Case Study 1: Consent, Compensation, and Children

(Contributed by Bryan Benham)

Professor Wainryb specializes in developmental psychology and has extensive experience in researching the social-cognitive development of children in the U.S. and abroad. In a recent study proposed to the IRB she and her research colleagues plan to interview disenfranchised children in Colombia. The research is aimed at determining what effects that chronic exposure to displacement, poverty and violence have on children's well-being, especially on how children form moral judgments and reason about moral situations.

In Colombia a state of civil war has existed for many years. In the last 15 years alone, more than one million children have been forcibly displaced from their homes leaving them in a condition of severe instability and poverty. These children have witnessed abductions, tortures and killings perpetrated on members of their families and their community. Most of the children have lost one or both of their parents, or have minimal contact with their parents due to incarceration because of participation in illegal military or delinquent groups. The children have resorted to various survival techniques, including selling candy, washing cars, shining shoes, begging, scavenging and stealing.

The protocol Professor Wainryb proposes will include interviews with a total of 94 children between the ages of 6-9 and 13-16 years of age. The participants will be asked to provide two detailed narrative accounts of their own experiences, one in which they were harmed or wronged and another in which they harmed or wronged someone else. In addition, the participants will then be presented with hypothetical situations in which a character harms or steals from another character. The children will be assessed on how they reason about these hypothetical situations with special attention given to unusual expression of emotions, lack of resolution, and the disruption of relationships. Afterwards some background information will be elicited from the participating children, including demographic information, an exposure to violence measures, post-traumatic stress measures, and a depression inventory.

Because of a number of complicating factors Professor Wainryb has drawn attention to two unique features of her study. The first is a request that the normal written and parental consent requirements be waived. In the area she will be performing the study it is often difficult to establish parental oversight and the children to be studies are often responsible for their own survival, even when family contact is maintained. Children and parents alike often are illiterate and generally distrustful of strangers eliciting written information because of the unique risk of being identified and killed by illegal military groups. As a safeguard against potential rights violations Professor Wainryb proposes that the director of a local, non-governmental agency (Cooperativa Integral Cooperemos) that assists displaced communities in Bogota, Colombia, act as the children's advocate. Written consent will be obtained from the agency's director for the children as a whole, rather than granting individual permission, so that no children's names will be recorded. In addition, verbal consent will be asked of the individual children prior to the interview with another member of the agency present to act as witness. The second issue is a concern about the compensation for the participating children. Because many of the children have few possessions of their own other than their clothing, any form of incentive can be seen as potentially coercive. Moreover, monetary payment and the use of meal tickets redeemable at cafes and snack bars have been readily used to purchase drugs or alcohol by the children. In place of the usual material incentives Professor Wainryb and the staff of Cooperativa Integral Cooperemos proposes that participants be offered referrals to services and the opportunity to interact with caring adults. Past experience and recommendations from the agency demonstrate that children would welcome this opportunity. In fact, one of the possible results of the study is a clearer determination of what types of intervention might be used to alleviate the obvious human suffering in the case of the displaced children of Colombia.

Discussion Questions:
1. Do the proposed alterations to the informed consent process provide the proper protections for the children being studied?

2. Is the fact that the children, because of the circumstances, have been responsible for their own survival and exist relatively independently of adult supervision give adequate grounds for thinking that they are capable of giving informed consent (after all they are still extremely young)?
3. Is it ethically appropriate for an agency, such as Cooperativa Integral Cooperemos, to act as a surrogate or “community consent” for the children being studied? Might this be considered another form of coercion?

4. Is the alternative compensation proposed, especially the opportunity to interact with a caring adult, just another form of emotional coercion?

5. Professor Wainryb has argued that the effects of this research in other areas has not demonstrated any harm presented to the participating children, at least no more harm than they face in day to day life. Do the research goals merit the potential harm that the children will be exposed to during the research?

6. What other ethical issues are raised by this proposed study?

7. As a member of the IRB would you approve of the study? Why or why not?

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Case 2: Research on Prisoners
(Adapted from David B. Resnik's The Ethics of Science: An Introduction, Routledge, 1998).

Sam Adams and Wu-lee Wong are conducting cancer research in country X. So far they have only conducted statistical analyses of cancer rates in various populations. They have found that cancer rates are associated with various lifestyles and diets. While conducting their research, they have continually consulted with local authorities. Today, the authorities offer them the opportunity to conduct some experiments on a human population. The experiments are being proposed by some scientists at University Y and would be performed on prisoners serving long sentences. These experiments would offer researchers the opportunity to observe the long-term effects of various diets on cancer and could significantly impact human knowledge of cancer and its prevention. However, Adams and Wong have some strong moral reservations about these experiments, given the country's record on human rights. They believe that the prison system is a highly coercive environment and that their subjects will have no choice but to participate in the experiments. However, their colleagues from this country have no such reservations about doing this research and see it as one way that the prisoners can repay their debt to society.

Discussion Questions
1. In what way can the prison system be a coercive environment in regards to participating in research? Are Adams and Wong right to worry about this?

