UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

March 16, 2022

MEMORANDUM

SUBJECT: Ethics Review of Electrostatic Sprayer Scenario 2b of AEATF II Study (AEA14)

FROM: Michelle Arling, Human Research Ethics Review Officer
Office of Pesticide Programs (OPP)

TO: Anita Pease, Director
Office of Pesticide Programs
Antimicrobials Division (7510P)

REF: Rosenheck, L. (2021) A Study for Measurement of Potential Dermal and Inhalation Exposure During Pressurized Hand-Wand Spraying of Antimicrobial Products; Scenario 2b: Measurement of Potential Dermal and Inhalation Exposure During Indoor Electrostatic Spraying of Sanitizers and Disinfectants. Sponsored by the Antimicrobial Exposure Assessment Task Force II. Study Number AEA14(2b), 645 pages. September 20, 2021. MRID 51707701.

I have reviewed the available information concerning the ethical conduct of the research reported by the Antimicrobial Exposure Assessment Task Force II (AEATF II) in the referenced document. The overall study (AEA14) was sponsored by the AEATF II to determine the potential dermal and inhalation exposure to those using pressurized hand-held sprayers in various scenarios to sanitize and disinfect. Within this study, there were six distinct scenarios; this review evaluates the conduct of scenario 2b, whose results are presented in the above referenced document. The study report describes the implementation and results of research whose objective was to evaluate potential dermal and inhalation exposure of workers using electrostatic sprayers (ESS) indoors to sanitize and disinfect surfaces. The submission also includes correspondence with and submissions to the overseeing institutional review board (IRB).

After reviewing all available documentation, I have determined that the conduct of the AEATF ESS scenario (2b) under study AEA14 met applicable ethical standards for the protection of human subjects of research, and that it the submission satisfied requirements for documentation of ethical conduct of the research. Therefore, if the AEATF ESS study is determined to be scientifically acceptable, I find no barrier in regulation to the EPA's reliance on the results in actions under FIFRA or §408 of FFDCA.

In addition, under 40 CFR 26.1604, the EPA is required to consult with the Human Studies Review Board (HSRB) before relying on intentional exposure human studies covered by the EPA's

Human Studies rule that are initiated after April 7, 2006. The EPA will share the AEATF ESS study report, the associated support documents, and the EPA's science and ethics reviews of the study with the HSRB for their review. This memorandum and its attachments constitute the EPA's ethics review.

Summary Characteristics of the Research

This study was conducted to measure the dermal and inhalation exposure of workers using ESS to sanitize indoor surfaces. Subjects were experienced in using ESS in indoor locations and most performed cleaning activities professionally. Subject monitoring for the ESS scenario was conducted in a hotel and conference center in Orlando, Florida between November 14, and December 5, 2020. Subjects sprayed a variety of locations within the facility, including hotel guest rooms and meeting rooms of various sizes and configurations. Each used one of three types of ESS (Victory, ByoPlanet/Clorox, EMist) as a handheld sprayer, backpack sprayer, or cart sprayer. Subjects applied a target amount (0.5, 1, or 2 gallons) of a solution containing an EPA-registered sanitizer (Maquat® 5.5-M, DSV, 5.5% total quaternary ammoniums) diluted to target concentrations of 215 ppm to 860 ppm.

Subjects wore inner (long underwear) and outer (long-sleeved shirt, long pants) dosimeters, and a ball cap containing an inner gauze sample. Subjects did not wear gloves as they were not required by the product labeling. Hand and face/neck exposure were measured through washing/wiping at the end of the monitoring event. Inhalation exposure was measured using two personal air-sampling pumps placed in the subjects' breathing zones. Subjects were medically cleared and properly fit tested to wear a half-face respirator with cartridges or N95/KN95 filtering facepiece respirator during the study. The study uses the term "monitoring event" (ME) to refer to a single subject's one-day participation in the study. A total of 18 MEs were conducted under this scenario of study AEA14.

