

IRB Authorization Agreement CDC relying on a non-CDC IRB

This IRB authorization agreement is suitable for documenting a formal agreement between the Centers for Disease Control and Prevention (CDC) and an institutional review board (IRB) on which CDC relies for review of the research activities specified below. This agreement is permitted by human research regulations at 45 CFR 46.114 and 21 CFR 56.114.

1 Institution or organization providing IRB review (Institution A)

Name of Institution or Organization A: University of South Carolina (USC)

IRB registration #: IRB00000240

IRB registration expiration date: 5/20/2012

Federalwide Assurance (FWA) #: FWA00000404

FWA expiration date: 1/28/2012

2 Institution relying on designated IRB (Institution B)

Centers for Disease Control and Prevention (CDC)

FWA #: FWA00001413

FWA expiration date: 5/12/2012

3 Scope of authorization agreement

The officials signing below agree that CDC may rely on the designated IRB (University of South Carolina (USC)) both for review under 45 CFR part 46 (and 21 CFR parts 50 and 56, if applicable) and for continuing oversight of the involvement of human subjects in the research described below:

	Institution/Organization A: University of South Carolina (USC)	Institution B: CDC
Title of research protocol	Longitudinal Follow-up of Youth with ADHD Identified in Community Settings: Examining Health Status, Correlates, and Effects Associated with Treatment for ADHD	Longitudinal Follow-up of Youth with ADHD Identified in Community Settings: Examining Health Status, Correlates, and Effects Associated with Treatment for ADHD
Protocol reference ID	Pro0004020	5042
Principal investigator (name, phone, fax, e-mail)	Robert McKeown, PhD Phone: 803-777-6220 RMCKEOWN@mailbox.sc.edu	Susanna Visser, MS Phone: 404-498-3008 Email sfv1@cdc.gov
Primary contact (name, phone, fax, e-mail)	Lorie James, MPH Phone: 803-777-1124 LLJAMES@mailbox.sc.edu	Scott Campbell, Phone: 404-498-4026 Email: sic3@cdc.gov

Sponsor or funding agency: CDC

Contract Award number: 200-2006-18949

The review and continuing oversight performed by the designated IRB will meet the human subjects protection requirements of the HHS regulations (and FDA regulations, if applicable) for the protection of human subjects, as well as the requirements of CDC's FWA. The reviewing IRB must be designated on CDC's FWA. The IRB at University of South Carolina (USC) will follow written procedures for reporting its findings and actions to appropriate officials at CDC. Relevant minutes of IRB meetings and related records will be made available to CDC upon request. CDC remains responsible for ensuring compliance with the IRB's determinations and with the terms of CDC's FWA. This document must be kept on file at both institutions and provided to OHRP upon request.

4 Signatures

Institution/Organization A: University of South Carolina (USC)

Institution B: CDC

 10/19/09
Signature Date

Thomas A Coggins
Director, Office of Research Compliance
University of South Carolina
901 Sumter Street, Byrnes Building Suite 515
Columbia, SC 29208
(803) 777-7095 (voice) (803) 576-5589 (fax)
tcoggins@mailbox.sc.edu (e-mail)

 10/22/09
Signature Date

Constance Bonds, MPA
IRB Administrator, CDC
1600 Clifton Rd NE MS D-73
Atlanta GA 30333
404-639-4967 (voice) 404-638-5333 (fax)
ahsubjects@cdc.gov (e-mail)