Effective January 13, 2012

Southwestern Oklahoma State University
Weatherford Campus and Sayre Campus

Policy and Procedures For The Protection of Human Subjects (PHS) In Research Activities

SECTION 1. APPLICABILITY

This document sets forth the policy and procedures for the protection of human subjects involved in research activities conducted at or sponsored by Southwestern Oklahoma State University-Sayre/Weatherford, including research activities (a) by faculty, staff, and students, (b) performed in SWOSU/Sayre/Weatherford facilities, or (c) otherwise supported by University resources or facilities which are under the control of SWOSU officials. The policy and procedures herein are designed to conform to 45 Code of Federal Regulations (CFR) Part 46 as implemented by United States Department of Health and Human Services (DHHS) "Basic DHHS Policy for the Protection of Human Subjects," as revised June 18, 1991.

The procedures and safeguards herein shall apply to all sponsored research activities of the SWOSU-Sayre/Weatherford. However, where a sponsor agency has more restrictive or elaborate requirements for the protection of human subjects, those requirements shall take precedence over this policy and shall be followed in the review and approval of those research projects. Note that additional DHHS requirements exist for the protection of special populations--such as fetuses, pregnant women, in vitro fertilization of human ova, prisoners, and persons institutionalized as mentally disabled--and those requirements must be followed when subjects are to be drawn from any of those populations.

The procedures and safeguards herein shall apply to all unsponsored research activities of SWOSU-Sayre/Weatherford, except that the Institutional Review Board-Protection of Human Subjects Committee (IRB-PHSC) SWOSU-Sayre/Weatherford shall have the authority to modify these procedures and safeguards when it deems necessary, provided that such modifications preserve adequate protection for the rights and welfare of the subjects of unsponsored research. Such modifications for unsponsored research may include expansion of the coverage or modifications of the criteria or documentation for obtaining informed consent.

SWOSU-Sayre/Weatherford 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. SWOSU-Sayre/Weatherford may accept, for the purpose of meeting IRB-PHSC review requirements, the review of an IRB-PHSC establishment under another assurance of compliance with DHHS. Such acceptance must be in writing, approved and signed by the IRB-PHSC, and approved and signed by correlative officials of each of the other cooperating institutions.

SWOSU-Sayre/Weatherford will exercise appropriate administrative overview, carried out at least annually, to ensure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are in compliance with the requirements of 45 CFR 46 and this policy. This administrative overview shall be the responsibility of the IRB-PHSC.

Any research project, which is conducted with an expectation that the results of the research will be made public through publication, including publication in a thesis or dissertation, or presentation in any public venue, must be reviewed and approved by the IRB-PHSC before the project begins.

This policy statement supersedes all previous policy statements regarding the protection of human subjects for the SWOSU-Sayre/Weatherford.

SECTION 2. AFFIRMATION

SWOSU-Sayre/Weatherford hereby affirms its adoption of The Belmont Report, prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, as embodying the principles SWOSU-Sayre/Weatherford will apply in the discharge of its responsibilities for protecting the rights and welfare of human subjects. In addition, SWOSU-Sayre/Weatherford expects that when research takes place in a foreign country, the investigator must assure that his / her procedures meet all legal requirements of that country, as well as the requirements of this policy.

SECTION 3. 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 general 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 SWOSU-Sayre/Weatherford. "Sponsored research," means research that is supported in whole or part 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. "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. "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. Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

4. "Research investigator" or "investigator," means any faculty, staff, or student member of the SWOSU-Sayre/Weatherford Campus who engages in any research activity involving the use of human subjects.

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.

SECTION 4. RESEARCH EXEMPT FROM FULL BOARD REVIEW

The following types of research may be considered exempted from the requirements for full board review 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 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-PHSC for **full board review** and approval prior to the involvement of any subject who is a legal minor. The IRB-PHSC may, at the

discretion of the Chair, review the following types of research listed below when they involve legal minors via the expedited review procedures given in Section 11. **THE DETERMINATION OF WHETHER OR NOT RESEARCH WOULD BE CONSIDERED EXEMPT FROM FULL BOARD REVIEW WILL BE MADE BY THE IRB-PHSC. Note that, when support is being requested from a non-DHHS sponsor and that sponsor has more restrictive or elaborate requirements for the protection of human subjects, the researcher is responsible for being in compliance with the non-DHHS sponsor's guidelines.**

4.1 Educational Practices Research

Research conducted in established or commonly accepted educational settings, involving normal educational practices, may be exempt from full board review. 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, **except when the data obtained may be used to impact educational personnel.**

4.2 Educational Testing Research

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) may be exempt from full board review, **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 when the data obtained may be used to impact educational personnel.

