

“For this mixing/loading of water soluble packets study, the following inclusion criteria also apply:

- Have experience within the past year with mixing/loading water soluble packets (including the particular equipment to be used) (p. 92)

(b) What, if any, is the relationship between the investigator and the subjects?

None

(c) If any potential subjects are from a vulnerable population, what is the justification for including them?

Potential subjects are of necessity agricultural workers, and could potentially be subjected to undue influence either to participate or not to participate by their employers. This possibility is minimized through methods of recruiting growers and by requiring growers to promise in writing not to influence their employee’s decisions.

(d) What process is proposed for recruiting and informing potential subjects?

“For each selected site, AHETF will follow standard procedures (see SOP AHETF-11.B.4) to recruit potential participants for this water soluble packet mixing/loading study. Individual workers will be recruited during an initial site inspection or subsequent visit(s) to a potentially eligible grower facility.

“The Study Director or designated researcher will seek permission from the eligible grower to approach his/her employees to recruit volunteers for the study. Depending on the number of employees and size of the grower facility the Study Director or researcher may contact employees using an informational recruitment flyer posted in a common work area. Such a flyer will briefly describe the research study and provide a toll-free phone number for employees to express an interest in participating in the study. The flyer shall have been previously reviewed and approved by an IRB.

“Alternatively, or subsequent to the use of a flyer, the Study Director or researcher will arrange a meeting with the grower’s employees who express an interest in participation. Such recruitment meetings will always occur without the grower or supervisors being present (SOP AHETF-11.B.4). The Study Director or researcher shall make a presentation describing the AHETF Exposure Monitoring Program, the goals of the research study, the procedures used in exposure monitoring, and the risks and benefits to participants. A toll-free phone number will be provided, and individuals will be encouraged to contact AHETF if they desire additional information about the study or are interested in participating in the study. All presentation materials, such as handouts or visual aids, shall be reviewed and approved by an IRB prior to use in recruiting subjects.” (pp. 109-110)

(e) If any subjects are potentially subject to coercion or undue influence, what specific safeguards are proposed to protect their rights and welfare?

“In accordance with SOP AHETF-11.B.4, the individual growers will be asked to sign a non-coercion statement (Employer Cooperation Statement) affirming to their workers and AHETF that they will not coerce or unduly influence their workers to either participate or not participate in the study. Growers must also certify that alternate work will be provided on study days for workers who choose not to volunteer; and that the employee’s decision to participate or not will have no impact on their employment.” (p. 109)

3.3 Remuneration of Subjects

(a) What remuneration, if any, is proposed for the subjects?

“During recruitment, workers will be offered an opportunity to take part in a recruitment meeting with the Study Director or other designated member of the study team (but without the workers’ supervisors) to learn about participating in this study. No remuneration is offered for this introductory meeting. Workers who are still interested in participating in the study will attend a private consent meeting with a researcher who will obtain the informed consent of the worker. Workers will be paid \$20 for their attendance right after the consent meeting, whether or not they decide to participate in the study. Workers who decide to participate in the study will be paid an additional \$80 each time they suit up (i.e., put on the long underwear) to participate in the study. Usually, workers will participate in the study on only one day unless their participation is terminated due to weather or other unexpected occurrences. The additional \$80 is provided in cash at the end of the monitoring period or at the time the volunteer withdraws from the study. All workers who participate will receive the payment, even if they withdraw or their participation is terminated by the study team.” (pp. 208-209)

(b) Is proposed remuneration so high as to be an undue inducement? No.

(c) Is proposed remuneration so low that it will only be attractive to economically disadvantaged subjects? No.

(d) How and when would subjects be paid?

In cash, immediately after their participation

(c) What is the probability of each risk associated with the research? How was this probability estimated?

Quantitative probabilities are not estimated.

4.2 Risk Minimization

(a) What specific steps are proposed to minimize risks to subjects?

“The following practices, designed to minimize these risks and respond to injuries, will be followed during this study:

- Selecting only experienced pesticide handlers who consider themselves to be in good health
- Requiring experience with the mixing/loading equipment to be used
- Reminding workers of safe chemical handling practices
- Practicing the face wipe and hand wash procedures with each participant before pesticide handling begins
- Identifying nearby medical treatment facilities in case of emergency
- Monitoring the heat index and stopping the study if conditions warrant
- Providing transportation to medical treatment and covering the costs of treatment
- Having a medical professional on site to observe the workers and provide urgent care
- Observing study participants throughout the monitoring period
- Ensuring that all tank mix products are used according to approved label(s) and do not require any additional PPE that could adversely affect the study objectives (for example, chemical-resistant coveralls).” (pp. 98-99)

Risk reduction actions specific to each of the six identified kinds of risk are discussed in the protocol (pp. 93-99).

