

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 Wisconsin - Madison
 IRB registration #: IRB#00003739 IRB registration expiration date: 2/24/2017
 Federal wide Assurance (FWA) #: FWA00005399 FWA expiration date: 9/25/2018

2 Institution relying on designated IRB (Institution B)

Centers for Disease Control and Prevention (CDC)
 FWA #: FWA00001413 FWA expiration date: 02/26/2019

3 Scope of authorization agreement

The officials signing below agree that CDC may rely on the designated IRB of the University of Wisconsin-Madison for both 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 Wisconsin- Madison | Institution B: CDC |
|--|--|--|
| Title of research protocol | Oregon Child Absenteeism due to Respiratory Disease Study | Oregon Child Absenteeism due to Respiratory Disease Study |
| Protocol reference ID | 2015-1357 | 6594 |
| Principal investigator (name, phone, fax, e-mail) | Jonathan Tenite, MD, PhD Phone: 608-263-3111 Email: jon.tenite@fammed.wisc.edu | Yenlik Zheteyeva, MD, MPH Phone: 404-639-4790 Email: igg07@cdc.gov |
| Primary contact (name, phone, fax, e-mail) | Molly Lumley Phone: 608-265-2364 Email: mlum@medicine.wisc.edu | |
| Sponsor or funding agency: | CDC | CK13-003 |

Additional comments:

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 IRB at the University of Wisconsin- Madison 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 OIRP upon request.