4.3 Survey Research

Research involving survey or interview procedures may be exempt from full board review, **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 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.

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.

4.4 Observational Research

Research involving the observation (including observation by participants) of public behavior may be exempt from full board review, **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 are 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.

4.5 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, may be exempt from full board review.

4.6 Public Benefit or Service Programs Research

Unless specifically required by statute, research conducted by or subject to approval by United States Department of Health and Human Services (DHHS) which involves the study, evaluation or other examination of programs under the Social Security Act, or other public benefit or service programs may be 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 is determined by the Secretary of the United States Department of Health and Human Services (DHHS) that a research or demonstration project which may be considered exempt from review 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.

SECTION 5. STUDENT RESEARCH PROJECTS CONDUCTED AS CLASS EXERCISES

In most cases, class research projects which involve human subjects and which are conducted by students, as exercises to learn how to conduct research do not require review by the IRB-PHSC. Both students and their advisors and instructors are asked to inform themselves of the requirements associated with the use of human subjects in research projects such as maintaining confidentiality and obtaining written informed consent to participate in the study **before** the project begins to protect subjects from physical and/or mental harm, from putting themselves at risk of civil or criminal liability, and from revealing sensitive aspects about their own behavior. Class research projects which are conducted with an expectation that the results of the research will be made public through publication, including publication in a thesis or dissertation, or presentation at a meeting must be reviewed and approved by the IRB-PHSC **before** the project begins. In addition, all class research projects which involve protected groups as defined in 45 Code of Federal Regulations Part 46 (i.e., special populations, such as, but not limited to, fetuses, pregnant women, in vitro fertilization of human ova, children, prisoners, and persons institutionalized as mentally disabled) must be reviewed and approved by the IRB-PHSC **before** the research can begin.

SECTION 6. RESPONSIBILITIES OF SWOSU-SAYRE/WEATHERFORD RESEARCH INVESTIGATORS

When research involving human subjects is to be performed by any SWOSU-Sayre/Weatherford investigator, or with the aid of any University equipment or other resource over which he/she has responsibility or control, that investigator is responsible for meeting the following requirements:

1. The investigator shall not involve human subjects in the proposed research until the IRB-PHSC has informed him/her of full approval for the use of human subjects in the research.

2. The investigator shall abide by the decisions of the IRB-PHSC requiring changes (for approval) or disapproving the research. When the proposed research is to be funded by a federal agency, and that agency's regulations permit, an investigator may appeal an IRB-PHSC decision to the appropriate official (e.g., the Secretary of the DHHS) or section of that agency. However, for research activities not submitted to federal agencies for sponsorship, the decision of the IRB-PHSC shall be final.

3. The investigator shall obtain informed consent from all subjects in accordance with the requirements of this policy and of the IRB-PHSC.

4. The investigator shall ensure that subject consent is documented in the manner prescribed by the IRB-PHSC.

5. The investigator shall maintain consent documents signed by subjects in a repository approved by the IRB-PHSC.

6. The investigator shall maintain the confidentiality of data obtained from subjects in the manner required by the IRB-PHSC.

7. The investigator shall report the progress of the research to the IRB-PHSC at the intervals and in the manner prescribed by the IRB-PHSC but in no case less than once per year. All research protocols extending beyond three years must be resubmitted to the IRB-PHSC every three years for continued approval using IRB FORM # HS-1 (Human Subjects Application).

8. The investigator shall promptly report any injuries to human subjects resulting from the research to the IRB-PHSC. The investigator shall also promptly report any unanticipated problems, which involve risks to the subjects or others. Initial reports may be verbal; additional reports shall be in the manner required by the IRB-PHSC.

9. The investigator shall promptly report to the IRB-PHSC any proposed changes in the research which would result in a significantly different involvement of human subjects and shall obtain the approval of the IRB-PHSC prior to the changes being made, except where necessary to eliminate apparent immediate hazards to subjects.

10. The investigator shall promptly report to the IRB-PHSC any proposed involvement of human subjects in research which previously had no plans, or only indefinite plans, for subject involvement and shall obtain the approval of the IRB-PHSC prior to the involvement of any subjects.