(b) How do proposed dose/exposure levels compare to established NOELs/NOAELs for the test materials?

For both of the active ingredients that may be used in this scenario, the Margins of Exposure (MOEs) calculated for the highest level of exposure in this protocol “meet or exceed the minimum required MOE, or level of concern, for the individual dermal and inhalation routes of exposure, as well as for the combined exposure.” (p. 95)

(c) What stopping rules are proposed in the protocol?

“AHETF will monitor ambient conditions outside the cab to determine the heat index near the mixing/loading station and base monitoring decisions on the current heat index. Exposure monitoring will be discontinued if the heat index cutoff of 120° F

(adjusted for direct sun, if applicable) is reached or exceeded. The Study Director or other researcher shall stop the monitoring and/or move the worker to a cooler environment until monitoring can be resumed.” (p. 94)

(d) How does the protocol provide for medical management of potential illness or injury to subjects?

“As a safety measure, AHETF will have a medical professional on site during the study. This may be a paramedic, physician’s assistant, nurse, or emergency medical technician. This professional will also observe you for signs of illness. They will provide medical attention as needed.” (p. 131)

SOP AHETF-11.H.2 (SOP Supplemental Submission, pp. 35-38) defines procedures to be followed if a subject in an AHETF study requires emergency medical attention.

(e) How does the protocol provide for safety monitoring?

The protocol refers to various SOPs which define procedures for safety monitoring:

- SOP AHETF-11.E.1 (pp. 484-486) calls for researchers to monitor worker compliance with label and Worker Protection Standard requirements, and permits the Study Director to remove from the study a worker who engages in unsafe work practices.
- SOP AHETF-11.G.1 (pp. 489-503) calls for the Study Director, the on-site medical professional, and all researchers and observers to monitor subjects for any indication of heat-related illness.
- SOP AHETF-11.H.2 (SOP Supplemental Submission, pp. 35-38) defines procedures to be followed if a subject in an AHETF study requires emergency medical attention.

(f) How does the protocol provide for post-exposure monitoring or follow-up? Is it of long enough duration to discover adverse events which might occur?

“During the consenting process each volunteer will be provided the opportunity to request a summary of their personal results from the study. This will require the worker to provide a name and address (mail or e-mail). The results will include the distribution of chemical exposure among the various body areas measured so the worker can be aware of where most dermal exposure occurs and a comparison to the results for other workers performing the same task. Results are typically available six to nine months after monitoring occurs. The personal information related to this follow-up will be retained as described in SOP AHETF-6.D.0.

“Just prior to the completion of the worker’s participation in the study, a researcher will remind the participant he/she should bathe or shower as soon as practical and that they have received a copy of the signed consent form with phone numbers for reporting any health changes they think might be related to participation in the study.

Post-study inquiries will be forwarded to the Study Director who will deal with the situation as appropriate and notify AHETF management (SOP AHETF-11.B.4).” (p. 103)

(g) How and by whom will medical care for research-related injuries to subjects be paid for?

“If you are injured or get sick because of your participation in this study, medical treatment will be available at your workplace and at a nearby health care facility. If necessary, AHETF will arrange transportation for you to receive medical attention. You may refuse medical treatment *unless* you get sick from too much exposure to pesticides or from getting too hot, or if we believe you are too sick to make a rational decision about getting medical treatment.

“AHETF will cover the cost of reasonable and appropriate medical attention for a study-related injury or illness that is not covered by your own insurance or insurance provided through your employer. This includes deductible costs and any out-of-pocket expenses, including co-payments, you might have. The Study Director, in consultation with the on-site medical professional, will decide if you have an illness or injury that is due to your participation in this study.” (p. 132)

5. Benefits

(a) What benefits of the proposed research, if any, would accrue to individual subjects?

“There are no personal benefits to the study participants.” (p. 99)

Although there are no direct benefits to study participants, a potential indirect benefit is knowledge about how their exposure compares to that of others doing similar work; this is not addressed in the protocol.

(b) What benefits to society are anticipated from the information likely to be gained through the research?

“Since there are not sufficient existing data suitable for use in a generic database describing the exposure to workers from mixing/loading water soluble packets, society will likely benefit from data generated by this study through the improved risk assessments by EPA and other regulatory agencies.” (p. 99)

“Data from the AHETF exposure monitoring program has the potential to improve the ability of EPA and other regulatory agencies to accurately assess occupational risks associated with mixing/loading pesticides packaged in water soluble packets. Water soluble packets are considered an engineering control designed to reduce exposure potential for mixer/loaders. The knowledge likely to be obtained from this study is

generalizable and will contribute to assessments of the risks of both new and existing pesticides.” (p. 99)

(c) How would societal benefits be distributed? Who would benefit from the proposed research?

