A PI submits a WIRB study to the Temple IRB. Once a study is approved by WIRB, the investigator submits modifications and other post-approval items directly to WIRB. WIRB keeps the Temple IRB informed of the changes.

**Initial Review Process**

The PI needs to submit the following to the Temple IRB:

1. All WIRB initial review documents. The documents can be found at: http://www.wirb.com/Pages/DownloadForms.aspx

2. Temple’s "Application for Human Research."

3. The sponsor’s template consent form, when one is available. There is no need to edit the sponsor consent template. WIRB will make all necessary changes based on the information in your submission form. If you do not submit a sponsor’s template consent form, WIRB may call you to ask the sponsor for a copy. In the rare case when the sponsor does not have a template consent document, you may need to create your own. WIRB Client Services can guide you on the process. All consent forms will be placed on hold after they are approved by WIRB so that Temple legal counsel can review the language. If legal counsel has concerns, the changes will go back to WIRB for reconsideration. If the consent form is acceptable, it will be released to you.

**After you submit the study to the Temple IRB:**

1. Temple IRB ensures that all of the documents are complete.

2. Temple IRB confirms that all research personnel have current CITI training.

3. The Temple University Office of Clinical Research Administration submits a Payment Authorization Agreement to the Temple IRB.

4. Once these steps are complete, the Temple IRB will e-mail the submission, with a "Permission to Review" letter, to WIRB.