**PSJH eIRB Tip Sheet: Submitting Studies to be Reviewed by TTUHSC IRB**

**for HRPP Clearance**

New studies to be reviewed by the Texas Tech University Health Sciences Center (TTUHSC) IRB are required to be submitted in the eIRB system for clearance by the Providence St. Joseph Health (PSJH) Human Research Protection Program (HRPP) and subsequent tracking. This Tip Sheet provides instructions on submitting a new study to be reviewed by TTUHSC IRB in the eIRB system, as well as post-HRPP clearance submission requirements.

**Submitting a New Study:**

* **Access eIRB System:**
1. Click on this link to access the Click eIRB system: <https://eirb.providence.org>
2. New users will need to request an account. To request an account, users with a PSJH e-mail address should click the **Caregiver Logins or Account Requests** button. Users without a PSJH e-mail address should click the **External Partners Request an Account Here** button.

Once an account has been requested and approved, login as follows:

* 1. Users with a PSJH e-mail address should login using the **Caregiver Logins** button.
	2. Users that do not have a PSJH e-mail should log in under **External Partners**.
		1. Your e-mail address is your User Name.
		2. If it is your first time logging in, use the **Forgot password?** link to obtain your password.
* **Create Study:**
1. After logging in, click the **IRB** tab in the blue bar at the top of the page and then click the **Create New Study** button on the left side of the page.
2. You will now be presented with the pages of the Study Application. Answer each question on each page. You can navigate between pages by clicking the **Continue** button at the bottom of the page or via the menu on the left side of the page. Please note the following when completing the Study Application:
	1. On the *Basic Study Information* page:
		1. Question 4: select **Single-site study.**
		2. Question 5: select **Yes.**
		3. Question 6: if you cannot find your PI, this individual will need to create an account – see item 2. in the *Access eIRB System* section above.
		4. Question 8: upload the Protocol.
	2. On the *External IRB* page, Question 1: select TTUHSC IRB.
	3. On the *Study Funding Sources* page, Question 1: identify any funding agency(ies) or sponsors.
	4. On the *Local Study Team Members* page, Question 1: identify all key study personnel (sub-investigators, study staff, etc.) participating in the study at the PSJH facility(ies) where the study is taking place. If you cannot find an individual to add, the individual will need to create an account – see item 2 in the *Access eIRB System* section above.
	5. On the *Local Research Locations* page, Question 1: identify the PSJH facility(ies) where the study is taking place.
	6. On the *Local Site Documents* page:
		1. Question 1: if applicable, upload the consent form(s) with required institutional boilerplate language included.
		2. Question 3:
			1. upload a copy of the signed PI Eligibility Authorization (required for non-sponsored studies)
			2. upload a copy of the PI’s CV if not provided to the PSJH HRPP within the last 2 years.
			3. Upload any other relevant study-related attachments.
	7. *Study Properties and Categories* page: Answer all questions marked with an asterisk.
	8. *CITI Training* page: You may ignore the information on this page.
	9. *Final Page*: Click the **Finish** button to exit the application (note: this button does *not* submit the application to the IRB). When you have finished updating the application, and exited, you will be taken back to the study workspace.

Note: While updating the Study Application, if you need to stop and come back later, use the **Save** button to save your progress, and then the **Exit** button to exit the application. To return to the application to make further updates, in the study workspace, click the **Edit Study** button in the left sidebar. Studies that you have started, but not submitted, will be listed in your inbox which you can access by clicking the **Dashboard** tab in the blue bar at the top of the page.

* **Submit Study/HRPP Review:**
1. When you have completed the application, it will be ready for submission to the HRPP. Only the PI has the authority to submit studies in eIRB – see the guidance document “How to Submit a Study in eIRB (Click).”
2. Your submission will be reviewed by the HRPP to confirm facility approval has been obtained, for funded research: that investigators have filed financial interest disclosures/financial interests have been managed, and the protocol and consent form meet institutional standards, e.g., compliance with Ethical and Religious Directives for Catholic Health Care Services (ERDs).

When applicable, the HRPP review will also confirm that required institutional boilerplate language has been appropriately included in the consent form. Note: this review will only be done at the time of the initial submission of the study. If there are subsequent amendments with revised consent forms issued by the TTUHSC IRB, the study team will be responsible for ensuring institutional boilerplate language has been appropriately included in the consent form.

1. You will receive an automated email from the eIRB system with a notice that HRPP clearance has been provided or that additional information is requested. The email will contain a link to the submission where the HRPP Clearance Letter (or request for additional information) will be provided.
* **Post-HRPP Review:**
1. After HRPP clearance has been issued the study may be submitted to TTUHSC IRB to include the PSJH facility(ies) as a site. Once TTUHSC IRB approval has been issued, you may proceed with the study. The HRPP will be notified by the TTUHS IRB upon approval and will document the approval in eIRB. The same process will be followed for continuing review approvals through closure.
2. Further submission to the HRPP is only required in the following circumstances:
	1. Prior to the addition of study personnel or in the event of a change in Principal Investigator you are required to use the **Update Study Details** activity to add the personnel to the Study Application for HRPP review.
	2. If an investigator develops a previously undisclosed financial interest related to the research this new disclosureis required to be submitted for HRPP review.
	3. If the TTUHSC IRB determines an incident to be an Unanticipated Problem or Serious or Continuing Non-Compliance, the determination is required to be submitted as **Reportable New Information** for HRPP awareness and action, if necessary.

If you have any questions or encounter any issues, please contact the PJSH HRPP at IRBSharedServices@providence.org for assistance.