

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

**RESEARCH INVOLVING HUMAN PARTICIPANTS:  
POLICY AND PROCEDURES**

**A GUIDE FOR THE INSTITUTIONAL REVIEW BOARD MEMBERS, RESEARCHERS, AND  
ADMINISTRATORS**

**INSTITUTIONAL REVIEW BOARD MEETING TIMES:**

The IRB meets the third Wednesday of each month at noon, unless holidays interfere. Any information that needs to be reviewed/seen by the IRB must be submitted to the IRB Administrator, Office of Research, no later than the Wednesday, two weeks prior to the meeting (dates are posted on the Campus Calendar). If you are submitting a new protocol that is being reviewed by the IRB, you will need to be present to present your protocol to the Board. Please schedule this time with the IRB Administrator.

The Scientific Review Committee (SRC) meets the first Tuesday of each month, unless holidays interfere. The IRB may direct that any new protocols be submitted to this committee for review prior to being submitted to the IRB. Any information that needs to be reviewed/seen by the SRC must be submitted to the IRB Administrator, Office of Research, no later than two weeks prior to the meeting.

**LAST REVISED JANUARY 11, 2008**

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# PART I INTRODUCTION TO PROPOSAL REVIEW

## SECTION 1. INTRODUCTION: ROLES AND RESPONSIBILITIES

The review is a process designed to assist researchers and Oklahoma State University Center for Health Sciences (OSU-CHS) in complying with international, federal, and state requirements in protecting human participants involved in research.

Prior to initiation of any research project that involves the use of human participants, all individuals involved in the project must document training in the use of human participants. This policy applies to all individuals involved in any research project involving the use of human participants conducted at or sponsored by Oklahoma State University, Center for Health Sciences (OSU-CHS) or in which OSU-CHS personnel are involved at other organizations.

**The approved option for training in the use of Human Participants for all individuals involved in the project is: the Collaborative Institutional Training Initiative (CITI).**

If you are submitting new research, you will need to complete the *Biomedical Research Investigators* modules BEFORE you may begin an approved study, scoring an overall 90% or better on the modules. If you currently have an open research investigation with our IRB, you and your staff will need to have these modules completed BEFORE your next Continuing Review.

Here is the process:

- Go to [www.citiprogram.org](http://www.citiprogram.org) to register for CITI online training.
- Once there, simply click on "New Users Register Here".
- Next click on "The Protection of Human Research Subjects"
- Under "Select your institution or organization" page select "Oklahoma State University Center for Health Sciences" in the "Participating Institutions" drop down box.
- Next proceed to create your own username and password and select the CITI Recommended Learner group; Biomedical Research Investigators
- Begin the program

This includes research activity conducted by faculty, staff, and students, or performed in OSU-CHS facilities or supported in other ways by college resources or facilities, which are under the control and responsibility of OSU-CHS officials. For full time faculty, any research project is considered part of their academic efforts and normal IRB processes must be followed.

OSU-CHS accepts no involvement or liability for private research. Part time faculty and those with adjunct appointments who conduct research in private clinics or at sites not connected with OSU-CHS, and do not involve OSU-CHS students or employees in the studies, fully assume responsibility and liability for these projects, and may not in any way associate the name of the college with the project.

There are three main entities involved in this process: the investigator, the Institutional Review Board (IRB) and the Office of Research and Sponsored Programs (ORSP).

### The Investigator

- Requests IRB and its Scientific Review Committee (SRC) review of any proposed research involving human participants. The investigator must supply needed information for review.

- Does not involve human participants in the proposed research until the IRB has informed him/her of full approval for the use of human participants in the research.
- Abides by the decisions of the IRB. This may require some modifications of the proposal.
- Provides periodic progress reports to the IRB at least once per year, and incident reports of adverse effects as detailed in this guide.