11. The investigator shall promptly report to the IRB-PHSC any serious or continuing non-compliance with the requirements of this policy or of the IRB-PHSC on any research with which he/she is associated.

12. The investigator shall notify the IRB-PHSC, and cooperate with the IRB-PHSC in notifying the Food and Drug Administration, when he/she anticipates that an investigational new drug or device exemption will be required.

13. The investigator shall notify the IRB-PHSC of the proposed research by submitting a completed "Application to Protection of Human Subjects Committee" form, any existing proposal or project description, and/or any other material required for review in a timely fashion. This submission must include samples of proposed informed consent forms. All materials must be submitted to the IRB-PHSC.

14. The IRB-PHSC chair shall determine, based on the application provided whether the use of human subjects would be considered exempt from review or require expedited or full board review.

15. The investigator shall provide the IRB-PHSC chair with any additional information requested in a timely fashion.

16. An application returned by the IRB-PHSC chair to an investigator for modifications prior to approval must be resubmitted with modifications within six months or the application will be automatically withdrawn from further consideration.

SECTION 7. RESPONSIBILITIES OF THE OFFICE OF SPONSORED PROGRAMS (OSP)

The Office of Sponsored Programs (OSP) is responsible for coordinating the use of human subjects with other research requirements, providing services for the IRB-PHSC, and maintaining IRB-PHSC records. To meet these requirements, the OSP will provide an administrative officer, a secretary, and clerical services for the IRB-PHSC.

These responsibilities are defined as follows:

1. The OSP will review all sponsored research (whether exempt or not) and obtain institutional approval to permit the research. If approved by the IRB-PHSC, but not permitted by the OSP, the OSP will promptly convey notice to the investigator and the IRB-PHSC chair. Neither the OSP nor any other office of the University may approve a research activity that has been disapproved by the IRB-PHSC.

2. If the research has been proposed to an organization outside the University for funding, the OSP will forward certification of IRB-PHSC approval of proposed research to the appropriate organization only after all IRB-PHSC required modifications have been incorporated to the satisfaction of the IRB-PHSC.

3. The IRB-PHSC and OSP will designate procedures for the retention of signed consent documents for at least three years past completion of the research activity.

4. The OSP will maintain and arrange access for inspection of IRB-PHSC records as provided for in 45 CFR 46 Section 115 of the regulations.

5. The OSP is responsible for ensuring constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

6. The OSP will ensure:

   a. solicitation, receipt, and management of all assurances of compliance (whatever the appropriate format), and certifications of IRB-PHSC review (where appropriate) for all affiliates to this institution; and

   b. subsequent submission of these documents to the proper authorities as a condition for involvement in human subject research activities sponsored by DHHS or any other federal department or agency for which this Assurance applies.

7. When the OSP accepts responsibility for review of research which is subject to this Assurance and conducted by any independent investigator who is not otherwise subject to the provisions of this Assurance, the OSP will obtain and retain a Non-institutional Investigator Agreement (NIA) to document the investigator's commitment to abide: (a) by the same requirement for the protection of human subjects as does the University and (b) the determinations of the IRB-PHSC.

8. The OSP will be responsible for procedural and record-keeping audits not less than once every year for the purpose of detecting, correcting and reporting (as required) administrative and/or material breaches in uniformly protecting the rights and welfare of human subjects as required at least by the regulations and as may otherwise be additionally required by this institution.

9. The OSP will ensure compliance with the requirements set forth in this Assurance and 45 CFR 46 Section 114 regarding cooperative research projects. In particular, where the IRB-PHSC of another institution with a DHHS Multiple Project Assurance (MPA) is relied upon, the OSP will ensure documentation of this reliance will be in writing, approved and signed by the OSP, approved and signed by the correlative officials of each of the other cooperating institutions, and retained by the OSP for at least three years past completion of the related research project. Where an agreement between MPA IRB-PHSCs is planned, the OSP will forward a copy of the required signed understanding to OPRR for inclusion this Assurance as an addendum.

