

Dear Dr. Kringle:

At the regularly scheduled December 24 meeting, the IRB reviewed your protocol, "A Global Observational Study of Behavior in Children." While we believe it has many good features, it could not be approved as submitted. If you choose to revise your study, please address the following concerns:

1. You propose to study "children of all ages". Please provide an exact lower and upper age limit, as well as the precise number of subjects. Provide a statistically valid power calculation to justify this large of a study.
2. Your only inclusion criterion is "belief in Santa Claus." Please provide a copy of the screening questionnaire that determines such a belief. Provide a Waiver of Authorization under HIPAA in order to record these beliefs prior to enrollment in your study. The Board recommends that you obtain a Certificate of Confidentiality as beliefs are sensitive and personal information.
3. You propose to "know when they are sleeping and know when they are awake". How will this be done? Will children undergo video monitoring in their beds? Will they have sleep EEGs? You list 100 elves as research assistants. Are any of them a sleep physiologist?
4. Your primary outcome measure is to "know when they've been bad or good." What standard is being used to determine 'goodness'? Do children have to be good all year or just most of the time? What if they have been really, really, good except for one time when they hit their little brother?
5. You propose to conduct your research by entering the subjects' homes through the chimney. Have you considered the damage to the roof, carpeting, etc., that this will cause? Moreover, children are likely to be startled by your appearance late at night. Please revise your protocol to conduct your home visits between 9 am and 5 pm Monday through Friday with at least one parent being present.
6. You state that compensation for participation will be "sugarplums, candy, and toys" for the good little girls and boys. This may not be appropriate for the children with obesity, dental caries, and hyperactivity. Also, your proposal to leave a lump of coal in the stockings of the bad children will be unfairly stigmatizing to them individually and as a group. In general, the Board suggests a small token of appreciation for all participants. Perhaps a \$5 Toys-R-Us gift card would be better.
7. The database of good and bad children will be kept "on a scroll at the North Pole." Please describe the security provisions you have in place to protect the research data. Is the scroll kept in a locked cabinet in a locked room? Who has access to the scroll? Are there backup copies of the scroll and how often are they compared to the original?
8. You mention the participation of "eight tiny reindeer" in your protocol. Please provide the Board with documentation of Institutional Animal Care and Use Committee approval.
9. Please provide the Human Subjects Protection training dates for Mrs. Claus and the elves.
10. As this study involves prospective data collection and is more than minimal risk without prospect of direct benefit to the subjects, informed consent signed by both parents will be required. Please have the consent form translated into every language spoken by children.

Please submit 25 copies of your revised protocol to the IRB. The IRB will be on Holiday Season schedule for the next two weeks. If approved, you will be able to conduct your study sometime in January.

Sincerely,

E. Scrooge, MD – Chair, Institutional Review Board