Deception in Human Subjects Research

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IRB Members C E

Milgram Study – research on obedience
1963 at Yale University

- Subjects recruited to participate in a "teacher-learner" experiment
- On arrival all participants told they would be playing role of teachers and that the study concerned the effects of punishment on learning
  - each time a learner made a mistake, the teacher would administer an electric shock of 15 volts and for every subsequent mistake, shock would be increased by 15 volts (maximum 450 volts, two steps beyond "Danger – Severe Shock" warning on machine
  - If teacher balked, the investigator followed a script to urge continuing the research and told teachers that investigator would take responsibility for any consequences
- "Participants" who were "learners" were confederates of Milgram and were placed in separate rooms not hooked up to electrodes but there were tapes of sound of shock and cries of pain & pleas to stop from the learners that the teachers could hear as well as the learners banging on the wall

Milgram – predictions and results

- The study was not about learning but about how much shock a participant would give
- Prediction was that few people (<1%) would administer shocks to the high end of the scale
- Result showed 65% of participants gave shocks up to and including the highest possible levels
- Teachers continued to give shocks even though they were often visibly upset by their own behavior
- Study provided great insight into human behavior particularly regarding war-time crimes committed by those “just following orders”
- Some teacher participants have experienced long-term psychological effects related to their behavior in the research but most have been positive about their participation (80+%)

Placebo Effect of Medication cost in Parkinson Disease

Espay et. al., Neurology; 84, Feb. 24, 2015

- Objective: examine the effect of cost as a contributor to response to therapeutic intervention

  With successful treatment, performance of motor tasks improves and brain fMRI images show decreased activity.

- Methods: Prospective double-blind cross-over study in 12 subjects with moderate to advanced PD. Subjects randomized to receive SQ injections of a "cheap approved" or "expensive experimental" dopamine agonist. *Both injections were actually saline.* The usual motor assessments, including fMRI while performing motor tasks, were performed at baseline, after initial randomization and again after they were "crossed over" to the opposite arm 4 hours after initial randomization.

Results and Conclusions

- Results:
  - Both placebos improved motor function, but improvement was greater when patients were randomized to the expensive placebo.
  - Brain activation on fMRI was decreased with “expensive” placebo, as it is with levodopa, but not with “cheap “ placebo.

- Conclusion:
  - “Expensive” placebo significantly improved motor function and decreased brain activation on fMRI similar to but somewhat less than levodopa.
  - Patient perception of cost may alter the placebo response in clinical trials.

Alteration of Consent – federal regulations

- FDA does not allow alteration or waiver of consent except in medically emergent situations (21 CFR 50.23) or for planned emergency research (21 CFR 50.24); therefore studies regulated by FDA cannot involve deception.

- DHHS does allow (45 CFR 46.116)
- (d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

IRB Guidelines – research employing deception

Researcher Protocol:

- Must justify use of deception and explain why an alternative approach is not appropriate
- Explain if use of deception is likely to cause the participant psychological discomfort and how this risk will be minimized during the experiment
- Explain clearly the process for debriefing
- Indicate who will do the debriefing
- Provide a copy of the debriefing information that participants will receive and a script of anything they will be told during the debriefing.

Debriefing information to be given to subjects

- Study title
- Researcher name/contact information
- Explain the purpose and aim of the experiment in lay terms
- Explain why deception necessary
- Explain how results will be analyzed
- If video or audio tapes used give participant ability to withdraw consent for their use or withdraw from study entirely (allow 24-48 hours for decision)
- Offer to provide study results
- Provide list of counselling resources for participant should they be needed