Institutional Review Board Conundrums in Neuropsychiatry: Case Examples and Resolutions

Chair: Katherine L. Wisner Moderator: Paul S. Appelbaum Participant: Thomas Kosten

In this study group, we presented two cases from the survey we conducted and completed of the ACNP membership on Solutions to Common IRB Problems in Neuropsychopharmacology. The survey results were submitted for publication in December, 2010. The two cases were: 1) IRB disapproval of an already funded NIMH grant due to inclusion of a placebo control in a randomized controlled trial for postpartum depression; and 2) managing IRB denials in research with adolescent substance users. We wanted to use the study group to develop a model format for what we called an "IRB case log," also called a "decision bank" in a recent publication, to present other investigators the process of problem solving that occurred for these two situations. Since these appeals are time consuming to gather information and supporting data, write the rebuttal, and manage the process aspects, we were developing a strategy to save our members (and other investigators) lost time in common neuroscience issues. At this point, there is not structure to continue this work, since the Human Research Commitee has been officially disbanded. The manuscript is the final product unless some other plan is advanced by Council.