**INSTITUTIONAL REVIEW BOARD**

**Investigator Handbook**

**Phone 303-837-6529**

**Fax 303-837-6527Investigator Handbook for the**

**Exempla Healthcare Institutional Review Board (IRB)**

**INTRODUCTION**

The Exempla Institutional Review Board (IRB) is an administrative body chartered by the Exempla Board of Directors (BOD) to protect the rights and welfare of human participants in research activities conducted under the auspices of Exempla Healthcare.

Exempla is committed to conducting research with the highest regard for the welfare of human subjects. Exempla upholds and adheres to the principles of the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research by the National Commission for the Protection of Human Subjects in biomedical and Behavioral Research (1979).

These principles are:

1. Respect for Persons, which is ensured by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations;
2. Beneficence, which is assured by ensuring that possible benefits are maximized and possible risks are minimized to all human subjects; and
3. Justice, which is the equitable selection of subjects.

The IRB is designated by the BOD to review, monitor and act on all research activities within Exempla Saint Joseph Hospital (ESJH), Exempla Lutheran Medical Center (ELMC), Exempla Good Samaritan Medical Center (EGSMC), Exempla Physician Network (EPN), or any affiliated facility in which the research is conducted by medical staff appointees and/or employees of Exempla Healthcare. This includes any access of patients’ medical records for research purposes. The IRB may also, at its discretion and upon request of a member of the Exempla Medical Staff, review and act upon research performed in physician offices. .

**PURPOSE**

The purpose of this handbook is to give new and experienced investigators an overview of the IRB’s requirements for clinical research submissions and ongoing reporting requirements. The IRB Policies and Standard Operating Procedure and IRB Submission Forms should be reviewed prior to submitting a research study and any time that questions arise (See Resources below).

**RESOURCES**

The IRB Policies and Standard Operating Procedures and IRB Submission Forms are available on the Exempla Portal, and on the U drive. Paper or email copies can be obtained by contacting the IRB Office. If you need assistance or have questions, please call the IRB Office at 303-837-6529.

A recommended reference:

Dunn, Cynthia and Chadwick, Gary, 2012, *Protecting Study Volunteers in Research, A Manual for Investigative Sites,* Fourth Edition, Boston, MA

**PROTECTED HEALTH INFORMATION**

Protected Health Information, in any format, may be accessed, used and disclosed for research purposes only under the following conditions: (1. With a Health Insurance Portability and Accountability Act (**HIPAA)** compliant authorization signed by the study participant (HIPAA **Authorization for Research form)**

 (2. With a HIPAA Waiver of Authorization approved by the IRB/Privacy Board, (3. As necessary in preparation of the research protocol (reports run with approval) (4. As necessary for a study involving decedents, or (5. As part of a Limited data Set with a Data Use Agreement. The Exempla HIPAA Privacy Officer is a member of the IRB to ensure that research presented to the IRB is consistent with the HIPAA Privacy Rule requirements related to the using/disclosing of Protected Health Information (PHI) for research. For HIPAA related forms see Resources above.

**NOTE: The required forms need to be completed and approval granted prior to the start of any study (See Resources).**

**EDUCATIONAL REQUIREMENTS**

The Exempla Institutional Review Board requires that all Principal Investigators and Sub-Investigators complete the National Institutes of Health (NIH) Human Protections Training Module, and submit the certification received at the end of the module to the IRB. The internet link to the training module is <http://phrp.nihtraining.com>.

Other Human Subjects Protection (HSP) certification will be considered on a case by case basis.

**REQUIRED DOCUMENTS**

In addition to the Human Subject Protection certification the IRB requires a current CV or resume, and a completed Conflict of Interest Disclosure form, from each person involved in the research.

**MEETING INFORMATION**

The IRB meets on the second Monday of each month in the Mullen Board Room, which is located on the Exempla Saint Joseph Hospital Campus. Submissions must be received in the IRB office by the required date (See Resources). Late or incomplete submissions will not be added to the agenda. The IRB will not review a study or submission before receiving all appropriate documentation.

**NEW RESEARCH STUDY**

There are two types of new research studies: Treatment and Non-treatment Studies. Treatment Studies , are those that include an intervention or interaction with a research participant. Examples of some treatment studies are studies that include procedures, interviews, surveys, blood draws, or administration of a medication/drug.