Required Reviews of Protocol & Ethics-Related Chronology

The protocol for this study was conditionally approved by Advarra Institutional Review Board (IRB) on February 20, 2020, and as amended on June 16, 2020. The IRB-approved protocol, consent form, and related materials were submitted to the EPA for review. The protocol and the EPA's ethics review[1], dated June 22, 2020, were discussed by the HSRB on July 22, 2020. With regard to ethics, the HSRB's final meeting report concluded that "[t]he research proposed in the protocol 'A study for Measurement of Potential Dermal and Inhalation Exposure During Pressurized Hand-Wand Spraying of Antimicrobial Products', the 'Study Addendum: Addition of Electrostatic Sprayers' and related documents is likely to meet the applicable requirements of 40 CFR part 26, subparts K and L, given the recommendations of the EPA and HSRB are adequately addressed."[2] Attachment 1 contains the EPA's summary of the ethics-related recommendations from the EPA's review of the protocol and the HSRB's final report, and how the AEATF II addressed them.

Advarra IRB approved the protocol and consent forms (English) on October 12, 2020, and

[1] Leighton, Arling, & Cohen. Science and Ethics Review of AEATF II Pressurized Hand-Wand and Electrostatic Spraying Scenarios Design and Protocol for Exposure Monitoring. June 22, 2020. https://www.epa.gov/sites/default/files/2020-07/documents/a._epa_science_and_ethics_review_of_aeatf_hand_held_sprayer_protocol_aea14_june_22_2020.pdf.
[2] Cavallari, Jennifer. July 21-22, 2020 EPA Human Studies Review Board Meeting Report. https://www.epa.gov/sites/default/files/2020-10/documents/hsrb_july_2020_final_report.pdf, p. 20.

the recruitment materials on October 7 and 14, 2020. The IRB disapproved of one subject-facing document: a COVID-19 liability waiver and release document (pp. 642-3), noting that "regulations prohibit the use of exculpatory language through which participants are made to waive or appear to waive any of their legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence" (p. 642). Advarra IRB provided a certified Spanish translation of the consent form on October 22, 2020 (p. 621). Protocol and AEATF II Standard Operating Procedures (SOP) amendments and deviations are included on pages 79-80 of the study report. The IRB-approved consent form is included starting on page 364 of the study report. The IRB-approved protocol, amendments, and deviations are available in Appendix B to the report (pp. 140-363). A complete record of correspondence with the IRB are included in the study report in Appendix G, which begins on page 430.

At the conclusion of the research presented in this study report, the IRB did not approve close out of the study because the protocol includes 5 other distinct scenarios that must be completed prior to closing out the research.

Advarra IRB holds a Federal-Wide Assurance from the Office of Human Research Protection (OHRP) and is accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

Completeness of Submission

The submission by the AEATF II and additional materials provided by Advarra IRB satisfy the requirements of §26.1303. A checklist indicating how each requirement has been satisfied is provided in Attachment 2.

Recruiting

Recruitment was conducted according to the approved protocol and using advertisements approved by the IRB. The protocol indicated that recruitment would occur in English only, in order to limit the number of individuals involved in subject encounters due to the COVID-19 pandemic. Recruitment was conducted through online and print ads in The Orlando Sentinel; distribution of flyers to regional biocide chemical sales managers, ESS manufacturers, and an Orlando-based spray equipment retailer; and flyers distributed to hotels in the Orlando area. The advertisements all provided a brief description of the study, an overview of subject qualifications and a toll-free number to call for more information.

Using the IRB-approved telephone screening scripts, study staff interviewed interested callers via telephone to determine if they met the inclusion criteria and to provide an overview of the study to potential subjects. Subjects were asked what type and brand of ESS they used and whether they were currently employed in a position that involved using an ESS at least monthly. Those who were interested in participating and met the preliminary qualifications were invited to attend an informed consent meeting.

Consent & Enrollment

To minimize unnecessary close contact, the meetings were held virtually via Zoom video conferencing. Subjects were provided with a link for the Zoom video conference along with an electronic copy of the consent form that allowed digital signing. Subjects were allowed to print

and/or read the consent form, but were instructed not to sign it until after the consent meeting. The consent meetings included the prospective subject, Study Director, sometimes the Field Principal Investigator, and in two instances a bilingual researcher for subjects who indicated a preference for Spanish. Advarra IRB provided certified translations from English to Spanish of the consent form.

