



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

June 28, 2018

MEMORANDUM

SUBJECT: Materials for Review by Human Studies Review Board for its
July 25, 2018 Meeting

TO: Thomas O'Farrell
Designated Federal Official
Human Studies Review Board
Office of Science Advisor

FROM: Michelle Arling
Human Research Ethics Review Officer
Office of the Director
Office of Pesticide Programs

This memorandum identifies the materials that the Environmental Protection Agency's (EPA's) Office of Pesticide Programs is providing for review by the Human Studies Review Board (HSRB or Board) at the teleconference and virtual meeting scheduled for July 25, 2018. At this meeting, EPA will ask the Board to address scientific and ethical issues surrounding two topics, and to respond to specific charge questions focused on the research identified below.

Protocol titled "Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings"

The Board will consider a new protocol submitted by Pulcra Chemicals describing proposed research to determine the bite protection level provided by fabrics treated with permethrin. Because the proposed research involves scripted exposure, it meets the regulatory definition of "research involving intentional exposure of a human subject" and thus is covered by subparts K and L of EPA's amended rule for the protection of human subjects of research. The rule at 40 CFR §26.1125 requires a sponsor or investigator to submit to EPA, before conducting a study involving intentional exposure of human subjects, the protocol and related materials describing the proposed human research. In addition, EPA's regulation at 40 CFR §26.1601 requires EPA to perform science and ethics reviews of the submitted proposal and to seek HSRB review of the proposed research. EPA has reviewed the protocol, and has concluded that the research, with minor

revisions, is likely to generate scientifically sound, useful information and to meet the applicable provisions of the EPA regulations in 40 CFR part 26, subparts K and L. The charge questions and documents being transmitted to the HSRB for review are listed below.

Charge to the Board - Science:

- Is the protocol “Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings” likely to generate scientifically reliable data, useful for estimating the level of mosquito bite protection provided by the different fabrics treated with permethrin?

Charge to the Board - Ethics:

- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Documents

- a. EPA’s Science and Ethics Review of Protocol for Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings.
- b. Protocol titled “Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings”, dated January 27, 2018
- c. IRB Submission, Correspondence and Notifications package
- d. IRB-reviewed Informed Consent document
- e. Pulcra protocol recruitment materials