SECTION 8. INSTITUTIONAL REVIEW BOARD-PROTECTION OF HUMAN SUBJECTS COMMITTEE (IRB-PHSC)-SWOSU-SAYRE/WEATHERFORD CAMPUS

8.1 IRB-PHSC Membership

The IRB-PHSC shall have a minimum of eight members with varying backgrounds to ensure complete and adequate review of research activities commonly conducted on the SWOSU campuses. The Protection of Human Subjects Committee (PHSC) will serve as the IRB-PHSC for the Sayre and Weatherford campuses of SWOSU. The IRB-PHSC shall be sufficiently qualified through the experience and expertise of its members and the diversity of the members' backgrounds, including consideration of the racial and cultural background of members and sensitivity to such issues as community attitudes. In addition to possessing the professional competence necessary to review specific research activities, the IRB-PHSC shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

In addition to the above requirements, the IRB-PHSC:

1. Shall not consist entirely of men or entirely of women
2. Shall not consist entirely of members of one profession
3. Shall include at least one member whose primary concerns are in nonscientific areas,
4. Shall include at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University

When necessary or desired, the Chair of the IRB-PHSC may appoint one or more ad hoc members with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB-PHSC. These individuals shall not have the right to vote with the IRB-PHSC.

The IRB-PHSC shall have such ex-officio, non-voting members as needed to provide administrative support in carrying out its duties.

8.2 Members Appointments and Terms

IRB-PHSC members shall be appointed for three-year terms by the SWOSU Provost/Vice President for Academic and Student Affairs. These terms shall be staggered so that not more than one-third of the IRB-PHSC membership shall be appointed in the same year, excepting abnormal circumstances created by death, resignation, discharge, or other incapacitation of members. Member service may be limited to one three-year term; however, to retain needed expertise or IRB-PHSC composition, members may be appointed to multiple, consecutive terms.

The Chair of the IRB-PHSC shall be appointed annually by the SWOSU Provost/Vice President for Academic and Student Affairs.

Any member of the IRB-PHSC may be removed by the SWOSU Provost/Vice President for Academic and Student Affairs for cause, including insufficient attendance, lack of proper preparation for meetings, disruptive or other improper conduct at meetings, or other improper conduct within or outside the University.

Ex-officio, non-voting members shall serve at the pleasure of the SWOSU Provost/Vice President for Academic and Student Affairs.

SECTION 9. IRB-PHSC AUTHORITY AND RESPONSIBILITIES

To fulfill the requirements of DHHS regulations and this policy, the IRB-PHSC shall have the following authority and responsibilities:

1. The IRB-PHSC shall have the responsibility to review and the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research on the criteria given in Section 12 of this policy statement, using the procedures given in Section 10. For approved research, the IRB-PHSC shall determine which activities require continuing review more frequently

than every twelve months or need verification that no changes have occurred if there was a previous IRB-PHSC review and approval.

2. (Except when the proposed research has been determined to be exempt from review (see Section 4) or when an expedited review is used (see Section 11), the IRB-PHSC shall review proposed research at convened meetings at which a majority of the members of the IRB-PHSC are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

3. The IRB-PHSC shall not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB-PHSC.

4. The IRB-PHSC is responsible for reporting to the Provost/Vice President for Academic and Student Affairs any serious or continuing non-compliance by investigators. The Provost/Vice President for Academic and Student Affairs is responsible for providing appropriate information to Office of Human Research Protection within the U.S. Department of Health and Human Services.

5. The IRB-PHSC shall have the authority to observe or have a third party observe the consent process and the research.

6. The IRB-PHSC shall conduct continuing reviews of research at intervals appropriate to the degree of risk but not less than once per year. The IRB-PHSC shall have the authority to determine which research requires IRB-PHSC reviews more often than annually.

7. The IRB-PHSC shall determine which research projects need verification from sources other than the research investigators that no material changes have occurred since the previous IRB-PHSC review and shall have the authority to obtain that verification.

8. The IRB-PHSC shall have the authority to recommend to the Provost/Vice President for Academic and Student Affairs, suspension or termination of approved research that is not being conducted in accordance with this policy. Any recommendation for suspension or termination of approval shall include a statement of reason(s) for the IRB-PHSC action. The Provost/Vice President for Academic and Student Affairs shall notify the investigator of pending action or when warranted of action and shall when appropriate notify the appropriate external agency to include the OPRR.

9. The IRB-PHSC will receive from investigators all research protocols, which involve human subjects, keep investigators informed of decisions and administrative processing, and return all disapproved protocols to them.

10. The IRB-PHSC is responsible for reviewing the preliminary determinations of exemption by investigators and for making the final determination based on 45 CFR 46 Section 101. Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigators.

11. The IRB-PHSC will make the preliminary determination of eligibility for expedited review procedures based on 45 CFR 46 Section 110. Expedited review of research activities will not be permitted where full board review is required.