Consent meetings were conducted from October 22, 2020, to November 12, 2020. As per the protocol, each person was offered the option to have the meeting conducted in English or Spanish even though recruitment was conducted only in English. Although all subjects spoke English, two individuals requested that the consent form be provided in Spanish; this request was honored and a bilingual researcher was present for all interactions with these two subjects (consent meeting, fit test medical questionnaire completion, fit testing, monitoring event). At the meeting, the Study Director reviewed the consent form and answered any questions. Topics covered included the study purpose and the eligibility criteria, the requirement to wear a filtering facepiece respirator for the duration of the monitoring event and a facemask at all other times, and COVID-19-related study practices. During this review, the Study Director encouraged candidates to ask questions throughout the consent process and during the study itself and reminded candidates that they were free to withdraw from the study at any time.

Once a candidate decided to continue with enrollment, the Study Director asked a standard set of questions to ensure comprehension of the consent materials (SOP AEATF II-11J), and after demonstrating and understanding of the consent materials the candidate was asked to sign and date the informed consent form.

Next, the subject was provided with a link to take an online medical questionnaire as part of being fit tested for a respirator. All subjects passed the evaluation and were scheduled to attend a respirator fit test in person. Safety Links, an independent group hired by the study sponsor, administered both the questionnaire and fit testing process. Fit testing occurred in a hotel conference room over several days. All subjects were successfully fitted for respiratory protection or provided valid documentation of a fit test. At this point, they were shown the schedule of test days and asked to choose an option convenient for them. All subjects received a copy of their signed consent form.

A total of 22 individuals were enrolled in the ESS study. This represents all subjects who attended a consent meeting.

Demographics

Summaries of subjects' demographics and experience are included in Tables 4-6 (pp. 88-91). Of the 22 subjects enrolled, there were 5 females and 17 males. Subjects' ages ranged from 24 to 70 years old. Subjects had from 1 month to 3 years' experience using an ESS, with frequency of ESS use ranging from daily to once a month.

Randomization

Subjects were randomly assigned according to the study protocol. Subjects were assigned a unique identification number (W01-W22) and were randomly assigned to participate as a test subject or alternate. The subjects assigned for a monitoring day were also given an ME number corresponding to one of three spray volumes. The randomized assignments of subjects to monitoring events are presented in the Study Report in Table 7 (p. 92).

Subject Monitoring

Subject monitoring generally followed the protocol and certain SOPs from AEATF II (8A.3, 8B.5, 8C.3, 8D.1) (p. 30). Subjects were contacted by phone, email, or text to remind them about their scheduled monitoring day. Upon arrival at the test site and before starting any monitoring procedures, each subject was met by the Study Director and medical professional, and in two instances the bilingual researcher, and screened for COVID-19 and provided with a facemask to wear anytime they were not wearing the study-mandated respiratory protection. The study's medical professional checked the subject's skin for broken skin and open sores that would render the subject ineligible to participate in the monitoring event. Once these steps were completed, the subject was eligible to participate and was taken to the preparation area. At this point, the subject was reminded about the study's purpose and conduct, asked whether they had any questions, told again that they were free to withdraw at any time for any reason. If the subject was female, she was required to take a pregnancy test as described in the protocol, and a negative result was verified by a female member of the study team. After these steps were completed, the subject was directed to begin preparing for the ME. The subject was shown to a restroom, where they washed and dried their hands and face with soap and towels. Then they took off their street clothes down to their underwear and put on the provided inner and outer dosimeters with the assistance of a researcher of the same gender. After the subject was dressed, two air sampler pumps were attached to the subject's belt and the samplers was attached to either side of the collar. The subject put on the ball cap used to measure potential head exposure, was provided with their fit-tested respirator, and was given their choice of safety glasses to wear (p. 30).

After the subject was prepared for monitoring, the study staff provided the subject with safety and administrative information related to the study. This included reminders that subjects could take breaks and withdraw at any time, to wear the required safety equipment (eyewear and respirator), and to be alert for eye irritation and signs of heat stress. In addition, "to ensure that subjects sprayed in compliance with the product label and the EPA guidelines for electrostatic spraying, the Study Director read relevant parts of the DSV product label and the March 25, 2020, Nisus technical bulletin for disinfecting hard surfaces" (p. 31). Subjects were also reminded about the relevant instructions for operating the ESS they were assigned to use, though they already had some familiarity with the equipment. To ensure all information was covered before each ME, the researchers used a volunteer checklist. Following the completion of these steps, subjects were instructed to spray as they normally would and that they would be spraying until the designated spray volume was applied.