Non-Treatment Studies are those that do not include an intervention. Examples of some non-treatment studies are retrospective chart reviews, the analysis of previously collected data/samples, surveys/questionnaires and interviews.

Quality Improvement/Program Evaluations and Exempt Research Determinations all require IRB review and need to be submitted to the IRB using the Non-Treatment submission form.

The correct submission form must be submitted along with the required materials/documents appropriate for the study. The required materials/documents such as the Data Collection Sheets, translated Informed Consent Forms, surveys, questionnaires and advertisements, will depend on the type of study you are submitting. The last page of the submission form contains a checklist of the required materials/documents. Not every item may be applicable to your study.

Case Study/Presentations require IRB/Privacy Board review, refer to the Guidance for Case Study/Presentation (See Resources)

For all Submissions to the IRB each question on the application must be answered. If you are asked for more information or for clarification after you have submitted your research study, respond as quickly as you can to avoid delays. All submission materials must be typed, and the Investigator Acknowledgement must be signed, (Mentor Acknowledgement is required on Resident and student research)

**Please contact the IRB Office (303-837-6529) if you have any questions throughout the submission and approval process. Incomplete submissions delay the review/approval process.**

The IRB may request that the Principle Investigator for a new study attend the IRB meeting at which his/her study will be discussed. This is an important opportunity for you to answer any questions that the IRB may have.

**Reminder: You must have written IRB approval prior to starting a research study (this includes the collection of any data elements).**

**BOARD DECISIONS**

Each study will be given one of the following responses:

* Approved
	+ If your study is approved, your approval letter will contain an expiration date. This date will be for no more than one year - see Continuing Review section below.
* Approved with modifications
	+ The IRB may approve your study pending some specific modifications or changes. You will receive a letter detailing the changes that are required. These changes must be submitted to the IRB and approved by the IRB prior to starting your study. A response is needed within 30 days or the study will be inactivated.
* Disapproved
	+ If your study is denied, you will receive a letter stating the reason for the IRB’s decision. You will have a maximum of 60 days to respond before the study is inactivated.
* Tabled
	+ You will receive a letter stating the rationale for tabling your study. Usually, a study is tabled if there are substantial changes or additional information needed, that in the IRB’s opinion may or could possibly affect the risk to benefit analysis for study participants.

**TIMEFRAME FOR APPROVAL OF NEW RESEARCH**

Approval of a new research study generally takes 4 to 6 weeks from the time of submission. This timeframe may be longer depending on the completeness of the application and the timeliness of responses to any requests for additional information.

**MODIFICATIONS TO APPROVED RESEARCH**

A modification is any change to a research study after the initial approval. Examples of some modifications include changes to the protocol, consent, study population, investigator brochure, surveys, inclusion/exclusion criteria, study procedures, principal investigator study personnel, length of the study or the addition or deletion of any study documents.

A modification form (See Resources) must be completed when submitting a study modification. All changes must be clearly identified by submitting a copy with the changes tracked to the original document and a summary of the changes. The Version # and Date must be updated on all study documents.

You will be notified by letter if your modification is approved, approved with modifications, denied, or tabled (See Board Decisions above).

**Reminder: Modifications must be submitted for review and approval; some modifications will require review at the next IRB meeting. All modification must have written IRB approval prior to incorporating or initiating the change.**

**CONTINUING REVIEW**

Regulations require that research studies are reviewed not less that once a year. This timeframe may be less than a year depending on the risk to participants as decided by the IRB. Investigators must submit their Continuing Review Submission Form with required materials/documents approximately 60 days prior to the date that the study expires. This will allow adequate time for the IRB to review the ongoing studies prior to the date that their approval expires. The Research studies are considered ongoing until analyses of data are complete and the IRB acknowledges study closure in writing. The IRB Office will send a courtesy reminder to the Principle Investigator.

It is the responsibility of the Principle Investigator to submit the Continuing Review Submission Form with all required materials/documents. A check list of required materials/documents is contained on the submission form. IRB approval of a study lapses if the study is not reviewed and approved prior to their expiration date.

You will be notified by letter if your continuing review is approved, approved with modifications, disapproved, or tabled (see Board Decisions above).

