



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

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

September 29, 2017

**MEMORANDUM**

**SUBJECT:** Materials for Review by Human Studies Review Board for the October 25-26, 2017 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 October 25-26, 2017. During the October discussion, EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

- Protocol submitted by the Antimicrobial Exposure Assessment Task Force II (AEATF II) titled "A Study for Measurement of Potential Dermal and Inhalation Exposure During the Application of Paint Containing an Antimicrobial using an Airless Sprayer" (AEA10)

**Protocol for A Study for Measurement of Potential Dermal and Inhalation Exposure During the Application of Paint Containing an Antimicrobial using an Airless Sprayer**

EPA has reviewed the aforementioned protocol for a measuring dermal and inhalation exposure to an antimicrobial pesticide when paint is applied using an airless sprayer from both scientific and ethics perspectives. Scientific aspects of the proposed research are assessed in terms of the recommendations of the EPA Guidelines Series 875. 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 measure potential exposure to painters using airless sprayers to apply paint containing antimicrobial pesticides. EPA intends to use these data developed by the AEATF II for the airless sprayer painting scenario to describe typical occupational and residential

handlers' daily exposure to antimicrobial formulated products used in paints. The research has societal value because the existing data used to estimate exposure are incomplete and do not reflect current practices.

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

**Charge to the Board - Science:**

- Is the protocol "A Study for Measurement of Potential Dermal and Inhalation Exposure During the Application of Paint Containing an Antimicrobial using an Airless Sprayer" likely to generate scientifically reliable data, useful for assessing the exposure of those who apply products containing antimicrobial pesticides as preservatives using an airless sprayer?

**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 October 25-26, 2017 HSRB meeting.

1. EPA Science and Ethics Review of AEATF-II Airless Sprayer Scenario Design and Protocol for Exposure Monitoring (dated September 29, 2017)
2. Volume 1: AEATF-II Airless Sprayer Protocol Submission
  - Transmittal Letter
  - 40 CFR 26.1125 Checklist
  - Airless Sprayer Study Design Document (Study Number AEA10): Rationale for Study Design
3. Volume 2: A AEATF-II Airless Sprayer Protocol Submission
  - Study Protocol Dated 7/21/17 – Schulman IRB Approved 8/2/17
  - Approved Informed Consent Form Version 7/21/17 – Approved 8/2/17 (Finalized 8/4/17)
  - Approved Recruitment/Study-Related Materials
  - Approved Spanish Translation of Informed Consent Form
  - Approved Spanish Translation of Recruitment/Study-Related Materials
  - Schulman IRB Approval Letter
4. Volume 3: AEATF-II Airless Sprayer Protocol Submission
  - Records of Schulman IRB Review of Study AEA10 and Correspondence
  - Schulman IRB Meeting Minutes
5. Volume 4: AEATF-II Airless Sprayer Protocol Submission
  - CVs and Ethics Training Records
  - SOPs Referenced in AEA10 Protocol

As a courtesy to the HSRB, EPA is also providing the following documents to assist the HSRB in evaluating EPA's comments in the context of the protocol and informed

consent materials. These documents incorporate EPA's recommendations as discussed in the document "EPA Science and Ethics Review of AEATF-II Airless Sprayer Scenario Design and Protocol for Exposure Monitoring", as well as minor editorial suggestions.

6. Revised protocol that incorporates EPA's comments, as discussed in EPA's science and ethics review.
7. Revised IRB approved informed consent form that incorporates EPA's comments, as discussed in EPA's science and ethics review.