When the subject completed the monitoring event, they were walked back to the sample collection area. First, they removed their respirators and safety glasses and placed them on a plastic-covered table. Then the subject was provided with a new facemask to wear for the remainder of their interactions with the study staff. Their air sampling pumps were turned off and removed, the hat was removed, and the protocol-specified hand washes and face/neck wipes were conducted. The medical professional checked the subject's hands, face, and skin for signs of irritation or redness. In a private area, a researcher of the same gender assisted the subject with removing the outer and inner dosimeters to minimize contamination. The subject re-dressed in his or her own clothing and then washed hands and face with Ivory soap and water. The researcher provided the compensation for the ME and subject was free to leave.

Safety Precautions

The protocol called for several precautions to ensure the safety of subjects, which were followed. Subjects were screened according to the eligibility criteria, which ensured that subjects had experience performing the tasks to be monitored, were physically capable of handling the equipment, and did not have skin conditions that would be exacerbated by participating. Additionally, all subjects in this scenario were required to wear a properly fitted, half-face reusable respirator with cartridges or an N95/KN95 filtering facepiece respirator. Twenty-one subjects wore respirators provided and fit-tested by Safety Links, an independent organization. One subject wore her own half-face respirator with P100 cartridges; her fit test certificate, provided by her employer, was verified prior to her participation in the study (p. 23). Respirator fit testing was conducted from November 4, 2020, to November 14, 2020, in a conference room at an Orlando-area hotel.

The protocol required all subjects to wear eye protection during their MEs, and researchers offered safety glasses or safety goggles designed to be worn over eyeglasses. Just before the monitoring event, subjects were reminded to wear the safety glasses.

Researchers complied with AEATF II SOP 11-B.1 and the protocol language regarding heat stress with one deviation discussed below. The heat and humidity at study site were monitored; temperatures during the monitoring events ranged from 62.4º to 76.9º Fahrenheit and relative humidity ranged from 53.9 to 78.9% (p. 26). The monitoring occurred indoors in facilities with air conditioning. Subjects were briefed on the signs of heat stress and reminded to take breaks as needed and to alert the study staff if they felt overheated, sick, or experienced skin or eye irritation. The researchers provided subjects access to cold water and sports drinks for the duration of their participation in study.

The researchers complied with the protocol's process for having a medical professional on site during the monitoring events. For all but two of the events, the medical professional was an Emergency Medical Technician (EMT). For two monitoring events when the EMT was unavailable, a paramedic served as the medical professional. The medical professional was responsible for checking each subject's skin prior to and following the monitoring events and providing assistance if needed. All subjects' skin was clear at the start and end of their test days (p. 29). No adverse events were reported during or after the study.

Confidentiality

The study followed the measures outlined in the protocol regarding confidentiality. For example, as discussed on page 34 of the study report, photographs and short videos were taken while subjects were spraying and having their hands washed after the monitoring event. The photographers took care not to include subjects' faces, or to either delete or edit photos where facial features were clear. Subjects had assigned ME numbers, which were used rather than the subject's name in the study to identify individuals. Females were provided with a private place to take the pregnancy test, and all subjects changed into and out of the study-provided dosimeters in a private location with a member of the research team of the same gender.

Freedom to Withdraw

Subjects were informed of their freedom to withdraw from the study at any time, for any reason, as indicated in the informed consent form and in many interactions between researchers and subjects. No subjects withdrew from the study at any point and no alternates were needed to replace any of the original test subjects.

Compensation

Subjects were compensated according to the protocol. All eligible persons who attended a consent meeting received $50 regardless of whether they enrolled. Subjects were compensated $20 for filling out the online medical questionnaire for fit testing and $100 for attending an in-person fit test appointment. Subjects received $150 on their monitoring day. Because of the virtual consent session, subjects were offered the option to receive their compensation immediately via Venmo (electronic payment platform), at the respirator fit test, or by meeting with the Study Director prior to the fit test. Most subjects opted to collect payment for the consent, questionnaire, and fit test at the time of their fit test, Subjects received compensation for attending the consent meetings in cash at the end of the session. Subjects received compensation for participating in a monitoring event in cash at the end of the day. The Study Director confirmed that alternates received compensation in cash by traveling to the test site on the last day of the scheduled monitoring.