### **The Institutional Review Board and its Scientific Review Committee**

- Protects the participants so that their care or well being does not suffer as a result of participation in research; and determines that the project has scientific merit, thus justifying participation by participants.
- Acts as a resource both as a committee and as individual members, to help investigators initiate proposal development and seek IRB approval, thus facilitating research.
- Protects the college and investigators by reducing the risk of liability by insuring that experimental procedures are consistent with good medical practice; that standards of review and documentation are complete, on record, and are consistent with appropriate regulations.

#### The Research Office

- Provides assistance to individuals conducting research
- Coordinates the use of human participants with other research requirements.
- Provides administrative services for the IRB.
- Maintains IRB records.
- Submits IRB reports, assurances, and other documentation as required to the appropriate organization or entity.

This set of documents contains the OSU-CHS Institutional Review Board standard operating procedures (SOPs) , which describe how the research community must handle research involving human participants. These SOPs are designed to conform to 45 Code of Federal Regulations Part 46 , as revised June 18, 1991; as implemented by the United States Department of Health and Human Services (FEDERAL) “Final Regulations Amending Basic HHS Policy for the Protection of Human Participants,” January 26, 1981 and revised June 18,1995 as well as other federal and state regulations and laws, and Oklahoma State University, Center for Health Sciences policies. Any situation not covered within this OSU-CHS document should be evaluated in the context of additional guidance in 45 CFR 46, and other parent documents.

Part I focuses on information, which should be helpful to the investigator. Part II focuses on administrative areas. The Appendix contains a collection of helpful resources including a model Informed Consent document.

## **SECTION 2. RESEARCH REQUIRING AN IRB APPLICATION**

An application for review of research involving human participants (Appendix B) must be completed for all research involving human participants, which is associated with OSU-CHS.

For the purposes of this document, **research** is defined as any systematic investigation designed to develop or contribute to general knowledge. Activities, which meet this definition but may be called something else like development, demonstration, or instructional are still considered research. It does not matter whether the activity takes place within and as a part of some other activity, such as a demonstration or service program, or whether the research is the whole of a project. This includes:

- Intramural research, research that is unsupported or supported solely by OSU-CHS.
- Extramural or sponsored research, research that is supported in whole or part by any other institution or organization other than OSU-CHS
- Cooperative research, in which OSU-CHS investigators participate in projects administered by other organizations.
- Thesis and dissertation.

**Non-research** is defined as data gathering for which there is no foreseeable dissemination of the data. This includes such areas as data gathering for classroom training in research methods or for administrative purposes. Any record of the data (or interpretations and analyses of the data) remains private, i.e., used only for purposes that are appropriate to the class, institution, or agency in the normal conduct of its work. Also, some types of research are formally “exempt”, or qualify for an “expedited review”, in lieu of full IRB evaluation.

For the purposes of this document, **human participant** is defined as a living individual about whom an investigator conducting research obtains:

- data through intervention or interaction with the individual, or
- identifiable private information.

In any circumstance where this document refers to human participants, it also means the same as human subjects, human research volunteers, or similar expressions.

**Intervention** includes both:

- physical procedures by which data are gathered, and
- manipulations of the participant or the participant’s environment that are performed for research purposes.

**Interaction** includes:

- communication or interpersonal contact between investigator and participant.

**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 (e.g., medical records). In order to constitute research involving human participants, private information must be individually identifiable (i.e., the identity of the participant is or may be readily ascertained by the investigator or associated with the information).

Once an IRB application is completed, it should be submitted to the IRB Administrator in the Research Office. The IRB Administrator will conduct a brief administrative review for completeness, assist the applicant as necessary, and schedule the proposal for the appropriate committee (either SRC or IRB) and level of review. If there is any question about whether or not the activity is “research using human participants”, guidance can be obtained from the IRB Administrator or the chairperson of the IRB.

IRB approval means that an appropriately constituted Institutional Review Board has reviewed the proposed research and determined that it may be conducted within the constraints set forth by the IRB and by other Federal and institutional requirements.

