POLICY
The Food and Drug Administration's Expanded Access Program allows the use of an investigational medical product (drug, biologic or medical device) for treatment outside of clinical trials when there are no comparable or satisfactory therapies. Expanded access, sometimes called “compassionate use” is not considered a clinical investigation, however, FDA submission and IRB review are necessary. Expanded access does not involve the conduct of “research” as defined at 45 CFR 46 because there is no intent to develop generalizable knowledge. Guidance regarding expanded access to investigational test articles is provided for investigators on the IRB website.

Prior to treating a patient under expanded access, the physician must obtain approval from the IRB. Approval from the IRB is intended to protect the rights, safety and well-being of human subjects in clinical research. In non-emergency situations, treatment may not begin until the IRB has approved the Expanded Access plan. One IRB member, the IRB Chair or an IRB member, may approve the treatment. The member approving the treatment must have expertise in understanding the use of the test article (PharmD or MD).

Please note that this policy does not describe the emergency use of a test article (see SOP 506: Emergency Use of a Test Article and Planned Emergency Research). For single-patient emergency use, investigators should follow instructions for Emergency Use of a Test Article available on the IRB website.

PROCEDURES
   1.1. Investigators must submit a new study application to the IRB. Applications must include the following:
       • IND documentation or IDE documentation that includes the FDA determination of expanded access
       • Investigator’s Brochure or a package insert for the drug or device
       • Informed consent document
   1.2. The IRB Chair or designee reviews the application for expanded access plan for use of an investigational medical product.
   1.3. If the IRB Chair or designee agrees with the expanded access plan, the treatment may be approved.
   1.4. If the IRB Chair or designee has questions about or believes that the treatment justifies discussion at a convened board meeting, it may be referred to the convened IRB for review.
   1.5. If the IRB Chair or designee disagrees with the expanded access plan, it should be referred to the convened IRB for review. The convened IRB may approve or disapprove the expanded access plan.

1 https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm612009.htm
Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.