Protocol Amendments & Deviations

The report notes that the protocol for study AEA14, which covers the ESS scenario and 5 other scenarios, was amended after the ESS monitoring was completed. The amendments were related to scenarios other than the ESS scenario (pp. 345-7).

There were 11 reported deviations from the protocol and SOPs (pp. 348-63). Many of the deviations were administrative or related to sample collection and/or analysis. The following discuss those deviations related to subject safety or encounters. Protocol deviation 1 amends the specific quaternary ammonium analog to be analyzed from C14-ADBAC to DDAC because background levels of C14-ADBAC was found in several key sampling matrices. This deviation did not change the overall exposure to subjects, as both compounds are included in the products listed in the protocol and risk assessments did not raise concerns. Protocol deviation 3 includes several elements, one of which is related to subjects – the subjects' shoes were removed outside the changing room rather than inside the changing area (pp. 354-5). Another deviation changed the method for pre-study contact of subjects from telephone only to email, text, or phone call (p. 357). Finally, SOP deviation 5 notes that a Kestrel heat stress instrument was used to record temperature, relative humidity, and heat stress (p. 363).

From an ethics perspective, there is no indication that the deviations negatively impacted the study's conduct or subjects' health or welfare. The EPA's science review also discusses deviations related to the scientific conduct of the study and "accepts the study author's conclusions that these deviations did not adversely affect the outcome of the study".[3]

Applicable Ethical Standards

The following provisions of 40 CFR 26 Subpart Q define the applicable ethical standards which read in pertinent part:

> **§26.1703**: Except as provided in §26.1706, the EPA shall not rely on data from any research subject to this subpart involving intentional exposure of any human subject who is a pregnant

[33] Kliminsky and Cohen. Science Review of the AEATF II Scenario 2b: Electrostatic Spray (ESS) Human Exposure Monitoring Study (AEATF II Project ID AEA14; MRID 51707701). Section 1.3.3.

woman (and therefore her fetus), a nursing woman, or a child.

§26.1705: Except as provided in §26.1706, the EPA must not rely on data from any research subject to this section unless the EPA determines that the research was conducted in substantial compliance with all applicable provisions of subparts A through L of this part.

In addition, §12(a)(2)(P) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) applies. This passage reads:

> In general, [i]t shall be unlawful for any person . . . to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test.

Findings

Pregnancy testing of female subjects on the day of testing was conducted and no pregnant or lactating women were enrolled in the study. All subjects who participated in the ESS scenario (2b) of study AEA14 were at least 18 years old. Therefore, 40 CFR §26.1703 does not prohibit reliance on this research.

40 CFR §26.1705 requires that the EPA have "adequate information to determine that the research was conducted in substantial compliance with subparts A through L of this part." Within this range, only subparts K and L are directly applicable to the conduct of third-party research such as this. Based on the information submitted and reviewed, I conclude that the ESS scenario of study AEA14 was conducted in substantial compliance with subparts K and L.

As documented in Attachment 2 to this review, the central requirements of 40 CFR §26 subpart M, §26.1303 to document the ethical conduct of the research were addressed.

The requirement of FIFRA §12(a)(2)(P) that human subjects of research be "fully informed of the nature and purposes of the test and of any physical and mental health consequences reasonably foreseeable therefrom," and "freely volunteer to participate in the test," was met for this study.

Conclusion

This study reports research conducted in substantial compliance with the requirements of 40 CFR 26 subparts A through L. In its conduct, the ESS scenario of study AEA14 met applicable ethical standards for the protection of human subjects of research, and requirements for documentation of ethical conduct of the research were satisfied. From the EPA's perspective, if this study is determined to be scientifically valid and relevant, there is no regulatory barrier to the EPA's reliance on it in actions under FIFRA or §408 of FFDCA. This research will also undergo review by the HSRB.

cc: Ed Messina
Mike Goodis
Jeff Dawson
Steven Weiss
Melissa Panger

Alex Kliminsky
Timothy Dole

Attachment 1: AEATF II actions in response to comments from the EPA and the HSRB on the protocol
Attachment 2: §26.1303 Completeness checklist for AEA14 Study, Scenario 2b

