**Exempt Review**

Some studies on human subjects may be **exempt** from the need for full or expedited review by

the Institutional Review Board. Descriptions of such research must nevertheless be filed with the college for periodic review by the Institutional Review Board.

**What categories of research may be exempt from requirements of the Code of Federal Regulations (45 CFR 46)?** Many educational, behavioral, and social science studies present little or no risk to subjects and can be exempt from IRB review.

**Who decides that a project is Exempt?** The ENC IRB has determined that the decision to exempt a study is properly made by a faculty member who has completed the NIH *Protecting Human Research Participants* training and who is not associated with the project.

**The NIH certified faculty must confirm that the project meets criteria for exemption, including:**

* Low risk for participants. The Code of Federal Regulations (45 CFR 46.102(i)) defines minimal risk as:
* “The probability and magnitude or harm or discomfort … are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”
* Participants voluntarily provide informed consent
* The project fits in one of the following categories:

**Exemption 1 - Normal Educational Practices and Settings**

*Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as*

1. *research on regular and special education instructional strategies, or*
2. *research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.*

(Exemption 1 is limited to normal educational practices conducted in commonlyaccepted settings. For example, evaluation of the effectiveness of an existing instructional program. A study that involves evaluation of a radically new strategy or random assignment is not exempt because the methods employed are not normal educational practices.) (Ref IRB Mgmt and Function, p 94)

**Exemption 2 - Anonymous Educational Tests, Surveys, Interviews or Observations**

*Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior, unless:*

1. *information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and*
2. *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 reflects concern with protecting subjects’ privacy and avoiding any risks associated with breach of confidentiality. The participants’ responses to survey questions must be anonymous or de-identified before data analysis. Exempt survey research data must not be linked to individual subjects. If research data contain personally identifying information and if disclosure of data to unauthorized persons could harm the subject in any way, the research is not exempt. Survey research that deals with sensitive and private aspects of the subject’s behavior, such as sexual preferences and substance abuse, is not exempt if data can be linked to individuals. Even if the research has no subject identifiers, invasive questions that may cause emotional distress or discomfort negate exemption.)

**Exemption 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 Exemption 2 above, if*

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

**Exemption 4 - Collection or Study of Existing Data**

*Research involving the collection of 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.* (The data must be “on-the-shelf” at the time the research begins. The research data must be recorded so that subjects cannot be identified. This includes demographic information that could link the data to the subject. The existence of a code that could be used to identify a subject disqualifies the research from using this exemption.)

**Exemption 5**

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

1. *public benefit or service programs;*
2. *procedures for obtaining benefits or services under those programs;*
3. *possible changes in or alternatives to those programs or procedures; and*
4. *possible changes in methods or levels of payment for benefits or services under those programs.*

**Exemption 6**

*Taste and food quality evaluation and consumer acceptance studies,*

1. *if wholesome foods without additives are consumed or*
2. *if a food is consumed that contains a food ingredient at or below the level 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. Exemption definitions located in Title 45 CFR 46.101(b)*

**What research cannot qualify for exempt status?**

Research that cannot qualify for exempt status includes:

* Research involving interaction with children and minors
* Research involving prisoners
* Research that involves deception or withholding of information from subjects
* Research that involves intense physical exercise
* Research that may cause emotional distress or discomfort greater that what would be expected in daily life

**An exempt research project still requires that the complete application is filed with the Institutional Review Board. Accordingly, the same application procedure is required.**