### **SECTION 3. CATEGORIES OF REVIEW OF HUMAN PARTICIPANT RESEARCH**

For purposes of review, research involving human participants is grouped into one of several categories. The categories and their criteria, which define them, are presented below. An investigator may ask the OSU-CHS IRB for a review or for suggestions at any time, regardless of the category, and pre-application discussions are encouraged. For a list of definitions of terms, consult 45 CFR 46 (46.102).

#### **Full Board Review**

A full board review is when a research study is reviewed at a convened IRB meeting by the board members present. The purpose is to protect participants in research studies when the participant is exposed to greater than minimum risk. In any situation in which the proposed research cannot clearly be assigned to categories of “nonresearch” and thus not reviewed, or the research does not meet exempt or expedited criteria, a full board review is required. Additionally, the IRB chairperson can schedule a proposal for a

more detailed review if in his/her mind there are unresolved issues or reasons why the resources of a more extensive review may be needed, e.g., from expedited to full review.

### **Expedited Review (see the summary in Appendix A)**

Research that Health and Human Services (46.110 of 45 CFR Part 46, and page 17; 46 FR 8392; January 26, 1981) has indicated 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.
- those that present minimal risks to participants.

**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 are those risks encountered in the daily lives of the participants 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.

An expedited review is conducted by the IRB chairperson or one or more experienced reviewers from the IRB designated by the chairperson. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that they may not disapprove the research, an action which requires full IRB non-expedited review. The research protocols permitting expedited review are the following.

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

Collection 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.

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 veinipuncture, 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 procedure is 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.

### **Exempt Status (see the summary in Appendix A)**

Research that the regulations (45 CFR 46 46.101) specifically exempt from review does not require full review by the IRB. However, the investigator must apply to the IRB for assignment of that status to the project. Two IRB members OR one IRB member and the IRB administrator will review applications seeking exempt status, and may approve exempt status or schedule the application for full board review. Exempting an activity from review does not absolve the investigator(s) from ensuring that the welfare of participants is protected and that methods used to gain participant consent and information provided are consistent with statutory and ethical standards for research. Research involving special groups, e.g., children, mentally impaired, fetuses, pregnant women, human *in vitro* fertilization, and prisoners cannot be exempt. Criteria for exempt research are as follows:

#### EDUCATIONAL PRACTICES RESEARCH

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

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

#### RESEARCH UTILIZING EDUCATIONAL TESTS, SURVEY PROCEDURES, INTERVIEW PROCEDURES OR OBSERVATION OF PUBLIC BEHAVIOR

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.

#### COLLECTION OR STUDY OF EXISTING DATA

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

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

Taste and food quality evaluation and consumer acceptance studies are exempt if:

- wholesome foods without additives are consumed; and/or
- 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.

### **SECTION 4. REVIEW PROCESS**

The individual initiating research involving human participants is referred to as the Principle Investigator (PI). The PI responsible for ensuring appropriate committee review before undertaking any research activities. The process will vary with the category of research (full board, expedited, exempt). The chairperson will respond in writing to the investigator with the findings of the IRB. The process is summarized as follows:

#### **Application for Review**

The investigator(s) is (are) responsible for preparation of an Application for IRB review (see Appendix B). This application should be prepared for all categories of research. The application, with the supporting documents, should be submitted to the IRB administrator. While only the full IRB may disapprove a proposal, 45 CFR 46 allows the chairperson in certain defined situations the option to act for the IRB and approve the proposal. The chairperson always has the option of scheduling a proposal for full IRB review.

Upon receipt of the complete application, the IRB Administrator will route the study. See Appendix J. Most applications will be routed through the Scientific Review Committee (SRC), before going to the IRB. The SRC is a subcommittee of the IRB which reviews the study for scientific validity.