“Growers who allow the study to be conducted using their equipment, crops and facilities will be reimbursed for the pesticides used for the study. While this is beneficial to the grower, it is considered a minor benefit when compared to the costs of running their businesses. The AHETF member companies will likely realize a benefit by addressing regulatory data requirements generically, at lower cost (and using fewer human subjects), than if they conducted similar studies for individual pesticide ingredients.” (p. 99)

(d) What is the likelihood that each identified societal benefits would be realized?

Identified societal benefits are likely to be realized.

6. Risk/Benefit Balance: How do the risks to subjects weigh against the anticipated benefits of the research, to subjects or to society?

“By monitoring exposure to professional agricultural handlers who follow their normal practices, but wear an additional layer of clothing (as an inner dosimeter which traps chemical that penetrates the work clothing), this study presents a greater than minimal risk to participants. Participating in this study increases the risk of heat-related illness, but this risk is mitigated by a medical management program which emphasizes prevention measures and guidelines for stopping participation when warranted based on environmental conditions.

“The likely benefit to agricultural workers as a whole and to society in general, in the form of more accurate measurements of potential exposure to pesticides, must be weighed against the risks to participants. Pesticide products packaged in water soluble packets are becoming more common for many agricultural uses across the country and a variety of experts consulted by AHETF reported their use occurs widely throughout the country. Exposure data for this scenario meeting contemporary standards of reliability and quality will likely provide a significant benefit to society. Because the margins of exposure are acceptable for the products proposed for use in this research study, subjects are very unlikely to experience acute toxic effects, and because extensive procedures will be in place to minimize these and other risks to participants, the likelihood of serious adverse effects is very small. In summary, AHETF believes the risks to study participants from participating in this study are reasonable in light of the likely benefit to society of the knowledge to be gained.” (p. 100)

7. Independent Ethics Review

(a) What IRB reviewed the proposed research?

Independent Investigational Review Board, Inc., of Plantation FL

(b) Is this IRB independent of the investigators and sponsors of the research? Yes

(c) Is this IRB registered with OHRP? Yes

(d) Is this IRB accredited? No.

(e) Does this IRB hold a Federal-Wide Assurance from OHRP? No.

(f) Are complete records of the IRB review provided as required by 40 CFR 26.1125?

Yes.

(g) What standard(s) of ethical conduct would govern the work?

“This study will be conducted in accordance with EPA’s final regulation published at 40 CFR Part 26 that establishes requirements for the protection of subjects in human research (see SOP AHETF-11.A.1). The protocol, informed consent form(s), California Experimental Research Subject’s Bill of Rights, and other required documentation for this study will be approved by an institutional review board (IRB) and the California Department of Pesticide Regulation, and submitted to the EPA as required by 40 CFR 26.1125. The report of the completed research is subject to 40 CFR 26.1303 requirements to document its ethical conduct.

“The IRB for the proposed research shall be the Independent Investigational Review Board Inc. (IIRB) of Plantation, Florida. Complete records of the IIRB review as required by 40 CFR 26.1125 will be submitted to EPA for review along with this protocol and other documents.

“Researchers that participate in the study and interact with study participants must undergo ethics training (SOP AHETF-1.B.4). The training shall include successful completion of the course from the National Institutes of Health (Protecting Human Research Participants (PHRP)) and/or the Basic Collaborative IRB Training Initiative Course (CITI; The Protection of Human Research Subjects). Copies of the certificates of completion for the ethics courses will be submitted to the IRB and stored in the respective personnel files (maintained by the AHETF and all contract facilities.)” (p. 92)

“The person obtaining consent will inform the worker that he/she will receive \$20 for participation in the consent meeting, or the amount specified in the protocol, even if he/she decides not to participate in the study.

“During the private consent meeting the person obtaining consent will provide each worker with a full explanation of the study, its requirements, any potential risks, its benefits, alternatives to participation, *etc.* Workers will be advised of their right to withdraw from the study at any time and for any reason without jeopardizing their normal position with their employers or their daily wages. Workers will be told they will receive an additional \$80, or the amount specified in the protocol, if they decide to participate (don the dosimeters) even if they withdraw before the end of the monitoring period.

“The person obtaining consent will provide information about the risk of the surrogate chemical in the study, including signs and symptoms of acute overexposure. This information will be presented as an attachment to the Consent Form (referred to as Product Risk Statement {PRS}). WPS requirements, especially proper use of clothing, personal protective equipment, *etc.*, will be discussed. Refer to SOP AHETF-11.E.1 for details.

