APPENDIX C
DEFINITIONS AND ELABORATIONS

The definitions and elaborations herein are designed to conform to Title 45 Code of Federal Regulations (CFR) Part 46 as implemented by United States Department of Health and Human Services (DHHS) “Final Regulations Amending Basic HHS Policy for the Protection of Human Subjects,” revised June 18, 1991. They also apply to the 17 common Rule Agencies.*

University of Central Oklahoma will comply with DHHS requirements regarding cooperative research projects. When sponsored research is conducted at or in cooperation with another entity, all provisions of this policy shall remain in effect for that research. University of Central Oklahoma may accept, for the purpose of meeting IRB review requirements, the review of an IRB establishment under another assurance of compliance with DHHS. Such acceptance must be in writing, and approved and signed by the designated official of each of the other cooperating institutions. Specifically, we require that application for approval be filed with the UCO IRB and that Cooperative agreement and an approval letter from the other institution be attached.

Definitions

For Purposes of this policy, the following definitions shall apply:

1. “Research” or “research activity” means any systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute “research” whether or not they are regularly called “development,” “demonstration,” ”instruction,” or another term.

2. “Unsponsored research” means research that is supported solely by the University of Central Oklahoma. “Sponsored research” means research that is supported in whole or partly by any other institution or individual.

3. “Human Subject” means a living individual about whom an investigator conducting research obtains

   (a) data through intervention or interaction with the individual, or

   (b) identifiable private information.
(c) “Intervention” includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes.

*Common Rule Agencies are USDA, DOE, NASA, DOC, CPSC, HUD, DOJ, DOD, DEd, VA, HHS, NSF, DOT, EPA, AID, OSTP, SSA, and CIA*

“Interaction” includes communication or interpersonal contact between investigator and subject. “Private Information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

The idea of interaction with a human being is perhaps key in determining whether or not the human being is a subject with respect to the regulations. All forms of interaction are included by the regulatory definitions. Among the most common types of research interactions are:

(a) Mailed or Internet questionnaires or surveys
(b) Personal interviews, structured or unstructured, with or without recognized instruments.
(c) Personal (i.e., face-to-face) surveys
(d) Telephone interviews and surveys
(e) Classroom instruments, evaluations or exercises
(f) Examination of private records (e.g. medical, psychological, or school records as well as pathological specimens).
(g) Observation of public behavior by identifiable individuals (e.g., in a classroom, in a mall).

4. “Research investigator” or “investigator” means any faculty, staff, or student member of the University of Central Oklahoma Campus who engages in any research activity involving the use of human subjects. Please note that there are exceptions for educational activities. See Appendix D for specific details.

5. “Minimal risk” means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Risks of daily life mean those risks encountered in the daily lives of the subjects of the research, considering their actual life situations, as opposed to the daily life of “normal persons” or of “healthy volunteers” as the case may be.
COMMON FORMS OF Research Requiring Submission to IRB

From the list of types of interaction, we can see that many common forms of research that present little, if any, risk to human beings nevertheless require either review or certification of exemption simply because they are research and have human subjects. Some of the more common types are:

1. Oral history
2. Case studies of events or individuals, if interviews are involved
3. Workplace and school observations, whether activities are controlled or uncontrolled
4. Surveys for information, attitudes, opinions, and similar matters for publication or for report to a federal state, or local governmental agency
5. Classroom research which will later be disseminated to the public.
**EXEMPT RESEARCH**

The following types of research may be considered exempted from the requirements of 45 CFR 46 and approval under the regulations of the DHHS and this policy, except under the conditions noted and except when the subjects have not obtained their legal majority (18 years of age as of application date) in Oklahoma or in the locale where the research is to be performed. All research involving legal minors as human subjects must be submitted to the IRB for review and approval prior to the involvement of any subject who is a legal minor.

The IRB may, at the discretion of the chair, review the following types of research, when they involve legal minors, via the expedited review. **THE DETERMINATION OF WHETHER OR NOT RESEARCH WOULD BE CONSIDERED EXEMPT FROM REVIEW WILL BE MADE BY THE IRB.** Note that, when support is being requested from a non-DHHS sponsor which has more restrictive or elaborate requirements for the protection of human subjects, a review must be performed on that project in accordance with the regulations of that sponsor. Investigators should complete an IRB Checklist and send it and supporting materials to the IRB for determination.

**Educational Practices Research**

Research in conducted in established or commonly accepted educational settings, involving normal educational practices, is exempt. Examples of such research are:

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

**Educational Testing Research**

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) is exempt, provided that information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**Survey Research**

Research involving survey or interview procedures is exempt, except where all of the following conditions exist:

1. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.
2. The subject’s responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability.

3. The research deals with sensitive aspects of the subject’s own behavior such as psychological testing, illegal conduct, drug use, sexual behavior, or use of alcohol.

All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

**Observational Research**

Research involving the observation (including observation by participants) of public behavior is exempt, except where all of the following conditions exist:

1. Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.

2. The observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability.

3. The research deals with sensitive aspects of the subject’s own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

**Collection or Study of Existing Data**

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, is exempt.

