Human Subjects Activities Guidance Document

Purpose

The purpose of this document is to provide guidance on the federal regulations that govern research involving human subjects. All research activities involving human subjects must satisfy the requirements of the Common Rule for the Protection of Human Subjects, as provided for by the Department of Health and Human Services (HHS) in 45 C.F.R. Part 46, and codified by the Department of Commerce in 15 C.F.R. Part 27. The Common Rule, and the institutional policies that enforce its requirements in research involving human subjects, exist to ensure adequate protection of human subjects.

NIIMBL members who involve human subjects in their research activities, as defined below, must seek appropriate approvals prior to initiating their projects.

Definitions

Human subjects are defined as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable personal information (15 C.F.R. Part 27.102f). Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (15 C.F.R. Part 27.102d).

Exemptions to the Common Rule

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the federal regulations (15 C.F.R. Part 27.101b):

> (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
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> (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
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> > (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
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> (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Review and Approval of Human Subjects Activities

NIIMBL members who conduct human subjects research at their organization must seek appropriate approvals prior to initiating their projects. The organization must have a written assurance on file with the Office for Human Resource Protections (OHRP) in HHS in the form of a Federal-Wide Assurance (FWA) or directly with the Department of Commerce, NIST, that research has been reviewed and approved by an Institutional Review Board (IRB) provided for in the assurance, and will be subject to continuing IRB review. If your organization does not have an assurance on file with OHRP or NIST, please contact your NIIMBL Program Manager for more guidance.

All FWA documentation must be made available to NIIMBL, as well as all IRB approvals. Work cannot be initiated on any NIIMBL project that involves human subjects without written authorization.

Resources

Health and Human Services 45 CFR 46
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101

Decision Charts (exempt research, applicability of exemptions)

https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html