Designation: E3314 – 21

Standard Guide for Protection of Respondents and Informed Consent for Sensory Evaluation Studies[1]

This standard is issued under the fixed designation E3314; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide will cover the considerations that shall be made when testing products, materials, or ingredients with respondents for their sensory response to products and stimuli. A sensory study is defined as a study in which respondents' perceptions and responses to stimuli are measured and recorded. These data are used by companies to help design products that better meet consumers' needs, manage risk in developing products, and/or build knowledge of products sensory and performance attributes and consumers' product needs.

1.2 In this guide, the key principles driving safe sensory testing are summarized, and then in greater detail, the steps and processes to be considered to maintain ethical standards and ensure safety and confidentiality of human respondents to meet government and regulatory requirements globally are described. Respondents, test product/material, protocols and methods, study administration and oversight, and testing environment are all subject to oversight to maintain ethical standards, respondent confidentiality, and ensure a respondent's safety. Governmental and regulatory bodies, along with local organizations and professions, also provide requirements and guidance. It is incumbent upon the researcher to be aware of, and follow, these guidelines and requirements for any study for which they are responsible.

1.3 In this guide, all local regulations that may apply to sensory testing are not identified. The minimum standards and best practices for ethical treatment and safety of respondents during sensory testing are defined.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ICH Standard:*

ICH E6 (R1) Good Clinical Practices[2]

2.2 *ISO/IEC Standard:*

ISO/IEC 27002:2013 Information technology—Security techniques—Code of practice for information security controls[3]

3. Terminology

3.1 *Definitions:*

3.1.1 *adverse event, n*—unexpected/unusual reaction or health effect by a respondent during the exposure to or use of a product or test stimulus.

3.1.1.1 *Discussion*—Causality of the effect to the product or test stimulus is not necessary. **(ICH-GCP E6)**

3.1.2 *Declaration of Helsinki, n*—ethical principles for medical research involving human subjects (in this case, the sensory respondents), most recently updated in October 2013, as defined by the World Health Organization.[4]

3.1.3 *ethics committee, n*—independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects (respondents) involved in a study and to provide public assurance of that protection by, among other things, reviewing and approving/providing favorable opinion on the (study plan), the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

[1] This guide is under the jurisdiction of ASTM Committee E18 on Sensory Evaluation and is the direct responsibility of Subcommittee E18.07 on Personal Care and Household Evaluation.

Current edition approved Oct. 15, 2021. Published November 2021. DOI: 10.1520/E3314-21.

[2] Available from International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Secretariat, Route de Pré-Bois, 20, P.O Box 1894, 1215 Geneva, Switzerland, https://www.ich.org.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] "Declaration of Helsinki," *Bulletin of the World Health Organization*, Vol 79, No. 4, 2001, p. 373.

3.1.3.1 *Discussion*—The legal status, composition, function, operations, and regulatory requirements pertaining to independent ethics committees may differ among countries but should allow the independent ethics committees to (minimally) act in agreement with good clinical practices (GCP) as described in ICH-GCP E6. An ethics committee may also be known as an independent ethics committee (IEC), an institutional review board (IRB), or a research ethics board (REB).

3.1.4 *exposure/human (respondent) testing, n*—any research that involves respondents and one or more of: exposure (by means of taste, touch, smell, or any other physical contact) to a product, material, or ingredient; obtaining, handling, or sensory testing of human biological samples (for example, blood or any other type of tissue or body fluid); measures of human physiological responses (for example, biomedical, biometrics, neurometrics, and so forth); or use of biological sensors.

3.1.4.1 *Discussion*—When the research includes physically invasive tests or physiological procedures, these tests or procedures or both are to be conducted by personnel with the appropriate expertise.

3.1.5 *medical monitor, n*—fulfills the sponsor requirement of "medical expertise."

3.1.5.1 *Discussion*—Per ICH-GCP E6, "The sponsor should designate appropriately qualified medical personnel who will be readily available to advise on (human testing) related medical questions or problems. If necessary, outside consultant(s) may be appointed for this purpose."

