

Comment submitted by:

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I have reviewed the proposed study "Effects of Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder: A Functional magnetic resonance study" as a layperson and therefore cannot truly comment upon the scientific validity or utility of doing this study, particularly in normal children. I have concerns regarding the written information provided to the parents and subjects:

The consent document doesn't fully explain the procedures involved in the study. There is no mention of the physical exam that is part of the screening procedure or the teacher contact for rating scales; the genetic testing for the twins is glossed over, where a decision to test twins regarding their zygotic status could have emotional implications for the parent and/or the twins; few laypeople in this country are knowledgeable about weight measurement in kilograms, the subjects weight requirement should be in pounds; the MRI process should be much more fully described; throughout the consent there is language that is technical which is not explained in lay terminology.

The assent form does not mention the pregnancy testing which the IRB suggested be included for all females who have reached menarche nor whether the results will be shared with the parent.

The compensation section details a maximum of \$570 being paid, but doesn't describe who will be compensated. While the consent does detail "Inconvenience Units", the meaning of that should be explained. It seems like a fairly large amount for the child and it seems inappropriate to compensate the parent - it appears coercive. With no direct benefit to the child it would appear that the parent is benefiting financially, while putting the child at "some" risk and certainly an inconvenience. The benefits section refers to the compensation as a benefit; again this becomes coercive.

The consent form should detail an alternative to participation even if it is merely not to participate in the case of controls and to receive standard care in the case of ADHD patients.

Inclusion criteria in the protocol states "All subjects must be between 9 and 18 years of age, be able to give consent, and have a minimum IQ of 80". I believe they authors should have referred to being able to provide "assent".

I also cannot help but be concerned regarding the drug abuse potential that might be "suggested" by having one dose which might lead to curiosity about additional doses.

I do not feel comfortable about approving this study in its current form.