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Ethical Issues in Research with Children

Year

1999

Description

Case that discusses issues of researcher obligations, the role of informed consent, developmental factors; and options of action available to researchers who discover that minors may be in jeopardy.

Body

Dr. Morris Swakowski, a tenured epidemiologist, is working with Beatriz Piacere, a post-doctoral fellow, on a research project involving asthma and wheezing in African-American and white adolescents. They have just completed a school-based study in which they found a very high prevalence of diagnosed asthma and wheezing in eighth graders.

In the literature, the most current research is investigating the association of asthma with exposure and allergies to dust mites and cockroaches. Dr. Swakowski and Beatriz want to find out whether asthma and wheezing are associated with exposure and sensitivity to dust mites and cockroaches in their research population - an urban/suburban community in the South with high humidity, which provides a favorable environment for dust mites. They also want to evaluate several low-cost interventions that could reduce the children's exposure to these two allergens.

This research is being conducted in collaboration with the large public school administration of the city. The school population is 40 percent African-American, and 28 percent of the children are on the free school lunch program.

The researchers decided to address the following questions:

1. Do children with asthma or wheezing have higher exposures to dust mites and cockroaches compared with children who do not have asthma or wheezing?
2. Do children with asthma or wheezing experience a decrease in symptoms in response to exposure to the interventions, compared with children who are not exposed to the interventions?

The two investigators agree on the sampling strategy: children who, in the previous school-based study, self reported either 1) diagnosed asthma 2) wheezing symptoms with no asthma diagnosis, and 3) no wheezing symptoms and no asthma diagnosis. After parents have given their informed consent, the children will be brought to the health clinic, enrolled, and given a skin prick test for twelve different allergens. Skin prick tests are done to determine whether the children are allergic to specific allergens including cockroaches and dust mites, which may be triggers for their wheezing attacks. Dust mite and cockroach allergen levels also will be measured in their homes.

Half the participants will receive the environmental interventions at the start of the study, and the rest will receive the interventions at the end of the study. The interventions are plastic bedcovers to reduce the dust mite population and cockroach motels to reduce the number of cockroaches.

In discussing the research design with the pediatrician and the nurse working on the project, the researchers become aware of the issue of anaphylactic shock. The risk of anaphylactic shock from the skin prick test is 1 in 1 million in the general population. Although the risk to the child occurs only at the time the test is conducted, possible consequences include death. If a child begins to go into shock, the standard treatment is immediate administration of epinephrine, which will stop the reaction if a sufficient dose is given. However, the administration of epinephrine is best done by trained staff in a hospital setting.

The nurse in the study is very concerned about this risk of anaphylactic shock. However, she considers that the study might benefit the symptomatic children. If some children have unknown allergies that trigger their asthma or wheezing, this study would benefit them by identifying the allergens that trigger their wheezing attacks. However, the risk of anaphylactic shock is a risk for the control group to be used to answer the first question. Children in the control group will gain little from

participating in the research, and it will actually put them at risk. The researchers must consider whether it is necessary to drop the control group.

Discussion Questions

1. If you were a member of the IRB and were the primary reviewer of this proposal, what conditions would you impose on the investigators before you would recommend approval for this study? In other words, what are some of the ethical and risk concerns with the protocol? How would you suggest that the investigators address these concerns?
2. Do the principles of respect, beneficence and justice change when social and historical aspects of the research context are taken into account? How does this study honor these principles compared to the Tuskegee experiment?

Notes

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