3.1.6 *quality assurance, QA, n*—QA auditors assess compliance with the study plan and appropriate regulations and can be internal or external auditors.

3.1.7 *study manager, n*—person responsible for execution of the study plan, that is, how the respondent (sensory) test is conducted.

3.1.7.1 *Discussion*—The study owner and study manager can be the same person.

3.1.8 *study owner, n*—person (study sponsor) accountable for initiating the respondent (sensory) test and taking or recommending action based on the study results.

3.1.8.1 *Discussion*—The accountable person is responsible for making or approving all decisions related to the study design or plan or both, items to be tested, and issues that may arise during the study.

3.1.9 *study plan, n*—includes the study plan (protocol and methods) components described within this guide, as well as any amendments to the plan.

3.1.9.1 *Discussion*—A study plan should assure the test is scientifically sound and includes enough information to ensure reproducibility, as well as aid in compliance to relevant regulations.

4. Significance and Use

4.1 This global guide applies to all nonpharmaceutical sensory testing involving respondents (employees and non-employees). Testing with respondents can range from early exploratory studies to large-scale sensory studies and market claims tests regardless of the name assigned or the nomenclature used to describe the study.

4.2 The type of exposure or human (respondent) testing or both in scope is specified in 3.1.4. Definition of a product or material or both as pharmaceutical or non-pharmaceutical may vary by country. Knowledge of local laws and regulations is essential.

4.3 Respondents, products, protocols and methods, study administration and oversight, and the testing environment are all within the scope of this guide.

4.4 This global guide:

4.4.1 Does not cover pharmaceutical or professionally prescribed healthcare products;

4.4.2 Does not cover studies in which respondents are not exposed to a product (marketed or developmental) or material; and

4.4.3 Does not govern workplace manufacturing exposure to product and ingredients. Occupational safety and health policies govern these workplace manufacturing exposures.

5. Key Guidance Principles

5.1 The key guidance points in 5.1.1 – 5.1.9 summarize the basic principles and general guidance to be followed for ensuring the rights, safety, and well-being of human testing subjects (that is, respondents) are in compliance with global regulatory requirements and business, scientific, and ethical standards derived from the Declaration of Helsinki.

5.1.1 All individuals involved in conducting tests with respondents shall be trained and qualified to perform their role, including training to understand the rights, safety, and well-being of the respondents.

5.1.2 Testing involving respondents shall be scientifically sound, documented in a clear and detailed study plan before conduct, and the results recorded and maintained as per any regulatory requirements.

5.1.3 The study owner is accountable for all aspects of the study and, therefore, all planned respondent testing shall be reviewed and approved by the study owner without exception for compliance with regulatory and safety expectations.

5.1.4 Respondent testing will be evaluated by the study owner to determine if an ethics committee submission is required and this decision documented.

5.1.5 Freely given, documented informed consent shall be obtained from every respondent (or legal caregiver) before study participation. Documented informed consent shall be maintained with the study plan and results.

5.1.6 Confidentiality of records that could identify respondents (personally identifiable information) will be protected in accordance with applicable regulatory requirements (for example, local, regional, national, and so forth).

5.1.7 Safety plan and procedures are in place before the study is designed and implemented. The safety plan and procedures shall be appropriate for the products and stimuli that respondents are exposed to in the test. The same safety plans and procedures apply to on-site employee respondents, local area or convenience samples, trained respondent panelists, and consumer test respondents.

5.1.8 Any adverse events will be recorded by the study manger and managed according to protocol, which should reflect current business practices and applicable regulatory requirements.

5.1.9 Any decisions made for a respondent's medical care will be made by a qualified medical professional, including treatment of adverse events.

6. Detailed Guidance

6.1 *Training: Responsibility of the Study Owner or the Study Manager:*

6.1.1 Ensure all individuals involved in conducting the sensory testing are trained and qualified to perform their role.

6.1.1.1 This includes training for both their specific roles and general knowledge of the rights, safety, and well-being of the respondents.