“Information will be provided about the risk of heat stress, including signs and symptoms, and ways to prevent it. Information will also be provided about the availability of medical attention during the study. Details on heat stress and its presentation are outlined in SOP AHETF-11.G.1, while details on emergency medical procedures are outlined in SOP AHETF-11.H.2.

“During the discussions between potential participants and the person obtaining consent, ample time will be provided for questions and the person obtaining consent will provide any additional information or clarification that is requested.

“The IRB-approved Consent Form (and all supporting documents) will be presented in the preferred language (English or Spanish) of the worker. All sections of the Consent Form will be explained in detail. When the person obtaining consent is satisfied that the worker understands the requirements and risks of the study, and if the worker still wants to participate, he/she will be asked to sign and date the Consent Form and the person obtaining consent will provide a copy of the signed form to the worker.

“An additional IRB-approved document, “Product Risk Statement”, will be attached to the Consent Form. If the study is conducted in California, the IRB-approved “California Experimental Research Subject’s Bill of Rights” will also be attached. These documents (in the appropriate language) will be reviewed, signed and dated by the worker, and copies will be provided.

“In all situations, the person obtaining consent will not sign the Consent Form unless he/she believes the candidate fully understands the information presented. This will be ascertained by providing repeated opportunities to ask questions and by asking

questions of the potential workers that would require a response that indicates understanding of key issues. The form in Attachment 11-J-1 will be used to ascertain general understanding.

“The person obtaining consent will not sign the Consent Form unless he/she believes that the process has been free of any element of coercion or undue influence and the witness (when required) has signed the consent form.” (SOP AHETF-11.J.1 §3.2-3.11, SOP Supplemental Submission, pp. 46-47)

(h) What measures are proposed to ensure fully voluntary participation and to avoid coercion or undue influence?

“In accordance with SOP AHETF-11.B.4 the individual growers will be asked to sign a non-coercion statement (Employer Cooperation Statement) affirming to their workers and AHETF that they will not coerce or unduly influence their workers to either participate or not participate in the study. Growers must also certify that alternate work will be provided on study days for workers who choose not to volunteer; and that the employee’s decision to participate or not will have no impact on their employment.” (p. 109)

9. Respect for Subjects

(a) How will information about prospective and enrolled subjects be managed to ensure their privacy?

“The AHETF employs many procedures to protect subject privacy during recruitment, consent, study conduct, and maintenance of study records. The consent form also summarizes important confidentiality issues for subjects. These procedures are described in SOPs AHETF-6.B.1, 6.D.0, 11.B.4, 11.D.1, and 11-J.1.” (p. 100)

“Your name will only appear on the consent form, the Product Risk Statement, an optional form for you to request your personal study results, and if in California the California Experimental Research Subject’s Bill of Rights. In all other parts of the study you will be identified by a code. Records with your name will be stored in a secure place with limited access.

“Information about you taking part in this study will not be given to your employer.

“A study report will be written by AHETF and will be available to member companies. It will be sent to the US Environmental Protection Agency (EPA). It may also be sent to state government agencies and to governments in other countries. Your name will not be in the study report.

“We cannot promise you total confidentiality. There may be a need to give information to some organizations or to parties in legal actions, as required by law. Records which identify you may be looked at or copied by the AHETF and any consultants working with

the AHETF, by EPA or other government agencies, and by the Independent Investigational Review Board, Inc., (IIRB). IIRB is a group of people who review and monitor research to make sure the people who take part are protected.

“You may ask the Study Director for a copy of your personal results from this study. You will need to provide your name and a mail or e-mail address.” (pp. 132-133)

(b) How will subjects be informed of their freedom to withdraw from the research at any time without penalty?

“The absolute right for subjects to withdraw from the research is the cornerstone of protection of human subjects. Prospective and enrolled subjects will be informed of their right to withdraw without consequence prior to and during the conduct of the research.

“Any volunteer expressing a need or desire to withdraw from the research after exposure monitoring begins will be paid \$80 and allowed to return to their normal work duties for their employer. If a participant withdraws while being monitored, the long underwear and air sampling pump will be removed, and the hand and face/neck samples will be collected with the worker’s consent. The Study Director will decide whether these samples will be analyzed (SOP AHETF-8.K.0).” (pp. 100-101)

“Your employer has agreed to let us do the research and has confirmed that he/she does not care whether you take part in this study or not. Your decision to be in this study is voluntary. This decision is entirely up to you. If you decide to take part, you may change your mind and drop out of the study at any time and for any reason. A decision not to take part, or to withdraw from the study after it starts, will have no effect on your job or pay or include any penalty or loss of benefits you are owed.” (p. 133)

(c) How will subjects who decline to participate or who withdraw from the research be dealt with?

