

15.0 Exemption from Continuing IRB Review

Last Revised on 12 December 2003

15.1 Exemption

Certain types of human subjects research may be exempted from review. However, because the involved investigators and all research at the university may be put at considerable risk if a study is inappropriately excluded from IRB review, exemptions must be confirmed by the chair of the IRB or a designee upon review of applications for exemption. Since this constitutes a review, protocols that are deemed exempt at UNC-Chapel Hill are effectively “exempt from continuing review.”

An investigator may not initiate research involving human subjects that the investigator believes is exempt until the investigator has received formal written concurrence of this exempt determination from the IRB. Changes to exempted studies must be reviewed by the IRB just as amendments to studies receiving expedited or convened IRB review. In some instances, changes to an exempted study may render it no longer exempt.

15.2 Categories for exemption from continuing review

While human subjects research involving prisoners is never exempt from IRB review, research activities involving other human subjects may be exempted from IRB review if the only involvement of human subjects fits within one or more of the following categories (45 CFR 46.101(b)):

- Category 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; or
- Category 2 Research not involving children that is limited to the use of educational tests, survey procedures, interview procedures or observations of public behavior unless 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. This exemption does not apply to research involving children except for research involving observations of public behavior when the investigator does not participate in the activities being observed, or interact directly with the children. All other exemptions apply to research involving children. [45 CFR 46 101(b)(2) as modified by Subpart D 45 CFR 46.401 (b)]
- Category 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

Category 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

Category 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.

Category 5 Research and demonstration projects conducted by or subject to approval of a federal agency and designed to study, evaluate or otherwise examine some aspect of (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..

Category 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.

If information comes to the attention of the IRB suggesting that there are factors increasing the sensitivity and/or potential risk to human subjects in research that otherwise would appear to qualify for exemption under the criteria listed above, the IRB may, in its own sole judgment, deem the protocol to be subject to expedited or convened IRB review.

References:

21 CFR 56.104(d)
45 CFR Subparts B and C
45 CFR 46.401(b)