Database of Genotypes and Phenotypes (dbGaP) and National Database for Autism Research (NDAR) Certification Process Improvements
Tara Polek, PhD; Michelle Grienauer, JD, MPH; Dominic Chiarelli, JD; Kelly Hebner, JD; Laurie Bolton, JD
Seattle Children’s Research Institute

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Problem: The National Institutes of Health (NIH) has issued policies to encourage broad sharing of large-scale genomic and phenotypic datasets to empower scientific discovery. Per NIH policy, the IRB and the Institutional Official (IO) play an important role in the submission of data to dbGaP or NDAR. Our Human Subjects Protection Program (HSPP) did not have a well documented process for receipt, review, and routing of certification requests, which led to investigator uncertainty and slowed data submission. Using Lean methodology, which is known as Continuous Performance Improvement (CPI) at our institution, an improved process to handle certification requests was created.

Description: The CPI A3 tool is a 10-step scientific method that delivers a complete problem solving report on one side of an 11 X 17 inch piece of paper and is based on the “Plan-Do-Check-Act” (PDCA) cycle. The PDCA cycle is a structured cycle of process change. With the A3 tool, the issue, current condition, and root cause analysis are identified on the “left side,” and this information is used to inform a target condition, countermeasures, and an implementation plan on the “right side.” The “right side” aims to improve the problem identified on the “left side” and also includes a plan for testing and follow-up as part of the ongoing PDCA cycle. The A3 tool was applied to our existing dbGaP/NDAR certification process to create an improved process. This resulted in a new dbGaP/NDAR certification form, IRB policy, and revised template consent form language, which better defines roles and responsibilities and streamlines the certification process. These tools were designed to capture the subtle differences between submission of data to dbGaP versus NDAR, while remaining concise and understandable to researchers who are often unfamiliar with certification requirements. Additionally, standard operating procedures, template memos, and letters were created for HSPP staff use. These staff tools ensure that HSPP analysts are consistent with their review and presentation of certification requests to the IRB and IO. As with all new processes, the PDCA cycle will be implemented after several certification requests are completed and necessary changes will be made. Our defined process might aide other human subjects protections programs with handling certification requests, especially in this era of expanded data sharing.