

Criteria for Determination of Exempt Research

EXEMPT RESEARCH

Research may be exempt from IRB review. Maine CDC uses the criteria for exemption as described in 45 CFR 46.101. The Deputy ADS makes the final determination whether research is exempt. Documentation of the exemption (CDC form 0.1255) must include the specific category in 45 CFR 46.101 (justifying the exemption). Each exempt research study is tracked in the protocol tracking system. Exempt research is reviewed on an annual basis to determine whether it continues to meet the criteria for exemption.

Note: The exemption criteria below do not apply to research involving prisoners, fetuses, pregnant women, or human *in vitro* fertilization.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and any disclosure of human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. (Examples include: the collection of sensitive data regarding the subjects' [or relatives' or associates'] possible substance abuse, sexuality, criminal history or intent, medical or psychological condition, financial status, or similarly compromising information.)

Note: The above exemption of research involving survey or interview procedures or observation of public behavior, does not apply to research with children except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed.

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

Note: CDC can use this exemption criterion only in the case where a 308(d) Assurance of Confidentiality has been obtained to cover the research.

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 participants cannot be identified, directly or through identifiers linked to the participants.

Note: "Existing" data means existing before the study began. If a link is created by an investigator, even temporarily, for research purposes, this criterion is not met. If a temporary link is created by clinical staff who already have access to the data, this criterion is met.

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: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or 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, if wholesome foods without additives are consumed or 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.

Source: 1999 CDC Procedures for Protection of Human Research Participants , p34-35