Managing Expired Protocols: A Process Improvement Initiative
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Problem statement:
Massachusetts General Hospital has over 900 active animal research studies conducted over five campuses. Each month, approximately 20 protocols become due for the triennial de novo review. The institution historically has relied on e-mail communication to notify Principal Investigators (PIs) of renewal deadlines and about studies that reach expiration. In many instances, triennial review applications are submitted close to the expiration date, not leaving sufficient time for review and approval prior to expiration using standard procedure. This means the IACUC administration has to move quickly to secure protocol approval. Relying primarily on communication to the PI also means the animal care facility staff and research team members do not receive timely notice of expiration. The management of animals in the facility associated with expired protocols requires extensive time from the facility staff, the IACUC staff, and the research team, often with confusion and disruption to daily work. In addition, research team members are in jeopardy of conducting research once IACUC approval expires, exposing the institution to a compliance risk. To eliminate this risk, the IACUC administrative office and the Center for Comparative Medicine (CCM) collaborated to develop a reliable method to proactively manage protocols at risk of expiration. We employed lean methodology to fully understand and eliminate all factors contributing to this problem, and redesigned our communication strategies and work procedures to permanently solve it. Our goal was to have 100% of research animals on an approved protocol and completely eliminate the risk of research conducted on an expired protocol at this institution.

Description of research:
The process improvement team for this initiative included IACUC office staff members, animal care facility staff, program leaders, and IACUC investigator members. The current state was evaluated by reviewing past data, specifically the number of protocols that expired prior to approval each month (10-20), and the corresponding number of animal cages maintained by the facilities while approval was being secured (approximately 217). The current procedures used by the IACUC and the animal care staff were mapped on a process flow chart also referred to as a value stream map. All members of the team were provided the opportunity to identify “areas of concern” or “pressure points” that impacted their daily work and efforts were focused on making changes to these areas. Countermeasures to these pressure points were incorporated into a Future State Map and projections regarding these improvements were considered. First, a revised communication strategy was deployed: 1) notices to investigators were updated to clarify expectations and consequences, 2) a formal step-by-step communication plan between the IACUC and CCM was solidified and 3) greater emphasis was placed on in-person communication, particularly for high-risk protocols pending expiration of approval. Next, visual controls were deployed in the facilities to alert research teams that a protocol had expired to prevent the conduct of unauthorized research. Lastly, a management plan for protocols that reached expiration was put in place for veterinary oversight of animals during the period of expiration utilizing an AV managed Holding Protocol to maintain important research animals while ensuring regulatory compliance. Since the implementation of this initiative, the number of protocols
with animals on an expired protocol has been reduced to zero and the number of protocols reaching an expired state has significantly decreased. Investigators and their research staff, IACUC staff members, and CCM personnel have all attested that having a defined, reliable method that is transparent to all stakeholders has positively impacted their daily work and eliminated the risk of non-compliance associated with expired protocols.