



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF THE  
SCIENCE ADVISOR

**MEMORANDUM**

**SUBJECT:** Exempt from Human Subjects Regulations  
**REQUEST No.:** HSR-000541  
**DATE:** Apr 18, 2016

**FROM:** Toby Schonfeld, Ph.D.  
Human Subjects Research Review Official

A handwritten signature in blue ink that reads "Toby Schonfeld" with a long horizontal flourish extending to the right.

**TO:** Juliann Barta  
Region 10

I have reviewed the application cited below according to the requirements of EPA Order 1000.17 Change A1 (**Policy and Procedures on Protection of Human Research Subjects**) and EPA Regulation 40 CFR 26 (**Protection of Human Subjects**). From the information provided, it appears that this study is exempt from the regulations cited above.

The purpose of this study is to assess children's potential exposures to lead, allergens, pesticides, and PCBs in Pacific Northwest tribal child care centers. Public health officials from the Indian Health Service (IHS) will administer a questionnaire to child care center directors to assess building characteristics, maintenance and cleaning protocols, pesticide use, pest infestation history, and aggregate data about the children served. IHS will also ask pest control companies about pesticide use taking place at the center. None of the information collected will be identifiable private information. After the data is collected and analyzed, IHS will inform participating child care centers of research findings and provide recommended actions, indoor air quality action kits, and training to reduce exposures that exist in their facility. Study findings will also be compared with the First National Environmental Health Survey of Child Care Centers and other appropriate studies.

The IRB of record (Portland Area Indian Health Service IRB) has deemed the research to be exempt according to 40 CFR 26.101(b)(2). While it is not clear that this work constitutes human subjects research as defined in the regulation, for the purposes of this project I will concur with the IRB's determination of exemption and no follow-up with the HSRRO is required.

However, it is expected that any substantive changes to the protocol that result in changes to the risk/benefit relationship of the study, or to the recruitment or consent process for subjects, will trigger submission of those changes to the EPA HSRRO immediately. In addition, all researchers are expected to conduct their work with integrity and with attention to best practices in research ethics regardless of regulatory oversight.

Please refer to the HSRRO application number (HSR-000541) below on all future correspondence.

**Application Title:** Environmental Health Survey of PNW Tribal Child Care Centers  
**Principal Investigator:** Nicolle Tulve  
**IRB of Record:** Portland Area Indian Health Service IRB