Attachment 1
Ethics Comments from July 2020 HSRB Meeting & AEATF II Actions

EPA Comments on AEA14 Protocol, Scenario 2b	AEATF II Actions to Address Comments
Revise the protocol to include the ESS scenario, updated application rate information submitted to EPA, and the amount of experience individuals need in order to participate in the study.	The protocol was revised to reflect these recommendations – see Appendix B, pp. 140-364. The eligibility criteria specified that subjects must have occupational experience using an ESS and that they must be currently employed in a position where they use an ESS at least once a month (p. 167).
Revise the protocol to acknowledge risks associated with COVID-19 that are not directly related to the study conduct and include precautions that will be taken to protect subjects and study staff from these risks.	This information was added to the protocol; it was already included in the consent materials. A waiver releasing the study director and sponsor from liability in the event a subject contracted COVID-19 during the study was submitted to and rejected by the IRB.
Prioritize enrolling subjects who are familiar with the specific sprayer types that will be used for the ESS scenario to minimize the risks associated with using unfamiliar equipment.	The protocol was revised to include this information.
Clarify how Spanish-speaking subjects will complete the online medical questionnaire for respirator use, whether it will be available in English and Spanish, and how the bilingual staff member will offer assistance.	The protocol was revised to target English speakers, but included provisions for providing the consent form in Spanish and having a bilingual researcher present at the consent meeting, while a non-English speaker was completing the online medical questionnaire, during the fit test, and for the monitoring event.

HSRB Comments on AEA14 Protocol, Scenario 2b	AEATF II Actions to Address Comments
Include COVID-19-related precautions in the protocol, such as: - Pre-study screening for symptoms - Remote screening/consent - Study staff should maintain protocol for monitoring signs of COVID-19 in the staff - Develop a contact tracing protocol	The protocol was revised to include these recommendations. See, for example, pages 192-193 of the submission.

Attachment 2
§ 26.1303 Checklist for Completeness of AEA14, Scenario 2b Submitted for EPA Review

Any person who submits to the EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to the EPA, such information should include:

Requirement			Y/N	Comments/Page References
(a) Copies of all of the records relevant to the research specified by § 26.1115(a) to be prepared and maintained by an IRB	§1115(a)(1): Copies of • all research proposals reviewed, • scientific evaluations, if any, that accompany the proposals, • approved sample consent documents, • progress reports submitted by investigators, and reports of injuries to subjects.		Y	Appendices B, C, G
	§1115(a)(2): Minutes of IRB meetings which shall be in sufficient detail to show • attendance at the meetings; • actions taken by the IRB; • the vote on these actions including the number of members voting for, against, and abstaining; • the basis for requiring changes in or disapproving research; • a written summary of the discussion of controverted issues and their resolution.		Y	Appendix G
	§1115(a)(3): Records of continuing review activities.		Y	Appendix G
	§1115(a)(4): Copies of all correspondence between the IRB and the investigators.		Y	Appendix G
	§1115(a)(5): • A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; • any employment or other relationship between each member and the institution		Y	Separate IRB roster file
	§1115(a)(6): Written procedures for the IRB in the same detail as described in § 26.1108(a) and § 26.1108(b).		Y	On file with the EPA
	§1115(a)(7): Statements of significant new findings provided to subjects, as required by § 26.1116(b)(5).		n/a	
(b) Copies of all of the records relevant to the information identified in § 26.1125(a)-(f)	§ 1125(a) A discussion of:	(1) The potential risks to human subjects;	Y	Appendices B & C
		(2) The measures proposed to minimize risks to the human subjects;	Y	Appendices B & C
		(3): The nature and magnitude of all expected benefits of such research, and to whom they would accrue;	Y	Appendices B & C
		(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and	Y	Appendices B & C
		(5) The balance of risks and benefits of the proposed research.	Y	Appendices B & C
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.		Y	Appendices C & G
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.		Y	Appendices B, C, & G
	§1125(d): A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.		Y	Appendices B & C
	§1125(e): All correspondence between the IRB and the investigators or sponsors.		Y	Appendix G
	§1125(f): Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.		Y	Appendix G
(c) Copies of sample records used to document informed consent as specified by §26.1117, but not identifying any subjects of the research			Y	Appendices C & G
(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.			n/a	