“If you decide to take part, you may change your mind and drop out of the study at any time and for any reason. A decision not to take part, or to withdraw from the study after it starts, will not affect your job or pay or include any penalty or any loss of benefits you are owed.

“If you withdraw, the long underwear and air sampling pump will be removed. The hand and face/neck samples may be collected if you agree.

“Your part in this study may be stopped at any time by the researchers or the AHETF. The long underwear and air sampling pump will be removed. The hand and face/neck samples may be collected if you agree.

“If you withdraw or are removed from the study, you can go back to your usual work activities. If the study does not last an entire workday, you can go back to your usual work activities.

“No one can force you to take part in this study. Taking part is totally voluntary. If you choose not to take part in this study you will perform your ordinary activities on the day of the study. Your alternative is to not take part.” (pp. 133-134)

§ 26.1111 Criteria for IRB approval of research
AHETF Protocol AHE120: Mixing/Loading of Wetable Powder in Water Soluble Packets

Criterion	Y/N	Comment/Page Reference
(a)(1)(i) Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.	Y	
(a)(1)(ii) Risks to subjects are minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	n/a	
(a)(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.	Y	
(a)(3) Selection of subjects is equitable, taking into account the purposes of the research and the setting in which it will be conducted, and being particularly cognizant of the special problems of research involving vulnerable populations, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.	Y	
(a)(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §26.1116.	Y	
(a)(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §26.1117.	Y	
(a)(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.	Y	
(a)(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	Y	
(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.	Y	

§26.1117 Documentation of informed consent
AHETF Protocol AHE120: Mixing/Loading of Wetable Powder in Water Soluble Packets

Criterion	Y/N	Comment/Page Reference
(a) Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.	OK	
(b)(1) The consent form may be a written consent document that embodies the elements of informed consent required by §26.1116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or	OK	
(b)(2) The consent form may be a short form written consent document stating that the elements of informed consent required by §26.1116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.	n/a	

**40 CFR 26.1125 Prior submission of proposed human research for EPA review
AHETF Protocol AHE120: Mixing/Loading of Wettable Powder in Water Soluble Packets**

Any person or institution who intends to conduct or sponsor human research covered by §26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by §26.1115(a), and the following additional information, to the extent not already included:

Requirement		Y/N	Comments/Page Refs	
All information relevant to the proposed research specified by § 26.1115(a)	(1) Copies of <ul style="list-style-type: none"> all research proposals reviewed by the IRB, scientific evaluations, if any, that accompanied the proposals reviewed by the IRB, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects. 	Y n/a Y n/a	pp. 180-538 pp. 127-136, 149-158	
	(2) Minutes of IRB meetings . . . in sufficient detail to show <ul style="list-style-type: none"> 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 Y Y N n/a	pp. 550-552 The only required changes were minor typographical changes to the ICF No controverted issues	
	(3) Records of continuing review activities.	n/a		
	(4) Copies of all correspondence between the IRB and the investigators.	Y	pp. 80-84, 180, 182-183, 541, 543, 545, 548	
	(5) <ul style="list-style-type: none"> 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, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant. 	Y	IIRB roster and credentials on file with EPA.	
	(6) Written procedures for the IRB in the same detail as described in §26.1108(a) and §26.1108(b).	Y	Separately submitted to EPA under confidentiality claim	
	(7) Statements of significant new findings provided to subjects, as required by §26.1116(b)(5).	n/a		
The following information, to the extent not already included:	§1125(a) a discussion of:	(1) The potential risks to human subjects	Y	pp. 93-99
		(2) The measures proposed to minimize risks to the human subjects;	Y	pp. 93-99
		(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue	Y	p. 99
		(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and	Y	pp. 16-17 and AHETF Governing Document (reviewed at June 2008 HSRB meeting)
		(5) The balance of risks and benefits of the proposed research.	Y	p. 100
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.	Y	Original pp. 243-252 Approved pp. 127-136	
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.	Y	pp. 34-38, 92-93, 105-111, 145, 175	
	§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	pp. 100-103	
	§1125(e): All correspondence between the IRB and the investigators or sponsors.	Y	pp. 80-84, 180, 182-183, 541, 543, 545, 548	
	§1125(f): Official notification to the sponsor or investigator...that research involving human subjects has been reviewed and approved by an IRB.	Y	pp. 82-84	

