IRB Members and Researchers: A Quality Improvement Survey
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Submission Type: Scientific
Topic Area: Quality Assurance/Quality Improvement
Poster Number: 80

Problem Statement: It’s apparent from reviewing the literature that IRBs and researchers are at odds regarding IRB-requested changes. An article titled, “A Systematic Review of the Empirical Literature Evaluating IRBs: What We Know and What We Still Need to Learn” illustrates this. While IRB members feel they are fulfilling their duties, researchers feel IRBs are “nit-picking.”

Questions an IRB Should Ask: Is there a regulatory basis for the change and do the changes improve human subjects protections? If the answer is no, should the changes be required?

Description of the Research: An observational study was conducted to survey IRB members and researchers. Both groups were asked their opinions about IRB operations, the IRB review process, and educational needs. Data Analysis: Seven (7) IRB members responded (47%). Seventy (70) Researchers responded via Survey Monkey (35%). A frequency distribution analysis was used to interpret the IRB member survey data.

Results: The survey identified that both groups agree the purpose of the IRB is to ensure studies are conducted ethically and in accordance with the regulations to protect human research subjects. Both groups also agree that IRBs can focus too much on protecting the institution. Educational opportunities such as Ethics and Ethical Guidance, Genetic Research, and Food and Drug Administration Regulated studies were areas identified for further education. Interestingly, a number of respondents from both groups felt that scientific review was not a responsibility of the IRB. The main point of contention between the two groups is related to review of informed consent documents. The board feels that correcting spelling and grammatical errors is necessary and that “wordsmithing” documents to make them sound “better” is important. However, researchers feel that IRB reviewers are overly critical and that “wordsmithing” consent documents is “nit-picking” and the changes requested actually make their study unrecognizable and do not improve the study at all, but actually make them less safe.

Conclusions: It is clear from the responses that educational opportunities exist. Changes requested to a consent document must be based on the regulations and any changes “to make the consent read better” would not be “required,” but “suggested”. An IRB Action Plan will be implemented. A follow-up survey will be conducted in six months to determine if there is a change in opinions post-implementation.