NIMH IRB MINUTES 1/27/04 FINAL

2) PROTOCOL TITLE: Effects of Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder: A Functional Magnetic Resonance Study

PRINCIPAL INVESTIGATOR:

Summary of Protocol:
This protocol was previously reviewed by the board at the 10/28/03, and 11/4/03 IRB meetings at which time the board recommended the protocol be forwarded to a 407 review panel. An IRB subgroup has reviewed the protocol in depth and made recommendations for revisions to the PI. The PI is submitting the protocol to the IRB following changes, for a final review by the board before forwarding to Dr. Gottesman for submission to the 407 panel.

Discussion:
Dr. Rosenstein reviewed with the board the status of this protocol, which will be forwarded to Dr. Gottesman for submission to a 407 panel. This decision is based on the comprehensive review by this IRB and the decision by the board that this study was not approvable as a minimal risk study. (The vote on the risk level assignment for this study was split with 4 votes for a minimal risk category and 6 votes for more than minimal risk at the 10/28 meeting; and 5 votes for minimal risk and 7 votes for more than minimal risk at the 11/4/03 meeting). Based on the decision by the IRB that the protocol was more than minimal risk, without the prospect of direct benefit to subjects, the board found that the protocol was not approvable under regulation 46.406 of Title 45 CFR 46, thus it will require review by a 407 panel. Dr Rosenstein will draft a memo to Dr. Gottesman reviewing the deliberations by the board regarding this study and requesting a 407 panel review.

The purpose of today's review was for editing suggestions and final comments from the board. Dr's were present for the discussion of this protocol.

The following summarizes the suggestions from the board regarding the submission:

- Typos, reviewer comments and inconsistencies between consent forms should be corrected before forwarding to the 407 panel
- References to placebo should not suggest that it is "medicine" or "treatment"
- The discussion in the protocol of the Vaidya study should explain further the comparison between this study and the Vaidya study as that study uses methylphenidate rather than amphetamine
- The investigator's should propose a data safety monitoring plan and discuss it consistently in each consent form
- The investigators should emphasize the justification of this study based on the scientific merit of the study and the potential impact on future treatment for ADHD.
- Pregnancy testing should be done in all females who have begun menses
- Page 4 of 8 (parent of healthy volunteer consent), second paragraph, remove the sentence that begins with "based on the NIH studies….." or explain this more specifically.