**Reminder: You must have written IRB approval to continue any research study activities.**

**ADVERSE EVENTS AND UNANTICIPATED PROBLEMS**

During a research study, events or problems occur that may affect the research participants to various degrees. It is important that the IRB be made aware of these occurrences so that the IRB can determine whether the occurrence is anticipated or unanticipated and involves risks to participants.

Events can be internal (occurring to a participant enrolled in a study approved by the Exempla IRB) or external (occurring to a participant enrolled in the same study approved by an IRB other than the Exempla IRB [usually multi-site studies]). The regulations surrounding adverse events and anticipated problems are very exact. The IRB Policies and Standard Operating Procedures should be reviewed prior to beginning a study and referenced frequently during a study (See Resources).

**Internal Adverse Events**

Investigators must contact the IRB Office by phone or encrypted email within 2 business days and submit a written report within 5 business days of the Investigator becoming aware of the event. The Adverse Events and Unanticipated Problems Form must be completed and signed by the Investigator (See Resources) and submitted to the IRB for review.

**External Adverse Events**

Events occurring in participants enrolled in a multi-center study should be submitted for review and analysis to a central monitoring entity in accordance with a monitoring plan required in the approved protocol. The reports generated by the central monitoring entity should be submitted to the IRB within 5 business days of the Investigator receiving or becoming aware of them and at the time of continuing review. An Adverse Events and Unanticipated Problems Form must be completed (See Resources) and submitted to the IRB for review.

**Review of Internal and External Adverse Events**

Internal and External Events will be reviewed by the IRB Chair and may be reviewed by the convened IRB. The IRB may determine that additional information is needed, changes need to be made to the informed consent, protocol, or other study documents, and enrollment must be suspended until the concerns are resolved, or the approval of the study must be terminated. Changes to the informed consent may require study participants to sign the revised consent.

**Protocol Deviations and/or Violations**

Protocol deviations occur whenever there is a variance in the conduct of the research study and the protocol that has been reviewed and approved by the IRB. The Investigator must report Protocol Deviations and/or Violations to the IRB Office by phone or encrypted email within 2 business days and submit a written report within 5 business days of the Investigator becoming aware of the occurrence. Definitions of minor and serious protocol deviations or violations and reporting procedures are contained in the IRB Policies and Standard Operating Procedures (See Resources).

**HUMANITARIAN USE DEVICES (HUD)**

The Food and Drug Administration (FDA) requires IRB approval prior to the humanitarian use of a HUD, although this is specifically acknowledged by the FDA as a non-research activity (data may not be collected or used for research).

**Initial Review**

A Humanitarian Use Device Submission Form must be completed and submitted to the IRB for review along with any other required materials/documents. The last page of the submission form contains a checklist of the required materials/documents. The HUD will undergo Continuing Review at least annually.

**Continuing Review**

Investigators must submit a HUD Continuing Review Submission Form with required materials/documents approximately 60 days prior to the date that the study expires. This will allow adequate time for the IRB to review the documents prior to the date that the approval will lapse. Physicians will not have access to the HUD if the manufacture does not receive notice of the IRB’s continued approval.

**STUDY CLOSURE**

A study closure report (See Resources) must be submitted to the IRB to ensure proper closure of a research study. A study can be closed when all research participants have completed all follow-up as required by the study protocol and data analysis is complete, (contact the IRB for questions regarding data analysis of de-identified data).

A study needs to be closed even if the study has been cancelled or terminated without any participants being enrolled.

Retention of Study Records: The Investigator is responsible for the study records during the study and after the study has been closed.

1) For studies in which identified data has been collected, and/or Informed Consent and HIPAA Authorization were obtained, and/or study participants were reimbursed for their time and effort; all study related records shall be retained for at least 3 years, after completion of the research. It remains the investigator’s responsibility to ensure that all records shall be securely stored and accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner. Please be advised that there may be additional requirements for record retention under applicable federal regulations, state laws and/or the study sponsor, and it is the investigator’s responsibility to remain in compliance with these requirements.

2) For studies such as retrospective chart reviews, where only de-indentified data has been collected all study records must be securely destroyed when the study is closed. The Investigator must confirm that the study data does not include identifiable data or subject identifying codes or links to the de-identified data, and that all I all study-related documents are destroyed in a secure method.

**PLEASE CONTACT THE IRB OFFICE IF YOU HAVE ANY QUESTIONS.**

**WE LOOK FORWARD TO WORKING WITH YOU.**