



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

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

June 29, 2017

MEMORANDUM

SUBJECT: Materials for Review by Human Studies Review
Board for the July 26, 2017 Meeting

TO: Jim Downing
Designated Federal Official
Human Studies Review Board
Office of Science Advisor

FROM: Michelle Arling
Human Research Ethics Review Officer (Acting)
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 26, 2017. During the July discussion, EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

- Protocol for Field Evaluation of Three Topically Applied Insect Repellent Products Containing IR3535 Against Mosquitoes in Florida.

Protocol for Field Evaluation of Three Topically Applied Insect Repellent Products Containing IR3535 Against Mosquitoes in Florida

EPA has reviewed the aforementioned protocol for a field testing at two sites of three different formulations of skin-applied skin repellents containing IR3535 from both scientific and ethics perspectives. The EPA review evaluates the scientific aspects of the proposed research for an efficacy study to assess complete protection time of three skin-applied repellents. Ethical aspects of the proposed research are assessed in terms of the standards defined by 40 CFR 26 subparts K and L. This study is designed to determine the median complete protection time for lotion, wipe, and pump spray formulations of skin-applied repellents containing IR3535. The repellents will be tested against mosquitoes in the field. The data collected in the study will be used to support product registration. The research has societal value because people are at

risk of contracting mosquito-borne diseases, and the data supporting currently registered skin-applied repellents do not show the efficacy of these formulations of products containing IR3535. The rationale for this testing is to collect data to show the efficacy of these products at repelling mosquitoes. As intended, the data resulting from this proposed study will be used to support registration of one or more of these skin-applied repellents.

The charge questions for the HSRB's consideration are provided below:

Charge to the Board - Science:

- Is the protocol "Field Evaluation of Three Topically Applied Insect Repellent Products Containing IR3535 Against Mosquitoes in Florida" likely to generate scientifically reliable data, useful for estimating the amount of time each of the products tested repels mosquitoes?

Charge to the Board - Ethics:

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

Documents for Review

The documents provided to the HSRB for review are listed below. EPA appreciates the HSRB members taking the time to review these materials in advance of the July 26, 2017 HSRB meeting.

1. EPA Science and Ethics Review of Protocol;
2. Completeness checklist;
3. IRB Approved Protocol for Field Evaluation of Three Topically Applied Insect Repellent Products Containing IR3535 Against Mosquitoes in Florida;
4. Revised protocol that incorporates EPA's comments, as discussed in EPA's science and ethics review. EPA thought this would facilitate the HSRB's review. **Please Note: This is the protocol on which EPA believes the HSRB should focus;**
5. IRB approved informed consent form;
6. IRB correspondence between the University of Florida and the overseeing IRB;
7. Protocol and consent form originally submitted to the IRB;
8. IRB minutes;
9. IRB roster;
10. IRB written procedures;
11. EPA's comments on the informed consent form; and
12. EPA's comments on the telephone screening script, follow-up script, and advertisement.