2. Is the problem that research will be conducted in a prison system, or that it will be conducted in a prison system in country X? If it were legal, should these experiments be conducted on prisoners in a US or UK prison?

3. How persuasive is the argument that doing research on prisoners is one way they can pay their debt to society? Is this a reasonable thing to expect from prisoners? (Consider that for WWII some prisoners were released to fight for the US military and received a pardon or alleviation of their sentence upon completion of their service; is this analogous to the potential for research participation?)

4. In the end, do you think Adams and Wong should help conduct these experiments? Why or why not?
Case 3: Alzheimers Genetics Research
(Adapted from Shamoo and Resnik, Responsible Conduct of Research, p. 210)

Subjects with Alzheimer’s disease will be recruited from 10 nursing homes in the area. Subjects or their legally appointed representatives will give consent. Subjects will provide a blood sample for genetic testing. Personal identifiers will be removed from the samples, although researchers will retain the ability to link samples to subjects. Researchers will develop a DNA database and attempt to find common genes associated with the disease, including variants of the APOE gene. Researchers will also compare the database with a database drawn from a matched set of patients without the disease.

Discussion Questions:
1. If you had a mother or father eligible for this study, would you encourage him or her to enroll? Why or why not?
2. Imagine you are on the IRB that is considering this protocol. What concerns, if any, would you raise about this proposed study? How should the researchers address these concerns?
3. What are the risks and benefits of the study? Do these have any bearing on your evaluation as a member of the IRB?

Case 4: An AZT Trial
(Adapted from Resnik’s The Ethics of Science: An Introduction. Routledge, 1998).

Four physicians from the US are conducting a clinical trial in country Z on the effectiveness of AZT, a drug used to treat HIV and AIDS. Patients are randomly assigned to one of two groups, a group that receives AZT and another that receives a placebo. The Clinical trial would be unethical and possibly illegal in the US and other industrialized nations because AZT is a standard treatment for HIV/AIDS in those countries. However, Country Z is very poor, and most HIV/AIDS patients in this nation do not have access to AZT. The physicians maintain that their trial is ethical and humane because it is providing the possibility of treatment to patients who would not receive any treatment at all.

Discussion Questions:
1. Is this trial ethical? If you were on an IRB evaluating this trial, would you approve it in country Z? Why or why not?
2. Is it possible for a clinical trial to be unethical in one country but ethical in another? Which country’s standards for research should be used in this case?
3. Is this a case of exploitation of the patients in country Z? Imagine that the potential benefits of this trial are extremely high, would this fact change ethical permissibility of this study?
Case 5: Longitudinal Research with At-Risk Children and Adolescents

PART 1

Dr. Judy Brewster, long interested in the effects of exposure to maladaptive environments on development, plans to design a study to examine resilience. Why are some individuals able to fend off the deleterious consequences associated with stressful environments and adverse circumstances, while others are not? What characteristics are associated with adaptation to such environments? To learn more about the characteristics associated with resilience to environmental insult, Judy will study fourth, sixth and eighth graders who have been exposed to violence within their communities.

Youths will be assessed at six-month intervals for a period of four years. Assessments will be conducted in school through group-administered written surveys and individual interviews of approximately one to two hours in length. The amount and frequency of exposure to community violence will be measured, as well as short- and long-term psychological (anxiety, depression, perception of social support), behavioral (academic achievement, risk engagement) and adaptational (psychological and behavioral coping) responses. Aside from assessment interviews, participants will have no contact with the researcher.

Ms. Rosen, the principal of a private parochial school, has agreed to allow her school to participate in the study. She is eager to assist her students and suggests that Judy begin at once. When Judy asks for advice on how to approach parents for their permission, the principal says that it is not necessary, as the school supports the study. Judy is unsure of how to respond. She recalls that ethical guidelines do not require parental consent to conduct evaluations of educational curricula; however, she is not evaluating a curriculum.

DISCUSSION QUESTIONS

1. What are Judy’s responsibilities to the students, parents and Ms. Rosen, if any?
2. What are the potential consequences of not obtaining consent for the students, parents, Ms. Rosen, and Judy, if any?
3. Given the potential consequences, should Judy obtain parental consent?

PART 2

Approximately two years into her study, Judy notices two distinct patterns of adaptation. Some of the children exhibit signs of distress, anxiety and depression, and report that they have begun to engage in the multiple risk behaviors such as substance use, delinquency, violence and sexual promiscuity. Other children show no signs of distress, or have outgrown and discontinued such behaviors. Judy is concerned about the acting-out youth, but she notes that many children have engaged in such behaviors and later discontinued engagement.

