

**OKLAHOMA STATE UNIVERSITY
CENTER FOR HEALTH SCIENCES
COLLEGE OF OSTEOPATHIC MEDICINE**

**OFFICE OF RESEARCH AND SPONSORED PROGRAMS
INSTITUTIONAL REVIEW BOARD**

APPENDIX A SUMMARY OF CRITERIA FOR EXEMPT STATUS AND EXPEDITED REVIEW

Exempt Status: Research conducted in established or commonly accepted educational settings involving normal educational practices, e.g., 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 may be exempt.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior is exempt, unless: that information taken from these sources is recorded in such a manner that participants could be identified directly or through identifiers linked to the participants, and any disclosure could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability, or reputation (e.g., drug use, sexual behavior, or use of alcohol).

All research involving survey or interview procedures that is not otherwise exempt as listed above, is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office, or if Federal statute(s) require(s) confidentiality of the personally identifiable information be maintained during and after the research.

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, is exempt if these sources of information 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.

Research and demonstration projects which are conducted by or participant to the approval of (Federal) 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.

Taste and food quality evaluation and consumer acceptance studies are exempt 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.

Expedited Review: Research that IRB may consider by expedited review are minor changes in previously approved research during the period (one year or less) for which approval is authorized, and research that presents minimal risks to participants in one or more of the categories:

The collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth and permanent teeth if patient care indicates a need for extraction.

Collection of excreta and external secretions including sweat, un-cannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

Recording of data from participants 18 years or age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a

distance and do not involve input of matter or significant amounts of energy into the participant or an invasion of the participant's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., x-rays, microwaves).

Collection of blood samples by vein puncture, in amounts not exceeding 450 milliliters in an eight-week period and not more often than two times per week, from participants 18 years of age or older and who are in good health and not pregnant.

Collection of both supra- and subgingival dental plaque and calculus, provided the procedures are not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

Voice recordings made for research purposes such as investigations of speech defects.

Moderate exercise by healthy volunteers.

The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

Research on individual or group behavior or characteristics of individuals such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate participants' behavior and the research will not involve stress to participants.

Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required. Thus if an exemption is required, then the review may not be done as or assigned in the "expedited" category.