

**HUMAN RESEARCH REVIEW COMMITTEE**  
**DEPARTMENTAL REVIEW OF RESEARCH USING HUMAN SUBJECTS**

ATTN: Human Research Review Committee

The attached research protocol entitled: Development of an Assent Process for Children Enrolled in the NCS Vanguard Study submitted by Robert Annett, Ph.D., Principal Investigator, has been reviewed regarding its purpose, design, methods, and scientific merit. [Investigators may not review their own research.]

Provide a brief description of PI's scientific training and qualifications relevant to research (particularly with regards to specialized procedures): Dr. Robert Annett, Professor of Pediatrics at the University of New Mexico, is the Principal Investigator of the New Mexico site of the National Children's Study. He was a Co-investigator on the ASSENT study; an NHLBI funded examining assent processes in adolescent and young childre and on the Childhood Asthma Management Program (CAMP), an NHLBI funded multi-center clinical trial with long term follow-up carried out in children with mild to moderate asthma. He has expertise in the neuropsychological assessment of children with chronic medical conditions and is an expert in the psychological factors associated with pediatric asthma.

Circle the appropriate response for each question.

- 1. Is the rationale for the study clearly stated and is the rationale scientifically sound?  Yes  No
- 2. Are the specific aims and objectives of this study clearly stated and measurable?  Yes  No
- 3. Are the standards for conducting this research in line with any guidelines by relevant professional associations and scholarly disciplines?  Yes  No
- 4. Does this research incorporate the least risky procedures that are scientifically sound and appropriate to the purpose of the research?  Yes  No
- 5. Is the study design adequate to achieve the specific objectives of this study?  Yes  No
- 6. Are the principal and any other investigators well qualified to conduct this study?  Yes  No
- 7. Is the proposed subject population appropriate?  Yes  No
- 8. Are the data to be collected necessary to the meet the objectives of the study?  Yes  No
- 9. Has adequate literature review been done to support this study?  Yes  No
- 10. Are study facilities and resources adequate for the safe conduct of this research?  Yes  No
- 11. Are statistical considerations, including sample size and justification, estimated accrual and duration, and statistical analysis clearly described and adequate to meet the study objectives?  Yes  No

Based on this review it is:

APPROVED:  DISAPPROVED:  by the Department of Pediatrics

H. William Kelly, Pharm.D.  
Typed Name of Person Reviewing

[Signature]  
Signature of Person Reviewing \_\_\_\_\_ Date \_\_\_\_\_

This review was conducted by:	
<input checked="" type="checkbox"/>	Review Committee
<input type="checkbox"/>	Department Chairperson
<input type="checkbox"/>	Reviewer Designated by Chair

Comments: \_\_\_\_\_

Principal Investigator must attest to the following:

I hereby attest that I am aware that the UNMHSC Subject Recruitment Fees ("finder's fees") Policy prohibits offering/receiving finder's fees in human subject research, and that I follow that policy.

# Robert D Annett PhD

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Signature, Principal Investigator

Digitally signed by Robert D Annett PhD  
DN: cn=Robert D Annett PhD, o=University of New Mexico HSC, ou=Pediatrics,  
email=rdannett@unm.edu, c=US  
Date: 2010.12.16 16:37:59 -0700'

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Date