

Having Direct Policy Input: Comments on IRBs

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You don't have to be on an advisory committee to have input into the federal policies that affect psychology's research. Science agencies are always encouraging direct comments from individuals in the field as the agencies draft guidelines and regulations, make organizational changes, or develop research programs. Here's one example: As reported in the March *Observer*, the National Bioethics Advisory Committee (NBAC) had solicited comments on its draft report on guidelines for protecting human research subjects, which included recommendations for Institutional Review Boards (IRB). Many APS members took the time to respond to NBAC's recommendations. One person said the following:

[In the NBAC report] it is recommended that "Continuing review should not be required for research studies involving no more than minimal risk, research involving the use of existing data, or research in the data analysis phase where there is no additional contact with participants." While I greatly appreciate the NBAC's desire to decrease IRB workloads, I find this recommendation problematic for the following reason:

Minimal risks are still risks. As such, the benefits of a research project may not outweigh the risks. Consider this scenario: a researcher submits a minimal risk protocol that is not designed to benefit the subjects directly, but the benefits of performing the research outweigh the risks. The project is approved. The incompetent researcher performs the project with 50 subjects, but the project yields no useful data (i.e., no benefit resulted from the project). So, the incompetent researcher performs the project again, with another 50 subjects. No useful data results. The researcher performs the project again, and again, and again. There is no "project change," so the researcher doesn't need to report to the IRB. The researcher may report an "unanticipated problem" [per the recommendation], but insofar as he is incompetent, this may not happen. The IRB should step in and stop this researcher from wasting the time of his/her subjects, but if there is no continuing review of minimal risk projects, this may not happen. This is only one case that illustrates the need for continuing review of minimal risk projects.

Agree? Disagree? Want to air your opinions on IRBs in general? We'll publish your views and experiences on IRBs. Email them to apsobserver@aps.washington.dc.us. Although the deadline for commenting on the NBAC report has passed, you know the deliberations around human subjects and IRBs will be ongoing.