When an investigator is submitting a new study **-if-** the investigator presents a copy of a scientific review on the study **-and-** study registration with ClinicalTrials.gov **-then-** the study may be put on the IRB agenda for review, bypassing Oklahoma State University Center for Health Sciences' (OSU-CHS) Scientific Review Committee (SRC)

#### **Full Board Review**

Applications requiring full board review are first sent to the IRB administrator for review of the application's completeness and to determine the need for additional information. After receipt of any requested information or changes. The IRB Administrator then submits the application to either the SRC, followed by the IRB, or directly to the IRB.

#### **Expedited Review**

Applications for research meeting the criteria for an expedited review will be reviewed by two IRB members of the IRB for an expedited review. Only projects of one-year duration or less may be submitted for expedited review. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized.

IRB member(s) shall review the research in accordance with the requirements of this policy, obtain additional information from the investigators if necessary, and obtain other expert opinions when helpful. If approved, the chairperson shall notify the investigators that the research has been approved for the use of human participants. If unfavorable, the investigator may revise the proposal and resubmit it for expedited review, or the current research proposal may be scheduled by the IRB Administrator or at the request of the investigator for full board review. Only a full IRB review may disapprove proposed research involving

the use of human participants. The chairperson has the option of forwarding a proposal submitted for expedited review for full board review.

### **Exempt Review**

Two IRB members OR one IRB member and the IRB administrator will review applications asking for exempt status, and may approve exempt status or schedule the application for full board review. Researchers requesting exempt review should fill out Appendix B and Appendix L and submit both to the IRB administrator.

### **Research in a Foreign Country**

In addition OSU-CHS expects that when research takes place in a foreign country, the investigator must ensure that his/her procedures meet all legal requirements of that country, as well as the requirements of this policy.

### **Research Requiring Additional Review: Cooperative and Multisite**

What is commonly referred to as collaborative or cooperative research (45 CFR 46, 46.112 and 46.114) involves several cooperating institutions connected by personnel working together on a research project. Each institution is responsible for safeguarding the rights and welfare of human participants, and for complying with the policies of 45 CFR 46. If our faculty, students, patients, or facilities are involved in an activity involving human participants at another institution, including a hospital or clinic, a review by each IRB may be necessary. (Consult the section of this document describing non-research and exempt activities.) OSU-CHS will comply with Federal requirements regarding cooperative research projects. When extramural research is conducted at or in cooperation with another entity, all provisions of this policy shall remain in effect for the research. For cooperative (inter-institutional) research to proceed based on a single joint review, each institution must choose to do so, and obtain in writing a reciprocal Written Authorization Agreements that are recognized by the Office for Human Research Protections (OHRP) to accept approval decisions made by the other institution's IRB when research protocols involve both institutions or as deemed appropriate, based on the expertise of a respective institution's IRB. Decisions regarding which IRB should review the research will be based on the Written Authorization Agreements and the Standard Operating Procedures of the respective IRBs and administrative support offices

If the research is originated elsewhere, reviewed and approved by the IRB at that institution, any full time faculty are still required to undergo IRB review at OSU-CHS to assure local compliance.

Documentation showing IRB approval as a result of that review, and that any changes required have been made, need to be included with the application form. Further, if OSU-CHS participants are involved, the consent form must show the OSU-CHS contacts with telephone numbers: either a physician for medical questions or faculty member responsible for managing the project at our site, as appropriate; and IRB Chair for general questions by participants. Consent form language must meet Oklahoma State statute, which often requires rewording of forms developed for use elsewhere. The application asking for review should clearly specify the Principle Investigator or trial chairperson, the OSU-CHS representative and his/her role, the involvement, if any, of other OSU-CHS personnel and their roles, and of our patients/participants. All updated relevant documents in clear readable form must be included. Clarity and thoroughness at this point can prevent delays in approval.

Requests from other institutions for information on the composition of our IRB, approvals of the proposed research to enable our personnel to participate, etc., should be directed to the ORSP.

