Exempt Research Review

All research using human subjects must be reviewed and approved by the institution. Exempt research is exempt from continuing review. However, Exempt research is still subject to an initial review and a must be approved by an IRB chairperson (or committee member if the chairperson is not available) before data collection begins. Exempt research, once approved, is non-renewable. The principle investigator is responsible for submitting all required documentation noted in the Initial Review section of this document to the IRB chair or designee. The Chairperson of the IRB or designee will notify the investigator in writing of the decision surrounding whether their research qualifies as an exempt status and its non-renewable status.

Categories of Research Permissible for Exemption From Continuing Review Research activities in which the only involvement of human subjects will be in one or more of the following categories can be exempt from continuing IRB review according to 45 CFR 46.101 (www.hhs.gov/ohrp/humansubjects/guidance)

(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.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) 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.

(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 (2), 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: data, 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 Federal 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.

(7) Research that uses only publicly available data or specimens that are existing (i.e., collected – "on the shelf" – prior to the beginning of this research project for a purpose other than the proposed research)

Research that Cannot Be Exempt From Continuing Review Some research always requires IRB review, even if it falls under one of the 7 categories of research permissible for Exemption listed below. Research that cannot be exempt according to 45 CFR 46.01 (b) and 45 CFR 46.401 www.hhs.gov/ohrp/humansubjects/guidance iincludes:

Research involving children—except for research involving observations of public behavior when the investigator does not participate in the activities being observed. Research involving Prisoners, fetuses, pregnant women, persons who are cognitively impaired, human in vitro fertilization, or persons who are economically or educationally disadvantaged Research in which information will be recorded by the investigator in such a way that it can, in any way, be linked to the subject.

Submission of and Deadline For Exempt Protocols Protocols believed to meet the requirements for exempt status should be submitted to the appropriate department chair or to the OU IRB chair for review at least two weeks prior to the date on which investigators plan to start data collection and include requirements identified in previous section Initial Review. Human subjects may not be recruited or research initiated until final IRB approval has been received in writing.