12. The IRB-PHSC will receive from investigators applications with modifications stipulated prior to approval by the IRB-PHSC within six months or the application will be automatically withdrawn from further consideration.

13. The IRB-PHSC will arrange for and document in its records that each individual who conducts or reviews human subject research has first been provided with a copy of this Assurance, as well as with ready access to copies of 45 CFR 46, regulations of other

federal departments or agencies as may apply, the Belmont Report, and all other pertinent federal policies and guidelines related to the involvement of human subjects in research.

14. The IRB-PHSC will report promptly to the OSP, appropriate institutional officials, the Office for Protection from Research Risks (OPRR), and any sponsoring organization:

a. any injuries to human subjects or other unanticipated problems involving risks to subjects or others,

b. any serious or continuing noncompliance with the regulations or requirements of the IRB-PHSC, and

c. any suspension or termination of IRB-PHSC approval for research.

SECTION 10. IRB-PHSC PROCEDURES FOR REVIEW OF RESEARCH

Except for proposed research that has been determined to be exempt from review by IRB-PHSC (see Section 4) and for expedited reviews (see Section 12), the IRB-PHSC shall use the following procedures for: (a) conducting its initial and continuing review of research and reporting its findings and actions to the investigator and the Provost/Vice President for Academic and Student Affairs; (b) determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB-PHSC review; (c) ensuring prompt reporting to the IRB-PHSC of proposed changes in a research activity and ensuring that changes in approved research, during the period for which IRB-PHSC approval has already been given, may not be initiated without IRB-PHSC review and approval except where necessary to eliminate apparent immediate hazards to the subject; and (d) ensuring prompt reporting to the IRB-PHSC and to the OPRR of unanticipated problems involving risks to subjects and others.

1. The IRB-PHSC Chair shall review research summaries received by the IRB-PHSC and determine whether the project shall be given an expedited review or a full IRB-PHSC review. The Chair shall instruct the IRB-PHSC to process each summary according to these decisions.

2. Prior to each IRB-PHSC meeting, the IRB-PHSC Chair shall prepare and distribute an agenda for that meeting which shall include copies of research summaries and accompanying information to be reviewed.

3. When it is determined in advance that consultants or experts will be required to advise the IRB-PHSC in its review of proposed research, those individuals will be given copies of the appropriate materials prior to the meeting and asked to provide written or verbal responses to the Chair or the full IRB-PHSC as the Chair elects.

4. The IRB-PHSC shall normally meet on a monthly basis; however, meetings may be held more or less frequently, as circumstances require. The IRB-PHSC shall not conduct any reviews or make any determinations on projects or policies unless (a) a quorum of members, which consists of a simple majority of voting members, is present and (b) at least one member is present whose concerns are primarily in non-scientific areas. If a convened meeting of the IRB-PHSC meets these requirements, then the IRB-PHSC shall take the following actions on proposed research before it:

a. The IRB-PHSC shall review each proposed research project in accordance with the criteria for approval given in Section 12 and make a decision to approve, require modifications in prior to approval, defer for additional information, or disapprove the use of human subjects in the research. A project may be approved or disapproved only by a majority vote of the voting members present.

b. As a part of the approval for each project, the IRB-PHSC shall require that information given to subjects be in accordance with the informed consent requirements of Section 13. The IRB-PHSC may require that information, in addition to that specifically mentioned in Section 13, be given to subjects when in the IRB-PHSC judgment the information would meaningfully add to the protection of the rights and welfare of subjects. The IRB-PHSC may require documentation of informed consent in accordance with Section 13 or may waive documentation in accordance with Section 13.

c. For approved projects, the IRB-PHSC shall determine whether that approval shall be for one year or for a lesser period before a continuing review is performed. This information shall be given to the investigator with the notification of approval.

d. For approved projects where the IRB-PHSC determines verification that no material changes have been or will be made should be obtained from sources other than the research investigator, the IRB-PHSC shall determine which sources shall be used and at what frequency the ORA shall check those sources.

5. The IRB-PHSC shall notify each investigator in writing of its decision to approve or disapprove his/her proposed research activity, or if any modification required to secure IRB-PHSC approval of the activity. If the IRB-PHSC disapproves a research activity, the notification shall include a statement of reasons for its decision and the investigator shall be given an opportunity to respond in writing or in person. The IRB-PHSC may, at its discretion, re-review and reconsider its decision to disapprove a research activity at any time.