### **Research Developing the Need for Human Participants.**

In the event the research or application/funding process reaches a point at which the use of human participants is considered, application for review should then be undertaken and no use of human participants begun until IRB approval is provided. (See 45 CFR 46 , 46.118, 46.119)

## **General Steps in Proposal Submission and Review**

For all submissions, the investigator will fill in the form to request review (see Appendix B) and supply information as indicated. Investigators are encouraged to make inquiries for clarification of requirements at any time by contacting the IRB Administrator in the Office of Research. Either the IRB chair or the SRC chair will review the application and respond in writing to the investigator. If modifications are needed, these will be listed in writing. For cooperative research, the investigator must include approval documents from the originating institution.

## **Exempt Status or Expedited Review**

The general requirement is for a full IRB review. However, in some clearly defined circumstances the process can be simplified. A memo indicating one of these categories of assignment will be sent to the investigator by the IRB chairperson stating that the project meets the requirements, or that it does not, and that the chairperson will schedule the proposal for IRB review. A request for exempt status may become an Expedited or Full IRB review, and a request for Expedited Review may become Full IRB review.

## **Results of Review from the SRC**

The SRC evaluates proposals to determine that the project has scientific validity justifying participation by human participants. Thus the investigator must clearly formulate the experimental questions, approaches, mean of data analysis, significance of the project, and risks to participants, so these may be weighed by the SRC.

After reviewing the proposal including attached documents, the SRC will inform the Principle Investigator of any concerns or problems with the proposal's scientific process, content, or design. If the PI chooses to address any of the problems identified by the SRC before the IRB meeting, he or she may do so by submitting amended documents to the IRB administrator. The investigator is free to make the suggested changes or also free to not make any changes and submit the documents as is. The investigator should understand the SRC is a subcommittee of the IRB and can not approve nor disapprove any research submitted, only the IRB may do this. The investigator should understand the SRC as a subcommittee to the IRB is given the responsibility of advising the IRB as to the science of the study and will review the SRC's findings before approving or disapproving a study.

## **Results of Review from the IRB**

After reviewing the proposal including attached documents, the IRB may take the following actions:

- "Tabled" pending acquisition of additional information needed to complete deliberations. The IRB administrator will make arrangements to acquire the information for the IRB.
- "Approved", which is communicated to the investigator in writing by the chairperson. The IRB may include suggestions (changes not required but useful or advisable in the future).
- "Approved pending required revisions", meaning that everything seems fine except for the indicated items which are communicated to the investigator in writing by the chairperson, who is also available to discuss the problems and interpret the IRB stipulations. The revised form of the proposal should be returned to the chairperson via the IRB administrator. Members will evaluate the revisions, render final approval in the mode of an expedited review of those changes, and notify the investigator. If the revisions are major, the proposal could be disapproved.
- "Disapproved", meaning there were serious flaws which are communicated from the IRB to the investigator in writing by the chairperson.

All correspondence passing in and out of the ORSP will have copies placed on file by the IRB administrative assistant.

## SECTION 5. 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:

- Risks to participants are minimized
  - a. by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and
  - b. whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB will 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.
- IRB is required to evaluate proposals and by its approval attests that the project has scientific merit justifying participation by participants. The IRB has appointed a subcommittee, the SRC, that is responsible for the scientific review of studies referred to them and of informing the IRB membership of its findings. Thus the investigator must clearly formulate the experimental questions, approaches, means of data analysis, significance of the project, and risks to participants, so these may be weighed by the IRB.
- Selection of participants is equitable. In making this assessment, the IRB will take into account the purposes of the research and the setting in which the research will be conducted. Investigators should be aware that some funding agencies require inclusion of individuals of various genders, ages, racial groups, etc. unless there is justification for exclusion.
- Informed consent will be sought from each prospective participant, or the participant's legally authorized representative (refer to the section on informed consent, Section 7).
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to assure the safety of participants.
- There always are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- Where some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, 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 participants. Fees and other incentives for participation may be compensatory but not coercive.

