Problem Statement: Lean is an approach to quality improvement rooted in the Japanese automobile industry. In recent years, Lean has been implemented by healthcare institutions to improve quality and efficiency of healthcare delivery systems. Its principles are based on a commitment to continuous incremental improvement and respect for people. By learning how to think Lean, IRBs, both large and small, can leverage the powerful impact of Lean thinking to improve IRB processes. Our IRB identified a need to streamline the process for translation of informed consent documents. The translation process addresses the Department of Health and Human Services and Food and Drug Administration regulations (45 CFR 46.116; 45 CFR 46.117; 21 CFR 50.25; and 21 CFR 50.27) that require “informed consent information be presented in language understandable to the subject and, in most situations, that informed consent be documented in writing.” While the IRB’s translation process was functional and met ethical obligations and federal regulatory requirements, researcher and sponsor needs demanded a critical look at the efficiency of the process. Staff identified opportunities to improve information flow among IRB staff, translation vendors, researchers and sponsors, as well as improve turnaround time of outcome documents.

Additional Information: Using the translation improvement project as a case study, this poster presentation will: Briefly describe Lean principles; describe how the IRB used Lean principles and methodologies to improve the translation process; and demonstrate how the use of tools such as Kaizen events and value stream mapping can provide an objective way to approach complex issues and facilitate incremental improvement over time.