6. *An application returned by the IRB-PHSC to an investigator for modifications prior to approval must be resubmitted with modifications within six months or the application will be automatically withdrawn from further consideration.*

7. Each notification of approval to an investigator shall include a reminder that the investigator is responsible for promptly reporting to the IRB-PHSC any proposed changes in the research activity and for ensuring that those changes are reviewed and approved by the IRB-PHSC prior to being made. The investigator will also be reminded that he/she is responsible for promptly reporting any injuries or unanticipated risks to subjects and others resulting from the research. The notification shall state whether the IRB-PHSC approval of the research is for one year or for some lesser period from the date of notification.

SECTION 11. EXPEDITED REVIEW CATEGORIES AND PROCEDURES

Expedited review procedures may be used for certain categories of research under DHHS regulations and this policy. Note that when support is requested from a non-DHHS sponsor and that sponsor has more restrictive or elaborate requirements for the protection of human subjects, the researcher is responsible for being in compliance with the non-DHHS sponsor's guidelines.

11.1 Expedited Review Research Categories

The research categories permitting expedited review are:

1. Collection of: hair and nail clippings, in a nondisfiguring 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 of 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 than 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 subjects.

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

11.2 Expedited Review Procedures

The IRB-PHSC may, at the discretion of the Chair, review some or all of the research in the above categories through the following expedited review procedures. The IRB-PHSC may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized.

The expedited review procedures for SWOSU are:

1. SWOSU investigators shall submit the required materials for review to the IRB-PHSC Chair in a timely fashion.

2. The IRB-PHSC Chair shall review each proposal and determine whether the research can appropriately be reviewed under the expedited review procedures. If so, the IRB-PHSC Chair shall then, at his/her discretion, assign the research to two experienced IRB-PHSC members for expedited review or take it before the full IRB-PHSC.

3. If assigned to two IRB-PHSC members, those members shall review the research in accordance with the requirements of this policy, obtain additional information from the investigators if necessary, obtain other expert opinions if necessary, then report their findings to the IRB-PHSC Chair. If favorable, the Chair shall notify the investigators that the research has been approved for the use of human subjects. If unfavorable, the research shall be reviewed by the full IRB-PHSC for final disposition. IRB-PHSC members conducting expedited reviews may not disapprove the use of human subjects in proposed research; only the full IRB-PHSC may disapprove proposed research involving the use of human subjects.

4. Each IRB-PHSC member conducting expedited reviews shall report on his/her actions to the full IRB-PHSC at the next regularly scheduled meeting. This report shall include the names and departmental affiliations of the investigators and any substantive issues concerning human subjects that the research presented.

SECTION 12. CRITERIA FOR IRB-PHSC APPROVAL OF RESEARCH

Prior to approving research covered by this policy, the IRB-PHSC 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-PHSC 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-PHSC 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-PHSC 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 by, Section 13 of this policy.

5. Informed consent will be appropriately documented in accordance with, and to the extent required by, Section 13 of this policy.

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

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

7. 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.

SECTION 13. INFORMED CONSENT

Except as provided for in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimizes the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence.

13.1 Basic Elements of Informed Consent

Except as provided in Section 13.3, the following information shall be provided to each subject when seeking informed consent.

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

2. A description of any reasonably foreseeable risks or discomforts to the subject.

3. A description of any benefits to the subject or to others that may reasonably be expected from this research.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

7. A statement of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty, or loss of benefits to which the subject is otherwise entitled.

13.2 Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently foreseeable.

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequence of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

6. The approximate number of subjects involved in the study.

13.3 Alterations and Waivers of Informed Consent Procedures

13.3.1 Waivers for Demonstration/Evaluation Projects

The IRB-PHSC may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided that the IRB-PHSC finds and documents **both that:**

1. The research is to be conducted for the purpose of demonstrating or evaluating: (a) Federal, state, or local benefit or service programs which are not themselves research programs; (b) procedures for obtaining benefits or services under these programs; or (c) possible changes in or alternatives to these programs or procedures.

2. The research could not practicably be carried out without the waiver or alteration.

13.3.2 Waivers for Minimal Risk Projects

The IRB-PHSC may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or may waive the requirements to obtain informed consent, provided that the IRB-PHSC finds and documents **all of the following:**

1. The research involves no more than minimal risk to the subjects.

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

3. The research could not practicably be carried out without the waiver or alteration.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

5. When the IRB-PHSC determines that the knowledge sought is important enough to justify whatever invasion of privacy may be required either to obtain information about unconsenting (or unaware) subjects to involve them in research under false pretense.