The investigator shall abide by the decisions of the IRB requiring changes (for approval) or disapproving the research

**The investigator shall not involve human participants in the proposed research until the IRB has informed him/her in writing of full approval for the use of human participants in the research.**

## **SECTION 6. SUSPENSION OR TERMINATION OF RESEARCH**

IRB may suspend or terminate approval of research that is not being conducted in accordance with the Code of Federal Regulations, the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall be based on full board review and include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Federal Department or Agency head or other funding sponsor.

## **SECTION 7. DOCUMENTATION OF CONSENT TO PARTICIPATE**

### **Informed Consent (see Appendix C)**

**Informed Consent is a process and not a piece of paper.** The agreement of a research participant to participate is informed consent, and is not a release from liability (45 CFR 46, 46.116). Except as provided for in 45 CFR 46, no investigator may involve a human being as a participant in research covered by this policy unless the investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or representative. The information that is given to the participant or the representative cannot ask the participant to waive or appear to waive any of the participant's legal rights, or release or appear to release the investigator, the sponsor, OSU-CHS or its agents from liability for negligence. The requirements for informed consent in this policy are not intended to pre-empt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

### **Assent Forms**

PIs proposing to involve pediatric or other vulnerable persons as participants in the proposed research should consult with the IRB administrator to determine if an ASSENT FORM is necessary.

### **Basic Elements of Informed Consent**

Under Oklahoma law, all documents written for participants in a research study must be readily understandable by the participants in the study [Oklahoma's subjective standard differs from other state's objective standard, i.e. the reasonable person standard]. Thus all consent forms, verbal explanations including all technical terms must be defined in language understandable to participants in the study. This applies both to the written expression and the choice of language used (e.g., English, Spanish, Cherokee). All PIs must assure that the participants understand the information before giving consent. The PI should be aware that not all purposed participants function at the same level of understanding either written or orally given information.

The participant must be given the opportunity to consent to participate in the study without any element of force, fraud, deceit, duress, coercion, or undue influence. If the participant consents, he or she must be given a copy of the informed consent form which they have signed. Except as detailed below under Waivers and Alterations, key elements of information must be provided to each participant when seeking their agreement to participate.

Key elements of informed consent include:

1. A statement that the study involves research
2. An explanation of the purposes of the research
3. The expected duration of the participant's participation
4. A description of the procedures to be followed

5. Identification of any procedures which are experimental.
6. A description of any reasonably foreseeable risks or discomforts to the participant.
7. A description of any benefits to the participant or to others which may reasonably be expected from the research.
8. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
9. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
10. For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.
11. A statement of whom to contact for answers to pertinent questions about the research (principal investigator of the project) and research participants' rights and unresolved questions stemming from their participation (IRB Chairperson), and whom to contact in the event of a research-related injury or medical question, with relevant telephone numbers of contacts.
12. That participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
13. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable.
14. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
15. Any additional costs to the participant that may result from participation in the research and/or a description of any financial compensation that will be paid to the participants.
16. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant, although the participant can terminate involvement at any time.
17. A statement that significant new findings developed during the course of the research will be reported to the participant and may influence the participant's willingness to continue participation.
18. The approximate number of participants involved in the study.
19. The proposal must, and consent form may need to describe clearly inclusion and exclusion criteria, staging criteria, and other similar aspects of the protocol's experimental design.

### **Alterations and Waivers of Informed Consent Procedures**

These are categories that can have alterations and waivers.

#### Public Programs

The IRB 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 finds and documents **both** that:

- the research is to be conducted by or participant to the approval of state or local government officials and is designed to study, evaluate or otherwise examine:

- 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, or
  - d. possible changes in methods of levels of payment for benefits or services under those programs.
- and that the research could not practically be carried out without the waiver or alteration.

