IRB Navigation: A Resource for New Investigators
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Problem Statement: We describe a program at our institution, a major academic medical center in the northeast, which is designed to provide new investigators with guidance and education about the human research requirements and the IRB process during the early stages of research development and preparation of an IRB submission. Few institutions provide comprehensive training and education in the human research regulations and how those regulations are operationalized in a research protocol. Furthermore, the IRB process can vary across institutions as the local context plays a significant role in how an IRB discharges its mandate.

Overview: The IRB Navigation Program began as a pilot program in our Department of Medicine in 2009 with a percent effort of one Navigator, Anna Johansson (AJ), and has since spread to all major departments with a combination of departmental and institutional support for three Navigators. IRB Navigators are all IRB members (AJ is a Vice Chair) and investigators.

Process: IRB Navigators provide guidance for new projects and existing projects. Investigators who seek an initial consultation for a new study must complete a consult form that prompts a brief response for all components of a new protocol submission. Navigators work with investigators both in person and via email as investigators develop their IRB submissions by: Assessing the level of risk and appropriate IRB review mechanism; selecting an appropriate informed consent process; translating a research proposal to the relevant IRB forms; providing guidance for post-approval actions; facilitating communication with other departments as required by the research; and reviewing the completed forms prior to submission to the IRB and providing feedback to investigators.

Results: IRB Navigators provide guidance for approximately 180 investigators and up to 200 projects each year, which comprise new applications, amendments to existing applications, continuing review, and determinations about quality improvement and human subjects research determinations. Approximately one third of consults are conducted with fellows or residents. Navigators also deliver group presentations, which includes a mandatory new investigator orientation, conduct outreach to fellowship and residency program directors, and publish monthly IRB “Fast Facts” to the research community.

Conclusions: Qualitative data suggests that the Navigation program improves the cycle time for IRB review, and enhances compliance with human research regulations. Navigators who understand the local process is a key feature of the program. Next steps include a one-on-one orientation with newly appointed faculty members, and a satisfaction survey with current users.