Research Subjects Want to Know: An IRB Asks Investigators to Consider Dissemination Strategies
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Problem Statement Background: Amid growing discussion around the return of results to research subjects and dissemination strategies in support of this practice, IRBs grapple with developing policy that responds to the preferences of research subjects and the needs of researchers. At a minimum, dissemination of research results includes the return of individual test results, as well as a lay-language summary of aggregate data. More broadly, institutions and IRBs have not developed dissemination strategies that support acknowledgement of subjects nor the translation of research to practice. While the details of which individual results should be returned remain to be debated, IRBs need not delay asking researchers about their dissemination plans. Asking the question could be an important step to promoting practice.

Methods: An academic medical center IRB introduced a question on the IRB protocol application that directed investigators to indicate how subjects would be acknowledged for their participation and how results would be shared. Responses were coded into four primary indicators: dissemination plan, acknowledgement plan, scope and audience, and feasibility. Data from 1,073 consecutive applications were coded accordingly. Each indicator was analyzed individually.

Results: Thirty-five percent of applications stated an intention to proactively share results with subjects. Seventeen percent indicated plans to share information only upon request. An additional 5% indicated plans for the broad sharing of results. Close to 60% identified a variety of means for to share results. Thirty-nine percent planned to share results through providing peer-focused publications to subjects. Of those that planned to share research results, 14% indicated a plan to return individual results to the subjects. Twenty-six percent indicated plans to acknowledge subjects. Where feasibility of sharing results or acknowledging subjects was a concern, applicants cited barriers such as lack of contact information, length of study, retrospective nature of study, etc.

Limitations and Next Steps: Interpretation by investigators of the IRB question’s aims varied. Applicants most often responded to part, but not all, of the question. We plan to revise the question asked on the IRB application to increase clarity and hope to determine investigator dissemination preferences among different research categories. The responses would enable a more detailed comparison of the proposed dissemination plan to actual practice in order to assess proactively barriers to execution of a dissemination/acknowledgement plan. This information will help shape guidance, and eventually policy, to better support more effective communication of research findings and positive engagement with research subjects.