REVIEW OF EXPANDED ACCESS USE REQUESTS – DRUGS OR BIOLOGICS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Institutional Review Board Committees

PURPOSE:
To outline the process and steps the IRB Committee takes in reviewing and evaluating requests for expanded access use of an investigational drug or biologic by a physician.

When a patient has a serious or life-threatening condition that is not addressed by current approved treatments, options may exist to use an investigational medical drug/ biologic (i.e., one that has not been approved or cleared by FDA) to treat the patient. A variety of FDA mechanisms exist to grant this expanded access, including:

- Expanded access for individual patients
- Expanded access for intermediate-size populations
- Expanded access for widespread use via a treatment IND or treatment protocol (designed for a larger population)

This policy only addresses these pathways which still require both IRB and FDA approval prior to expanded access. If a physician needs to treat a patient in an emergency capacity in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB or FDA approval, please see *IRB SOP: Emergency Use of Investigational Drugs or Biologics.*

DEFINITIONS:

Expanded Access for Treatment Use [21 CFR 312.300]: The use of an investigational drug in the context of expanded access is to diagnose, monitor, or treat a patient's

persistent or recurrent. Whether a disease or condition is serious is a matter of clinical