

Note:

Approval from Oklahoma IRB is contingent upon changes, i.e., modification of the consent and inclusion of assent, and upon receipt of a Certificate of Confidentiality.

The requested modifications have been made, and the application for Certificate of Confidentiality is in progress. An amendment to the Oklahoma IRB will be submitted when the Certificate of Confidentiality is received.



# The University of Oklahoma

## Health Sciences Center

### INSTITUTIONAL REVIEW BOARD

IRB Number: 10345  
Meeting Date: October 16, 2006

October 23, 2006

Mark Wolraich, M.D.  
Pediatrics Adolescent Medicine  
1100 N. E. 13th, CSC 2B2308  
Oklahoma City, OK 73117-1099

**RE: IRB No. 10345: ADHD School-Based Prevalence & Health Risk Behaviors**

#### **Amendment Summary:**

- 1) Extend study to follow participants for 5 years for longitudinal study.
- 2) Revise questionnaire
- 3) Add questionnaire to be addressed to children.

Dear Dr. Wolraich:

The Institutional Review Board (IRB) reviewed your protocol modification form at the meeting on October 16, 2006 and determined that it was approvable with the specified changes noted below:

#### **PROTOCOL**

1. Obtain a certificate of confidentiality to protect participants from prosecution, as there is a possibility that criminal activity could be revealed through questionnaires.
2. Provide clarification: As medical records have not been checked since the beginning of this study, should these records be re-checked to ensure that diagnoses have not changed?

#### **CONSENT FORM**

1. Change font to Times New Roman, size 12.
2. Last line of first paragraph: place with sentence under the new heading, "Why Have I Been Asked To Participate In This Study?"

#### **How Long Will I Be in the Study?**

1. Second line in section: Delete the word "brief".

#### **What Are the Risks of the Study?**

1. Delete first sentence of this section, "There are no known risks for participating in this study."

#### **What About Confidentiality?**

1. Include information about the certificate of confidentiality and that this will prevent disclosure of information unless required by law.

#### **Will I Be Paid For Participating in This Study?**

1. Outline how participants will be compensated.


#### **What are My Rights As a Participant?**

1. Second paragraph, first line: Delete "You understand that"
2. Second paragraph, second line: Delete "However, you agree that"

As soon as I, on behalf of the IRB, have reviewed and approved your revisions, written approval will be sent to you. Please note that this amendment cannot be implemented until these revisions have been verified and approved. Any proposed change in approved research including the protocol, consent document, or other recruitment materials cannot be initiated without IRB approval except when necessary to eliminate immediate hazards to participants. Changes in approved research initiated without IRB approval to eliminate immediate hazards to the participant must be promptly reported to the IRB. Completion of approved research must be reported to the IRB. This request can be placed in a pending status for a period of 45 days. If revisions have not been approved within that time period, this amendment may be administratively withdrawn.

If you have any questions about the revisions requested in this letter or the procedures described here for completion of the approval process, please do not hesitate to call the IRB office at (405) 271-2045 or send an email to [irb@ouhsc.edu](mailto:irb@ouhsc.edu).

Sincerely yours,



Karen J. Beckman, M.D.  
Chair, Institutional Review Board