A Protocol Navigation Training Program at the National Institutes of Health (NIH)
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Problem Statement: In an effort to attain the highest ethical standards in clinical research, a government agency established one of the first ethical peer review systems in the country to evaluate clinical research prior to subject recruitment and to monitor ongoing clinical research studies. However, developing a clinical study and moving the study protocol through the ethical review process has become increasingly time-consuming and challenging to some investigators. In a 2007 internal survey, investigators from our agency identified several barriers to conducting clinical research at our organization, one of which was the ethical review process and the required approval of an IRB. In an effort to assist investigators in overcoming this barrier, programs were developed to assist investigators to move their protocols through the ethical and regulatory review process, known as protocol navigation. Despite the fact that some Institutes and Centers have created successful programs, many investigators do not have access to protocol navigation expertise. In response, we created an advisory committee that recommended the development of the Protocol Navigation Training Program. The Protocol Navigation Training Program is an on-line, self-guided teaching tool-kit for staff and contractors engaged in protocol navigation at our agency. For this program, our agency is defining protocol navigation as the complex process of providing administrative and regulatory assistance to progressively move a protocol through its lifecycle from conception to termination.

Additional Information: The trans-agency program consists of three components: an on-line training resource housed on the agency’s web site and available only to our community; a seminar series consisting of monthly lectures featuring experts in the fields of clinical research, human subjects protections, clinical research ethics, and protocol navigation; and a mentorship program, that pairs experienced experts in protocol navigation with staff new to the field. The Program is constantly being evaluated by its users through evaluation surveys sent to attendees of the seminars and through a suggestions email mailbox located on the Program web site. Since many of the policies and regulations for ethical clinical research are universal, our hope is that this program can become a model for protocol navigation programs at other institutions around the country.