6.1.1.2 This also includes training on the handling and reporting of adverse events.

6.1.1.3 This training should be conducted and documented.

6.1.1.4 When using a supplier/vendor, ensure this training expectation is included in the relevant contracts, agreements, and/or statements of work with training completion documented by the supplier/vendor.

6.1.2 Commercial training (direct, in-person training, or digital training) regarding the requirements in 6.1.1.1 – 6.1.1.4 is available if desired or needed.

6.2 *Study Plan Documentation: Responsibility of the Study Owner and the Study Manager*—Ensure that 6.2.1 – 6.2.4 are documented in a traceable, retrievable way in a human readable format.

6.2.1 A study plan/design, including objective(s) and/or relevant success criteria, methodology, products/test material evaluated, number of respondents, respondent characteristics (recruiting qualification in the case of consumer tests), and any other information critical to the study design;

6.2.2 Confirmation that the study plan was followed as designed or changes to the plan are recorded or both;

6.2.3 Technical testing verifying the test product/material is "as intended" for the objective and duration of the study; and

6.2.4 Study results are documented.

6.3 *Pre-Study Decisions: Responsibility of the Study Owner:*

6.3.1 Determine and document if an ethics committee review is required.

6.3.2 Determine and document if a medical monitor or medical/safety contact is required.

6.3.3 Ensure that product, material, and/or method of physiological response measurement are appropriately evaluated for human use/exposure and documented.

6.3.4 Ensure that any product preparation done before human use/exposure is appropriately evaluated for safety and documented.

6.3.5 The study owner should work with their regulatory/safety/clinical support/legal personnel to ensure appropriate assessment of the risk/benefit of the study and ensure that all governmental, regulatory, and local regulations regarding safety and ethics committee review are considered.

7. Additional Documentation

7.1 If required, ethics committee review or medical monitoring needs or both shall be completed and documented. At a minimum, the study manager shall document that these steps were either done or appropriately considered or both.

7.2 An informed consent document for participants in the planned study is the responsibility of the study owner and shall have the following minimum content:

7.2.1 Description of the research study (this may include, for example, ingredient or material content listing or product usage information or both) and the respondent's responsibility,

7.2.2 Statement that the respondent's participation is voluntary,

7.2.3 Statement describing the risks/benefits of participation,

7.2.4 Statement regarding how an adverse event would be handled,

7.2.5 Statement regarding confidentiality and what groups/people will have access to the two types of data:

7.2.5.1 Protected personally identifiable information and

7.2.5.2 Study results,

7.2.6 Compensation and expenses (as applicable), and

7.2.7 Identified contact for respondents' questions.

7.3 Ensure an informed consent document for each respondent is signed and dated appropriately before the start of the study and stored. The study manager and study owner should align on where the informed consent documentation will be stored and for how long.

8. Confidentiality

8.1 The study manager should ensure that study design for both internally and externally conducted testing maintains confidentiality of personally identifiable information in line with appropriate privacy practices for the country/region where the study is conducted. The information is defined in many ways but fundamentally refers to any information that can be used to identify specifically an individual. The specific regulations currently vary significantly by country or local regions (state, province, and so forth) or both. Industrial standards such as ISO/IEC 27002 and SOC2/3[5] can help provide procedures and demonstrate compliance with proper documentation.

9. Participant Safety

9.1 The study manager should confirm proactive plans are in place before study start regarding any potential need for medical care because of an adverse event and that this care is provided by a qualified health care provider (either provided by the study or the participants' own qualified care provider). This information should be available to the respondent in the informed consent.

9.2 The study owner should ensure that the label for test product/material (as well as the informed consent document)

[5] SOC 2 - SOC for Service Organizations: Trust Services Criteria and SOC 3 SOC for Service Organizations: Trust Services Criteria for General Use Report (trademarked), AICPA, 220 Leigh Farm Rd., Durham, NC 27707-8110.