Emergency Use for Investigational Drugs and Biologics

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 drug or biologic 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**:

- ☐ Life-threatening or severely debilitating condition with no comparable or satisfactory alternative treatment;
- ☐ No available IRB-approved protocol for expanded access for this individual patient;
- ☐ The potential benefit to the patient justifies the potential risk of the use and those potential risks are not unreasonable in the context of the disease or condition and the probable risk to the patient from the investigational product;
- ☐ Emergency use will not interfere with the initiation, conduct, or completion of any clinical investigation;
- ☐ Full IRB approval for the use of an investigational drug or biologic cannot be obtained in time to prevent serious harm or death to a 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 IND.
- ☐ Contact the FDA by calling 1-866-300-4374 or 1-301-796-8240 for drug products or 1-240-402-8360 for biological blood products.
- ☐ 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.

(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 uses.
- ☐ Documentation of sponsor/manufacturer approval for emergency use
- ☐ Documentation of FDA approval for emergency use