SEAOES Criteria

In 2008, the **National Exposure Research Laboratory (NERL)** of the **Office of Research and Development (ORD)** at the EPA established a resource tool that indicates best practices for those conducting observational exposure studies. The **Scientific and Ethical Approaches for Observational Exposure Studies (SEAOES) document** includes a series of considerations that will help investigators design research projects that meet the highest ethical and scientific standards.

Many of the proposed considerations listed in the SEAOES document will be very helpful for *all* investigators as they prepare their IRB application. However, EPA Policy Order 1000.17 Change A1 in July 2011 requires the HSRRO to apply the SEAOES criteria to any observational exposure study conducted or supported by the EPA. **Therefore, if you are conducting observational exposure research, you must include responses to all items in your submission for final approval**.

1. Human subjects involvement, characteristics, and design.
    a. Describe and justify the proposed involvement of human subjects in the work being proposed.
    b. Describe the characteristics of the subject population, including their anticipated number, age range, and health status if relevant.
    c. Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulations.
    d. Describe the research material that will be obtained from or about living individuals in the form of data, specimens, or records.
    e. List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in the research.
    f. Describe and justify any compensation being provided to subjects for their participation in the research.
    g. Describe the plan for communicating individual and/or aggregate research results to participants, if relevant.
2. Potential risks to subjects.
    a. Describe the potential risks to human subjects (physical, psychological, financial, legal, or other) and assess their likelihood and seriousness to the human subjects.
3. Adequacy of protection against risks.
    a. Describe planned procedures for protecting against or minimizing potential risks and assess their likely effectiveness.
    b. Describe planned procedures for the process of obtaining and maintaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.
    c. If waiver of some or all of the elements of informed consent or of documentation of consent will be sought, provide justification for the waiver.
    d. Where appropriate, discuss the plans for ensuring necessary medical or professional intervention in the event of adverse effects to subjects.
4. Protection of vulnerable groups, see 40 CFR Part 26, subparts C & D.

a. Explain the rationale for the involvement of any vulnerable populations, including pregnant women, fetuses, and children if relevant.
b. Describe the additional protections in place, if any, for protecting vulnerable populations included in the research.
c. If children are included in the research, describe the process for obtaining parental permission and child assent if relevant.

5. Protection of privacy and confidentiality.
    a. Describe how data, specimens, and/or records will be collected, managed, and protected, including at collaborating sites, if any, as well as at the primary site.
    b. Indicate who will have access to individually identifiable private information about human subjects.
    c. Describe any additional procedures for the protection of privacy and confidentiality of the human research subjects.
    d. Discuss any mandatory reporting requirements with the potential to come into play during the conduct of the research and describe how these will be communicated to participants if relevant.
    e. Discuss the potential of the research to obtain information about third parties and describe how this will be handled if it occurs.
6. Relationship between researcher and community.
    a. If the research will take place in a community setting, describe the procedures in place for defining the community, obtaining its involvement in the research, and establishing and maintaining trust.
7. Potential benefits of the research to the participants and others.
    a. Discuss the potential benefits of the research to the research participants and others.
    b. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits.
8. Importance of the knowledge to be gained.
    a. Discuss the importance of the knowledge to be gained as a result of the proposed research.
    b. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.
9. Projects involving intentional exposure of human subjects should only be considered if they have the potential of providing a clear health or environmental benefit or if acquisition of such information is not obtainable by any other means. In no case should the exposure cause lasting harm to study participants.
    a. Provide justification, in advance of being conducted, that the study could contribute to addressing an important scientific question that cannot be resolved on the basis of animal data or other study;
    b. Discuss how the study is designed in accordance with current scientific standards and practices to i) address the research question, ii) include representative study populations for the endpoint in question, and iii) meet requirements for adequate statistical power;
    c. Discuss how the study will be conducted in accordance with recognized good clinical practices, including appropriate monitoring for safety; and

d. Confirm that the grantee will report comprehensively to their EPA Project Officer, providing the full study protocol, detailed analyses of the data and report any adverse events promptly.

10. Value of Studies that Seek to Provide a Potential Public Health or Environmental Benefit
    a. Discuss the constitution of the IRB and their ability to consider whether a study has the potential of providing a clear health or environmental benefit to the community.
11. Criteria for Scientific and Ethical Acceptability
    a. Confirm that the following necessary conditions for scientifically and ethically acceptable intentional human dosing studies have been satisfied:
    b. prior animal studies and, if available, human observational studies;
    c. a demonstrated need for the knowledge to be obtained from intentional human dosing studies;
    d. justification and documentation of a research design and statistical analysis that are adequate to address an important scientific question, including adequate power to detect appropriate effects;
    e. an acceptable balance of risks and benefits, and minimization of risks to participants;
    f. equitable selection of participants;
    g. free and informed consent of participants; and
    h. review by an appropriately constituted IRB.
12. Participant Selection Criteria
    a. Discuss how the project design ensures that the following conditions are met in selecting research participants: (i) Selection should be equitable; (ii) Selection of persons from vulnerable populations must be convincingly justified in the protocol, which also must justify the measures to be taken to protect those participants; (iii) Selection of individuals with conditions that put them at increased risk for adverse effects in such studies must be convincingly justified in the protocol, which also must justify the measures that investigators will use to decrease the risks to those participants to an acceptable level.
13. Payment for Participation
    a. Discuss how IRBs, all relevant review boards, investigators, and research sponsors should ensure that payments to participants in intentional human dosing studies are neither so high as to constitute undue inducement nor so low as to be attractive only to individuals who are socio-economically disadvantaged. Proposed levels of and purposes for remuneration (e.g., time, inconvenience, and risk) should be scrutinized in light of the principles of justice and respect for persons.
14. Best Practices in Informed Consent
    a. Discuss the proposed process regarding informed consent in intentional human dosing studies and how it compares to best practices.
15. Compensation for Research-Related Injuries
    a. Discuss how you ensure that participants receive needed medical care for injuries incurred in the study, without cost to the participants.