DISCUSSION QUESTIONS

1. What are Judy’s responsibilities to the participants in her study? How do they differ from her responsibilities to the parents? the university? the funding agency?
2. Does Judy have the same obligations and responsibilities to fourth graders as sixth graders? What about eighth graders?
3. What options of action are available to Judy?
4. How well do each of these options protect the rights of the students? the parents?
Case 6: Personality Test


Social science research may cause harm to participant’s self-esteem or self-respect. One study deliberately manipulated feelings of self-worth among female participants and then related these changes to romantic liking. College students were given a “personality test” and then told, on the basis of rigged results, that their personalities were either healthy or constricted, unimaginative, and uncreative. While they were sitting in a waiting room after receiving the results, a handsome male graduate student posing as another subject struck up a conversation with each woman. He acted interested in her, told her something of his own background, and then asked her out to dinner in San Francisco. But the conversation was itself a key part of the research design. Through this ruse the experimenters hoped to test the effects of increases or decreases in self-esteem on the women’s attraction to the graduate student. At the end the subjects were told that it was all a hoax and that there would be no date. Although the women were debriefed about the entire experiment, we do not know if the information given removed the experimentally induced harm to self-esteem. If the manipulation had its intended effects, they may well have lasted beyond the debriefing.

Discussion Questions:
1. Should this study have been carried out?
2. Were the experimenters wrong to be deceptive about the aims of their research?
3. Was the harm that may have been created by the study the type of harm that should not be allowed to occur as a result of a study such as this, or was the harm created by the study insignificant?

Case 7: Alcohol Abuse in Identified Population

(Contributed by Bryan Benham)

Researcher Jermey Rifle is interested in the causes and effects of increased incidence of alcohol abuse among a specific ethnic sub-group in his state. He plans a longitudinal study that includes a series of interviews with members of this sub-group, and during this time period he plans to look at publicly available records from hospitals and state sponsored social programs for the number and frequency of enrollments by individuals from this sub-group. He plans to anonymize the data collected so no individuals may be identified, but is worried about how he should otherwise identify the population he is studying. He fears that if other scholars and even the public were to read his research they might identify and thus stigmatize this sub-population.

Discussion Questions
1. How should Rifle proceed? What protections can and should he provide for his participants?
2. What special ethical concerns does Rifle’s research raise?
3. In what way should this sub-population be considered a vulnerable population?
4. Are there other ways to pursue this research that avoid some or all of the ethical issues? If these alternative methods are not as likely to provide reliable results, should they still be pursued if it will provide greater protection for the sub-population?
Case 8: Willowbrook Hepatitis Studies  
(Adapted from Timothy Murphy’s Case Studies in Biomedical Research Ethics, MIT Press, 2004).

The Willowbrook State School was an institution for the retarded on Staten Island, New York. During the 1950s, Dr. Saul Krugman was the director of research at Willowbrook. He knew that many children there would develop hepatitis because of overcrowding and other unsanitary conditions. In fact, many members of the staff developed hepatitis as well. Dr. Krugman also knew that the virus responsible for hepatitis did not have hosts outside human beings. He was persuaded that these conditions justified research on the disease in humans. He initiated a project at Willowbrook to study gamma globulin injections to determine whether they would protect the children from infection. The injections did seem to have a strong protective effect.

Dr. Krugman then admitted new residents of the school to special quarters and fed them virus samples he had collected from the other children. By tracking virus exposures and the pattern of symptoms that followed, he was led to the conclusion that hepatitis had two strains, A and B. A had shorter incubation and was highly communicable, whereas B had longer incubation and was less communicable.

When protest arose regarding his exposure of these children to hepatitis virus, Dr. Krugman defended his work. If he had not infected the children as part of research, they would have developed hepatitis anyway because of their school’s communal housing. This research, he said, was akin to an experiment in nature, and no level of improved hygiene would have protected the children. He noted, too, that he had been given permission from parents to experiment on their children.

It is true that children were enrolled with parental consent. A letter explaining the research was sent to parents whose children were on a waiting list for admission to Willowbrook. Immediate admission was the reward for parents who signed the letter; parents who did not provide consent were not assured of immediate admission. The letter is reproduced below.

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WILLOWBROOK STATE SCHOOL  
Office of the Director  
Staten Island, New York  
November 15, 1958

Dear __________________:

We are studying the possibility of preventing epidemics of hepatitis on a new principle. Virus is introduced and gamma globulin given later to some, so that either no attack or only a mild attack of hepatitis is expected to follow. This may give the children immunity against this disease for life. We should like to give your child this new form of prevention with the hope that it will afford protection.

Permission form is enclosed for your consideration. If you wish to have your child given the benefit of this new preventative, will you so signify by signing the form.

Sincerely,

H. H. Berman, MD  
Director

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Discussion Questions

1. The hepatitis studies that took place at Willowbrook is considered invaluable. In fact, these studies established for the first time that two strains of hepatitis existed. Although the value of the studies has never been in question, their methods remain under continuing debate. They involved, for example, feeding live hepatitis virus to retarded children and the recruitment methods have also
been a matter of controversy. What other issues does this study raise for the use of human research subjects?

2. How did researchers justify exposing children at Willowbrook to hepatitis infection? How persuasive is their argument?

3. Does the letter adequately express the nature, risks, and benefits of the study? Might aspects of agreeing to the experiment be viewed as coercive?

4. Even if the risks of this study were adequately disclosed, do you think researchers would have been justified in exposing children to hepatitis infection?