC.