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|  | Institutional Review Board**SUBMISSION INSTRUCTIONS**Return to the Office of Research Integrity1055 N. Curtis RoadBoise, ID 83706Phone: (208) 367-8897Phone: (208) 367-2233Nancy.Heaton@saintalphonsus.org  |
| Confidential pursuant to Idaho Code |

**Saint Alphonsus Health System (SAHS) Institutional Review Board (IRB) Submission Instructions**

The Federal Institutional Assurance filed for Saint Alphonsus mandates that all researchers who conduct human subject research at Saint Alphonsus complete appropriate human subject research educational training.To access the Clinical Researchers-Human Subject Research, Basic Course module, you will need to do the following:

* Go to **www.citiprogram.org** and register.
* Once there, click on "**New Users Register Here**".
* In the "Select your institution or organization" section, select "**Trinity Health – St. Alphonsus Health System (Boise, ID) Courses**" in the "*Participating Institutions*" drop down box. Selecting the incorrect institution may lead to completion of different or unnecessary modules.
* Create your own username and password, and then after logging in, select your Learner group (typically Group 1).
* After going through the registration process, you will be ready to compete the required "**Group 1: Investigators, Study Coordinators, and Research Staff - HSR – Basic Course" (course ID 253533) module**. After registering, you will be able to login as a returning user.
* You may use multiple logon sessions to complete the course.

The NIH offers an on-line human research ethics course than can be accessed at http://phrp.nihtraining.com/users/login.php. A copy of the certificate of completion will be required for a new study and for each annual continuing review application. This training will need to be updated every **three (3) years**.

**What do I submit for a new research project?**

**An initial application submission includes the following required items:**

* A submission **Cover Sheet** and an **Initial Submission Application** for either research that meets an **Expedited** category or requires **Fullboard** review.
	+ Initial Protocol Submission Application
	+ Expedited Review Application (if applicable)
* Your **Principal Investigator's** signature is required on the Application Form.
* A study protocol, Investigational Brochure, survey or any data collection tools that will be used must be included.
* Saint Alphonsus Regional Medical Center pre-formatted informed consent form
* Participant payment schedule (if applicable).
* Signed Financial Disclosure forms for all investigators and co-investigators.
* Human Ethics training and/or CITI completion reports for **all** Investigator's and study team members.
* Curriculum vitae (CV) for **all** Investigator's and Co-investigators, **signed and dated**.
* Copy of medical/professional license(s) for all investigators and study team members.
* For studies that are utilizing a device submit the Significant Risk determination from the Sponsor and/or the FDA and the FDA approval letter.
* Any documents such as advertisements, recruiting information, informational brochures or anything to be seen or used by a potential research participant must be submitted.
* Saint Alphonsus Institutional Review Board prior disapproval or termination letter, with explanation.
* Other Institutional Review Board approval or disapproval, with explanation.
* Documentation of any criminal or medical organization proceeding against the **PRINCIPAL INVESTIGATOR**.
* Documentation of any recent events in our community (deaths or serious injuries) related to this research or device.
* Sponsor/Investigator Contract (if applicable).
* Sponsor Site Agreement and/or Data Use Agreement (if applicable).
* Copy of Grant (if applicable).
* Copy of Federal Contract (if applicable).

For clinical trials - Investigational New Drug information, including:

 U.S. Federal Drug Administration form 1572 (if applicable)

 Investigator’s Drug Brochure, applicable package insert(s), or background information

For device trials - Investigational Device Exemption information, including:

 Copy of letters and supporting documentation from the device sponsor/manufacturer's application to the FDA

 for IDE status

 Copy of the FDA letter(s) granting IDE use

 Documentation for why the device is exempt from IDE requirements

**What do I do if there is a change to the approved study protocol?**

Complete a **Cover Sheet** and an **Amendment Application** as applicable (Full Board or Expedited). The use of these forms is required. Summarize the changes and how the changes alter the risks to participants.

* All changes to the previously approved documents must be submitted in track changed or highlighted versions. If the changes are not sent in the track change version the information will be sent back to the submitter.
* Attach the tracked changed Informed Consent, Protocol, and any other changed documents that were previously reviewed and approved by the IRB.
* Any modification that is substantive (e.g., change in risk - benefit ratio) will need Full Board review.
* Requesting expedited review in the submitted correspondence does not guarantee this type of review.
* The IRB reserves the right to conduct Full Board review on any changes.

**What do I do if I have to report an Internal Adverse Event (unexpected serious adverse effect)?**

Complete an Adverse Event Form and **submit within 3 days of knowledge**. The use of this form is required. Supply all the information as requested on the form.

If you have questions regarding what to report to the IRB please contact the Research Integrity Office at:

* **208-367-2233 or 208-367-8897**

**What do I do if I have to submit a Continuing Review Report (Annual Renewal)?**

Complete an Annual Expedited or Full Board review application. The use of this form is required. Supply all the information as requested on the form. Please be sure to summarize the activities that have occurred thus far in the study. Provide all the attachments as requested on the form.

**How do I submit to the IRB?**

Submit ALL materials for review electronically to the e-mail below.

Hard copy material is no longer accepted.

Please note: if any portion of the required materials/forms is not complete, it will be returned to the submitter. This includes signatures on the applicable forms, as well as human subject training and financial disclosures.

If the Principal Investigator feels the study will be considered "exempt", the Exempt Application, Study proposal, and applicable documentation is still required to be submitted and reviewed.

**Send all IRB submissions to** : kimberly.garst@saintalphonsus.org

***Please visit the IRB website for all of your resources and forms at*** <http://www.saintalphonsus.org/forms-and-resources>