Creating a Process for Use of Central IRBs
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Background: The human subjects research environment is trending towards the use of central IRBs. However, regardless of what IRB reviews the research, the institution and investigator still have responsibilities. It is important for institutions to assure those responsibilities are being met, even if a local IRB is not performing the review. In 2010, our Health System obtained an additional hospital. At the time of merger, this hospital relied heavily on central IRBs. It became clear, from an institutional perspective, that we needed to create a process to be alerted to and to manage the studies that were being reviewed by an outside IRB.

Methods: To address the issue at hand, the Office of the HRPP created a process to allow for some oversight of studies reviewed by outside, central IRBs. A form was created that contains information, that as an institution, we need to assure is in place. Once the form is submitted to the Office of the HRPP, it is reviewed for completeness to assure all required approvals have been obtained and investigator training is complete. Once all the requirements have been met, the Health System initiates an IRB authorization agreement to rely on the central, outside IRB. After this agreement is fully executed and the Central IRB approval is in place, a letter is issued to the investigator informing them that all human subjects protections issues have been addressed, and the study begins enrolling. Using central IRBs can free up IRB member and HRPP office staff resources to focus on research that is only being conducted locally.

Findings: The success of the process has been evaluated through the number of studies being opened, in which a central IRB is being relied upon. The number of studies opening at this institution through this process has increased by 100% over the past few years (2011-2013).

Conclusions: For institutions that are hesitant to allow the use of central IRBs, as they are afraid to lose oversight, we would suggest putting this type of process in place. It allows the institution to still retain knowledge about the study and to assure that studies are conducted in compliance with regulations and institutional studies. Allowing the use of central IRBs, allows for the more studies to be conducted at an institution without the need to increase the resources devoted to the IRB.