Tackling Complex Modification Submissions: One Institution’s Approach to the Development of Improved Resources for the IRB and the Research Community

D. Hoon Chung, MPH, University of Pennsylvania
Megan Kasimatis Singleton, JD, MBE, CIP, University of Pennsylvania
Tracy Ziolek, MS, CIP, University of Pennsylvania
Christine Davison, MBE, CIP, Virginia Commonwealth University

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Problem Statement: Screening complex modification submissions can be time-consuming and challenging. They may be as complex as screening a new protocol. The challenges in reviewing these submissions are often exacerbated by varied expectations about what constitutes a complete modification submission among IRB staff, board members, research teams, and sponsors. Incomplete submissions may lengthen the review process and contribute to dissatisfaction in the review process.

Initiative Description: In order to evaluate the barriers in processing complex modification submissions and streamline the submission process for research teams, the IRB office launched an evaluation of the modification review process. Each week, an IRB Administrator presented a modification that had been received for processing. IRB staff worked to identify 1) whether the submission was complete and ready for review; 2) what specific pieces of information were needed to complete the reviews; and 3) whether there were any deficiencies with the IRB application/guidance that may have contributed to incomplete submissions. Repeat issues while screening modifications were tracked. Common issues included: 1) failure to provide justification for the revisions made; 2) submission of sponsor-revised documents that lacked summary of changes (including tracked change versions of documents); and, 3) failure to address implications of the changes for subjects and for conduct of the study. Information collected through this exercise was used to create improved documents for the research community, IRB members, and staff. Final products included: 1) A revised modification application for the research community that better details the information required; 2) a revised screening checklist for IRB staff to facilitate screening of complex submissions; 3) a modification submission guidance document for the research community to outline IRB expectations; 4) an educational session to be presented “live” to research team members who deal with modification submissions; and 5) a letter for study teams to provide to sponsors outlining the IRB’s expectations related to modification submissions.

Future Directions and Implications for Other Institutions: This collaborative process served two goals: 1) through the evaluation of complex modification submissions in a joint setting staff were retrained on the information needed by the IRB and 2) the collective expertise of the IRB staff were utilized to improve documents used by the IRB and the research community related to modifications. This type of collaborative mechanism may be adopted at any institution struggling to identify challenges specific to IRB submissions. Further evaluation of the effectiveness of these new tools will follow.