Emergency Use for Investigational Devices

Use this document (1) to determine whether circumstances meet FDA requirements for emergency use and (2) as guidance through the procedures required by the FDA and Allina Health for emergency use, including (3) the notification of the Allina Health IRB within 5 business days after use.

(Step 1) Emergency use is defined as the use of an investigational device on a single human subject in a life-threatening situation in which no standard acceptable treatment is available.

All of the following criteria must be met to qualify as emergency use:

- ☐ The patient has a life-threatening condition that needs immediate treatment;
- ☐ No generally acceptable alternative treatment for the condition exists;
- ☐ Because of the immediate need to use the device, there is no time to use existing procedures to obtain prior FDA approval for the use;
- ☐ Prospective IRB approval cannot be obtained in time to prevent serious harm or death to the patient.

(Step 2) Emergency Use Procedures:

- ☐ Contact the manufacturer to determine whether the investigational product can be made available for emergency use and what mechanism to follow to obtain an IDE (if there is one).
- ☐ Seek approval from the Vice President for Medical Affairs (VPMA), designee, or administrator on call for emergency uses or, if prior approval is not possible, provide notification as soon as possible after the use. Written documentation of the approval must be obtained and submitted to the IRB within 5 business days of the approval.
- ☐ Obtain certification from an independent physician (a physician not otherwise involved in the decision to treat with the investigational product) that the criteria for an emergency use are satisfied. If immediate use is required to preserve the life of the patient and time is not sufficient to obtain the independent physician certification in advance of use, the physician shall document their determinations that the criteria for emergency use are satisfied and have these determinations reviewed and evaluated in writing by an independent physician.
- ☐ Obtain informed consent, where possible. There is a consent form template available for use on IRBNet in the Forms &Templates Library (Template – Emergency Use_Template Consent). Exceptions to the informed consent requirement can be found here and also must have independent physician certification and documentation.
- ☐ Following the emergency use, notify the FDA. If a manufacturer holds the IDE, provide the report to the manufacturer. Otherwise, it is the physician's responsibility to submit a report to the FDA including this information.

(Step 3) Report the emergency use to the IRB on IRBNet within 5 working days including the following documents. If you need assistance with an IRB submission, contact the Allina Health IRB Office at 612-262-4920 or irb@allina.com. The IRB forms can be found under Forms & Templates Library on IRBNet besides Application Part 1 (online smartform for all submissions on IRBNet):

- ☐ Allina Health – Application Part 1 (Type of Submission: Report of an Emergency Use of an Investigational Product)
- ☐ Form – Application 2- Emergency Use Report
- ☐ Form – Emergency Use Independent Physician Certification Form
- ☐ Consent Form (if consent was obtained) – Please REDACT or remove name and any other identifiers (template available in IRBNet Forms and Templates Library: Template – Emergency Use_Template Consent)
- ☐ Written documentation of approval from Vice President for Medical Affairs (VMPA), designee, or administrator on call for emergency use
- ☐ Documentation of sponsor/manufacturer approval for emergency use
- ☐ Documentation of FDA approval for emergency use, when applicable