In addition, the IRB-PHSC may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB-PHSC finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of State or local government officials and is designed to study, evaluate, or otherwise examine:

   a. Programs under the Social Security Act, or other public benefit or service programs;

   b. Procedures for obtaining benefits or services under those programs;

   c. Possible changes in or alternatives to those programs or procedures; or

   d. Possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

13.4 Preemption of Laws

The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

13.5 Emergency Medical Care

Nothing in this policy is intended to limit the authority of health care professionals to provide emergency medical care, to the extent health care professionals are permitted to do so under applicable Federal, State, or local law.

SECTION 14. DOCUMENTATION OF INFORMED CONSENT

Informed consent shall be documented by the use of a written consent form approved by the IRB-PHSC and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The consent document shall embody the elements of informed consent required in Section 13. This form may be read to the subject or the subject's legally authorized representative, but in any

event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

14.1 Waivers of Consent Forms

The IRB-PHSC may waive the requirements for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

3. When completion of the research survey is acknowledgement of consent. In such cases the first page of the survey should include the following statement in **boldface: "Completion of this survey is acknowledgement of my consent to participate."**

In cases where the documentation requirement is waived, the IRB-PHSC may require the investigator to provide subjects with a written statement regarding the research or may require the investigator to obtain a written document signed by the subject that evidences the subject's agreement to participate in the research activity.

SECTION 15. POLICY ON CASE REPORTS [1]

15.1 SCOPE OF POLICY

This section clarifies whether case reports require IRB review and approval at Southwestern Oklahoma State University.

15.2 DEFINITION

A case report is a description of (a) the course of medical treatment with one or more patients that has a unique outcome or (b) the handling of a unique clinical case; which in either case did not involve the investigator having any research intent at the time of the intervention [i.e., no prospective plan to systematically evaluate the outcome for purposes other than treating the particular patients(s)].

15.3 CASE REPORT ON SINGLE PATIENT

15.3.1 IRB REQUIREMENTS

A case report describing the treatment of a single patient does not meet the federal definition of human subjects research on the basis that the information in the case report is not generalizable knowledge. Therefore, investigators at the University are not required to obtain IRB approval for case reports of a single patient.

Investigators who are asked by a journal or other entity to provide documentation from the IRB that such a case report was either approved by the IRB or did not require review by the IRB may present this Policy as evidence that the case report does not require IRB approval. Some journals may require that the institution provide written attestation that the informed consent of the subject

has been obtained prior to publication of the case report. Such written documentation can and should be provided by the Department or facility with which the investigator is associated.

15.3.2 HIPAA REQUIREMENTS

In most cases, HIPAA requires any publicly presented information on the health of individuals to be de-identified, i.e., the presentation or article must not contain any of the 18 identifiers of an individual that are described in the Privacy Rule (name; addresses, all elements of date; telephone and facsimile numbers; email addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers; device identifiers; web URLs; IP addresses; biometric identifiers; full face photographic images and any comparable images; any other unique identifying number, characteristic, or code). The facility where the person is being treated should assist the reporting individual with HIPAA compliance.

15.4 CASE REPORT INVOLVING MORE THAN ONE PATIENT

IRB REQUIREMENTS

A case report involving more than one living individual **may** meet the definition of human research and may require IRB review. A brief summary describing the case, the type of information that will be included, and the safeguards for protecting confidentiality should be submitted to the IRB prior to abstracting patient data. This can be completed on the PHSC Preliminary Application form.

The IRB will make a determination whether the activity is human subjects research requiring further IRB review, and will so notify the investigator.

NOTES:

[1]Section 15 was adapted, in part, from the Case Reports Policy of the IRB at Columbia University.

February 2, 2004, revisions to the *Southwestern Oklahoma State University Policy and Procedures for the Protection of Human Subjects (PHS) in Research Activities* have been approved by the SWOSU Protection of Human Subjects Committee and the President of SWOSU.

February 22, 2007, revisions to the *Southwestern Oklahoma State University Policy and Procedures for the Protection of Human Subjects (PHS) in Research Activities* have been approved by the SWOSU Protection of Human Subjects Committee and the Provost of SWOSU.

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Approved:

Randy L. Beutler — Date
President