This document summarizes changes in *Policy 502 Expanded Access, Including Emergency Use of Investigational Drugs, Biologics, and Medical Devices (Test Articles)* (referred to as Policy 502 in this document) that NIH investigators should be aware of, from the SOPs mentioned below.

The policy describes the responsibilities of NIH investigators, NIH sponsors, and the NIH Institutional Review Board (IRB) when conducting or reviewing expanded access use protocols of a drug, biologic, or medical device.

This table is a high-level summary. It is not an in-depth review, and not all points raised in the policy will be included. Therefore, NIH investigators are responsible for reviewing Policy 502 and complying with the requirements of the policy.

Note: Text from the policy and other policy titles are italicized.

Policy 502 Expanded Access, Emergency Use of Investigational Drugs, Biologics, and Medical Devices	**SOP Superseded by Policies:**
Policy 502 partially supersedes	***SOP 15A Research Regulated by the Food and Drugs Administration (FDA): Information and Policies Specific to Research Involving Investigational New Drugs (Including Biological Products)*** When inactivated, this SOP will be archived in the Policy Archive.
Policy 502 partially supersedes	***SOP 15B Research Regulated By The Food And Drug Administration (FDA): Information and Policies for Investigational Device Exemption (IDE) Applications*** When inactivated, this SOP will be archived in the Policy Archive.

Applicability of Policy 502 - This policy applies to:

- NIH investigators when providing treatment to NIH subjects involving expanded access use of drugs, biologics or medical devices (test articles) subject to Food and Drug Administration (FDA) requirements at 21 CFR parts 50, 56, 312 and 812.
- NIH IRB as the Reviewing IRB.

Policy Requirement	**SOP Requirement**
Section C.1. – *NIH investigators must comply with the requirements set forth in FDA regulations at 21 CFR parts 50, 56, 312 and 812, as applicable, when treating patients under an expanded access protocol using a drug, biologic or medical device.*	**SOP 15A, Section 15A.8.1.A.** – *FDA's regulations at 21 CFR 312.300-312.320 contain the requirements for the use of investigational new drugs … when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition.* AND **SOP 15B, Section 15B.6.3.** – *FDA regulations at 21 CFR 812.36 describe the criteria, safeguards,*

a. Only persons enrolled in an NIH research protocol may be treated using an expanded access protocol. AND ***Section C.2.*** *– Expanded access use of a drug, biologic or medical device is not research. NIH Investigators may not perform research interventions or collect or analyze data for research purposes under an expanded access protocol.* Policy 502 is largely regulatory and reflects FDA and Common Rule requirements of which investigators and the IRB should already be aware.	*application procedures, and reporting requirements applicable to treatment use of an investigational device.* AND ***SOP 15A, Appendix D*** *– "… the patient may not be considered a research subject and any data generated may not be claimed as research."* Policy 502 has been reorganized for clarity.
Section E.1. – *Expanded access refers to the use of an investigational drug, biologic, or device product (test article) when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition rather than to obtain the kind of information about the drug that is generally derived from clinical trials. The regulations are intended to facilitate access to investigational drugs for treatment use for patients with serious or immediately life-threatening diseases or conditions who lack therapeutic alternatives.* AND ***Section E.1.a.*** – lists relevant federal regulations which must be followed AND ***Section E.1.b.*** – explains determinations which must be made and documented by the PI. AND ***Section E.1.c.*** – requires the NIH PI to obtain: • Letter of Authorization from Sponsor • FDA approval • IRB approval • Informed consent from the patient or LAR	SOP 502 is reorganized for clarity. There are no changes in regulatory obligations.

NIH investigators are responsible for reviewing Policy 502 and complying with the requirements of the policy.	
Section E.1.d. – This section of the policy describes the Principal Investigator's or NIH Sponsor's additional responsibilities including: • required reporting to the FDA, • submission of reportable events to the NIH IRB consistent with Policy 801 Reporting Research Events, • establishing an appropriate schedule for monitoring, • ensuring ongoing IRB review, • and maintaining drug disposition records, accurate case histories, and all other records consistent with 21 CFR 312.62. Investigators are encouraged to become familiar with the Policy 502 prior to requesting expanded access to a test article.	Regulatory obligations have not changed. Policy 502 is reorganized and adds specificity for clarity.
Section E.2. – *The treating physician may request emergency use of the test article (e.g. from the Sponsor and FDA) when, in their judgment, the use is needed to prevent death or serious morbidity and there is not sufficient time to obtain prospective IRB approval. (See Emergency Use of an Investigational Drug or Biologic or Expanded Access for Medical Devices.)* **Section E.2.** defines PI determinations which must be made for a patient to be eligible for emergency use of a test article. This section of the policy also describes Sponsor authorization, FDA approval, IRB Chair concurrence, and informed consent obligations. AND **Section E.2.c.** – *The NIH PI or the sponsor responsible for submitting an emergency use application has the same "Investigator*	Regulatory obligations have not changed. Policy 502 is reorganized and adds specificity for clarity.

Responsibilities" as a sponsor of clinical investigations. Investigators are encouraged to become familiar with the Policy 502 prior to requesting emergency use.	
Section E.3. – *a.The NIH IRB will evaluate the submission to determine whether the use complies with regulatory requirements described in E.1. and E.2.* *b. The NIH IRB will review the expanded access use request at a convened IRB meeting, unless a wavier for full IRB review has been granted by the FDA. (21 CFR 56.104)* However, NIH IRB Chair concurrence outside the convened IRB meeting may be appropriate under certain emergency or individual patient non-emergency use situations. See Policy 502 for additional information.	Policy 502 adds specificity for clarity. In addition, updated FDA guidance is reflected in Policy 502.