READ ME FIRST

Welcome to Creighton University’s Electronic IRB submission system-IRBNet.

Steps to start your submission:

**User Registration**

* All of the research team must be a registered user on the system.
* Refer to the Creighton University’s *Registering,* Notes for Researchers and Study Coordinators: *Registering, Managing Training & Credentials*

**System Training**

* The investigator (or their designee) enters everything in the system.
* The IRB# is generated by the system when you enter a project.
* Refer to the [Creighton University’s IRB Website](http://www.creighton.edu/researchcompliance/humanresearchprotectionprogram/investigatorandresearchstaffinformation/irbnetsubmissions/) to view the training tapes on the system, there are two 10 minute training tapes that review initial submission and follow up submissions.
* The tapes have usernames and passwords which are on the website.
* Username: Creighton; Password: training

**Sharing with project members**

* The project must be SHARED with the entire research team. This is the method that the IRB staff uses to verify that all members of the team are trained.
* The project will not be approved unless all members of the team have completed their required training. Training can be checked by the investigator on IRBNet prior to submission to the IRB (once the project is submitted this feature is not available).
* Go to the designer page and you will see “There are no Training & Credentials records linked to this package.   [|   Link / Un-Link Training Records”](https://www.irbnet.org/release/pt/pt_links.jsp?ctx_id=6); click ‘Link’ and all the training for members that the project has been shared will appear.

**Applications**

* The only unique thing that Creighton University has purchased is an on-line application specific to Creighton University.
* All projects that are entered must have an online application completed regardless of the type of review.
* To do this click on your study title under the “My Projects” page and then click on the blue link that says “Designer.”  Under Step 2 click on the “Add New Document” button and in the second blue outlined box that says On-Line Document select "Add" to begin our online document wizard titled Creighton IRB Application form.
* The IRBNet electronic submission program was initiated on July 1, 2014. Existing projects files are retained in paper form until study closes. However all submission on existing projects must be registered into the system if additional requests are made.
* The first time an existing project is registered in the system the on-line application must be completed even though the project already exists. The only request that the IRB office will accept is a study termination report to completely close an IRB file that is paper only.
  1. All applications and templates can now be found under the IRBNet forms and templates.

**Required Signatures**

* When you get all the documents uploaded, the online application completed, all members of the research team are trained and the project has been shared with all members of the team; the project is ready for final review by the Principal Investigator. After review the Principal Investigator must sign electronically.
* The person who may be designated to prepare the IRB submission may sign subsequent submissions on the project if the review does not require review by the convened committee (which indicates that a change or update to a project involves risk). If a resident, intern, or any student investigator is listed as the principal investigator, their mentor/advisor is also required to electronically sign off on the project.
* Note that undergraduate students are NOT allowed to be a principal investigator; the principal investigator must be their faculty mentor.
* If the project required internal scientific review the project must also have the electronic signature of the reviewer. If the project is being conducted at CHI-Health the project must be shared with *Kayleen Joyce* who will sign off to indicate site approval (this is required if CHI-Health is engaged in the research).

**Submission**

* When the study documents, training and signatures are complete, the study is ready to be submitted to the appropriate IRB. Creighton University has two Boards: 01-Biomedical and 02-Social Behavioral. Refer to [Policy #101 “Biomedical and Social-Behavioral”](http://www.creighton.edu/fileadmin/user/ResearchCompliance/IRB/Policies_and_Procedures/101_Biomedical_and_Social_Behavioral_Boards.pdf) for types of research reviewed by each Board.
* **Please note once a project is submitted, the project may not be removed from the system.**
* During the preparation of a project (prior to submission) the system can be used by the research team as a central site to develop the research. The project can be deleted prior to submission if the team decides not to proceed.

**Subsequent Submission**

* The system is set up that each separate submission on a project is called a package. Therefore you only enter a project one time. The first submission will have a six digit IRB# with a ‘-1’ after the six digit number. Once the submission has been reviewed and you receive a response letter from the Board the package is closed.
* If you need to respond to the IRB request for change or if approved the project requires modification you will open a new package and this package will have the six digit IRB project # with a ‘-2’, subsequent package ‘-3’ and so on.
* The review will start with an IRB administrator and if the submission is missing a required document or some document needs a revision the administrator can unlock the package, the investigator can update and then click update complete. (For this type of request do not resubmit but click to re-lock).

If you have any questions please contact the IRB office for assistance at 402-280-2126 or [irb@creighton.edu](mailto:irb@creighton.edu).