Creating a Reliable Method for Reviewing Emergency Uses of Investigational Drugs, Biologics, and Devices
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Problem Statement: The Human Subjects Protection Program (HSPP) lacked a standard process for handling emergency uses (EU) of investigational drugs, biologics, and devices. The combination of infrequent incidence, complex regulatory criteria, and no standard report form led to provider confusion and unnecessary HSPP staff time spent ensuring regulatory requirements were met. In 2011, using Continuous Performance Improvement (CPI) methodologies (aka Lean methodologies), HSPP staff refined the processes for receiving and reviewing an EU. As part of this CPI overhaul, a reliable method was created to handle EUs.

Description: Several actions were taken to create an accessible and well-documented process. HSPP staff refined IRB policy to help physicians and HSPP staff understand the different regulatory criteria for drugs/biologics and devices, and the physician’s and IRB’s responsibilities before and after initiating an EU. HSPP staff also created an EU report form to guide physicians step-by-step through the reporting process. This form serves several different functions including acting as an IRB follow-up report form and providing information on the timing of the other necessary players in the process – independent physician, manufacturer, sponsor and/or Food and Drug Administration approvals and reports. In conjunction with the EU report form, HSPP staff revised the office’s standard operating procedures to outline staff responsibilities and work flow throughout the entire EU review process. Although IRB approval of an EU consent form is not required, past experience indicated that many physicians looked to the HSPP for guidance. In response, HSPP staff generated an institutionally approved emergency use consent form template to assist physicians in providing as many patient protection measures as possible to recipients of the drug or device. HSPP staff also created a simple webpage outlining the emergency use process. This page is easily found from the IRB homepage and includes links to the IRB policy, emergency use report form, and emergency use consent form. Since implementing this reliable method, both HSPP staff and providers have seen an increase in consistency, transparency, and efficiency. This process could be used by other human subjects protections programs that struggle each time they handle an EU.