**Public Benefit or Service Program Research**

Unless specifically required by statute, research which involves the study, evaluation or other examination of programs under the Social Security Act, or other public benefit or service programs is exempt from review. This includes research of procedures for obtaining program benefits or services, possible changes in or alternatives to those programs or procedures, and possible changes in methods or levels of payment for benefits or services under those programs.

However, if it determined that a research or demonstration project which would be considered exempt under these criteria presents a danger to the physical, mental, or emotional well-being of a
participant or subject of the research or demonstration project, written informed consent of each participant or subject must be obtained before any federal funds may be expended.

**Investigational New Drugs or Devices**

The IRB is responsible for complying with the federal guidelines for investigational new drug or device certification requirement (21 CFR 312.22-23). The following procedures will be used to meet this requirement:

1. The IRB will identify the test article (i.e., drug, biologic, or device) in the certification to DHHS when the proposal involves a test article and will state whether the 30-day interval required for test articles has elapsed or was waived by the Food and Drug Administration (FDA).

2. If the 30-day interval has expired, the IRB will state whether the FDA has requested that the sponsor continue to withhold or restrict the use of the test article for application in human subjects.

3. If the 30-day interval has not expired and a waiver has not been issued, the IRB will send a statement to DHHS upon expiration of the interval.
Tests for Research

When dealing with data gathering within the context of training, demonstration, or service projects, you may want to ask yourself several questions to determine if any aspect of your work is research as it might be related to human subjects for review:

1. Do you anticipate in advance of conducting the project that you will analyze, interpret, and disseminate the findings or your investigation?

2. Will you seek out subjects (or settings that contain subjects) for your training, demonstration, or service project, rather than the subjects seeking the service or training from you in their normal pursuit of professional services?

3. Might the knowledge you gain from your encounter with the subjects be applied beyond the service of training project to similar encounter so as to lead a new procedure or process?

If you answer yes to any of these questions, then your training, demonstration, or service project has a research component. See Checklist at ORIC webpage.
Instances of Non-research

There are numerous forms of data gathering from human beings that do not constitute research within the context of human subjects review regulations. Some examples are:

1. Data gathering for classroom training in research methods for which the only foreseeable purpose is teaching. In other words, neither the instructor nor the student can foresee or anticipate any dissemination of the data gathered beyond the classroom situation. See Appendix D: Student Research Activities.

2. Data gathered for administrative purposes alone within the context of the normal efforts of a department or an institution to find out what is happening or how to improve services or operations. In other words, no dissemination of the information outside the unit or institution is foreseen or anticipated.

3. Evaluation data gathered for a contractor about a project or operation for which he or she is responsible, if neither the researcher nor the contractor intends or anticipates the dissemination of the data.

All these categories of data gathering fail to be research because there is no foreseeable dissemination of the data. Any record of the data (or interpretations and analyses of the data) remains private (used only for purposes that are appropriate to the class, institution, or agency in the normal conduct of its work).
Types of Expedited Research

Types one (1) through seven (7) pertain to both initial and continuing IRB review.

I. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which

1. an investigational device exemption application (21 CFR part 812) is not required; or

2. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

II. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and the health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

III. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

(c) hair and nail clippings in a non-disfiguring manner;

(d) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

(e) permanent teeth if routine patient care indicates a need for extraction;

(f) excreta and external secretions (including sweat)
(g) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(h) placenta removed at delivery;

(i) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(j) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the success is accomplished in accordance with accepted prophylactic techniques;

(k) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(l) sputum collected after saline mist nebulization.

IV. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy;

(b) weighing or testing sensory acuity;

(c) magnetic resonance imaging;

(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

V. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from DHHS regulations for the
protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt).

VI. Collection of data from voice, video, digital, or image recordings made for research purposes.

VII. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

VIII. Continuing review of research previously approved by the convened IRB as follows

(a) where

(1) the research is permanently closed to the enrollment of new subjects;

(2) all subjects have completed all research-related interventions; and

(3) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

IX. Continuing review or research, not conducted under an investigational new drug application or investigational device exemption where categories II (2) through VIII (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater that minimal risk and no additional risks have been identified.
CRITERIA FOR IRB APPROVAL OF RESEARCH

Prior to approving research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized
   (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

4. Informed consent will be sought from each prospective subject, or the subject’s legally authorized representative, in accordance with, and to the extent required this policy.

5. Informed consent will be appropriately documented in accordance with, and to the extent required by this policy.

6. Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.

7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are
economically or educationally disadvantaged, appropriate safeguards have been included in the study to protect the rights and welfare of these subjects.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review-expedited or convened-utilized by the IRB.

**Preemption of Laws**

The informed consent requirements in this policy are not intended to preempt any application of federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.
Research categories permitting expedited review are:

1. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

2. Collections of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording data from subjects 18 years of age or older using noninvasive 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 subject or an invasion of the subject’s privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiograph, 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).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight week period and not more often that two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

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

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

7. Moderate exercise by healthy volunteers

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

9. 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 subjects’ behavior and the research will not involve stress to the subjects.

10. Research on drugs or devises for which an investigational new drug exemption or an investigational device exemption is not required