



Incomplete Disclosure: A Partial Truth

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Affiliation: University of Michigan Medical School (UMMS)
Funding: None

Topic: Ethics and Risk Assessment

Problem/Issue Statement

Ever since the 1963 Milgram “teacher-learner experiment” raised controversy, deception research has been a contentious topic of discussion for IRBs, investigators and ethicists. A less well known, and growing, subset of deception research, “incomplete disclosure” has received significantly less attention. Because IRBs with a biomedical profile see this type of study infrequently, education that clearly articulates a definition, ethical implications and justification of incomplete disclosure in the context of IRB review is useful. (new 1P) Deception studies are fairly common in behavioral research and, until recently, have been used less frequently in biomedical research. Deception study designs, including incomplete disclosure, are increasing in biomedical areas of psychiatry and neuroscience primarily because of advances in brain imaging technology. These advances allow investigators to examine neurological responses to stimuli such as expectations, attitudes, fears, phobias and simulated clinical encounters or treatments. However, neurological responses are more measurable when more strongly elicited using designs such as incomplete disclosure.

Description of Program

This poster uses a case study approach to educate IRBs on ethics and on context for review of studies using incomplete disclosure. The case study presented is derived from an actual study that received full board IRB approval. A post-IRB approval review of the study triggered discussion, and stimulated a complete analysis and revision of IRB review for all studies using incomplete disclosure. The analysis included consideration of regulatory issues, scientific issues, ethics of participation, and study team characteristics such as research experience.

A program of didactic education focusing on deception studies, which included an emphasis on incomplete disclosure, was developed and presented to IRB members and staff. Program content was developed through ethical analysis of the incomplete disclosure study described in this poster. The content is applicable to IRBs at other institutions with researchers who submit studies in the areas of psychiatry and neuroscience.

Program Evaluation: Systematic changes to IRB review of incomplete disclosure and didactic education of IRB members and staff were evaluated through use of research evidence on participant effects of deception research and on ethical analysis of the study serving as the stimulus for change.

Limitations: This is a case study, an appropriate vehicle to describe events such as incomplete disclosure that occur infrequently. Any case study may be limited in its generalizability.