#### Waivers for Minimal Risk Projects

The IRB may approve a consent procedure which doesn't 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 finds and documents **all** of the following:

- The research involves no more than minimal risk to the participants, and
- The waiver or alteration will not adversely affect the rights and welfare of the participants, and
- The research could not practicably be carried out without the waiver or alteration, and
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

#### **Limitations**

Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law. The requirements of this policy are not intended to preempt applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

#### **Documentation: Consent Forms**

The consent form is the central item in the review performed by the Institutional Review Board (see Appendix C). In this document the investigator tells prospective participants the purpose of the study, what will happen if the participant participates, what the risks and benefits are, and also what happens if the participant decides to stop or additional information becomes available that might change the participant's mind about continuing to participate. The consent form must communicate effectively with the participant, not with people familiar with the terms used in the scientific protocol. Some of those scientific terms must be explained in the consent form; however, others are superfluous to what is needed by the participant to make a decision about the study and therefore should not be included in the consent form. Additionally, many of the terms that investigators take for granted must be explained, for example, MMPI, ECG/EKG, CAT scan, venipuncture, aspiration, and refractory. Quantities should be expressed in everyday measurements, for example, the amount of blood drawn in teaspoons or tablespoons. The IRB has information on how to determine the reading level of a particular document. To make something easier to read, a good rule of thumb is: shorter words and shorter sentences. In addition, many investigators have found that review of the consent form by a lay person (spouse, secretary, friend) is very helpful. Records must be kept for three years after the conclusion of the research must remain secured.

The consent of the participant must be given voluntarily and without pressure or coercion. Opportunity for questions must be provided with a person or persons capable of answering questions fully. The participant or legal representative must be able to give consent at the time of initiation into the study. Under some circumstances, the participant may be permanently incapable of legal consent (e.g., mental retardation, senile dementia) or only temporarily incapable (e.g., in a study investigating the treatment of septic shock, or increased intracranial pressure after brain surgery). Children (refer to 45 CFR 46, Subpart D) who are 17 years of age or younger must have parental consent in most cases

#### **Informed Consent Documents**

##### Written consent

As stated above, consent is a process. The documents record the process and memorialize the consent. Except in very unusual circumstances, written consent (using a form which embodies the elements of informed consent and which has been approved by the IRB) must be obtained from all participants or his or her legally authorized representative (e.g., guardian). This is read by or to the participant or their legally

authorized representative. The participant must have an adequate period of time to read and ask questions before being asked to sign. A copy of the signed consent form should be given to the patient.

### Oral Consent

The investigator should use written consent as described above. In rare situations, a solely oral consent process may be necessary. Under those circumstances, you must consult the IRB chair or administrator.

Oral consent is dependent upon a witnessed oral presentation which embodies the elements of informed consent using an **EXACT** script of the presentation approved by the IRB, its delivery to the patient or legal representative (guardian), and its documentation. It is expected that some discussion clarifying the script's contents will ensue between the person obtaining consent and the participant or their legal representative. Thus the script will also serve as a summary of the presentation.

A short form written consent document stating that the elements of informed consent have been presented orally to the participant or their legal representative is used and signed by the participant or their legal representative and by the witness.

The witness must both physically witness the signature of the participant/guardian on the short written consent statement, and sign a copy of that script and short form. The copy of the script signed by the witness is also signed by the person actually obtaining consent. Copies of the signed short form and signed script are given to the participant or his/her legal representative. These signed documents are important records that the investigator must place on file.

### Style of Documents

There are many versions of acceptable consent forms, but all must contain certain essential elements. Appendix C contains a model to help the investigator create a form suitable for the proposed study. The IRB expects certain language required by the State of Oklahoma to appear in the form, and if it does not, the applicant will bear the burden of a clear and detailed explanation as to the omission. This language appears in the model, as do areas, which will be specific to the individual project. Various models of project specific language are included as suggestions as well in Appendix C.

An attempt should be made to make the consent personalized to the participant and should be written as if you are talking to the person, "You will be asked to...." It should not change back and forth ("I" and "You").

### **Waivers of Consent Forms**

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds **either**:

1. that the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern, or
2. that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

### **Use of Experimental Material to Develop Commercial Products**

The investigator must anticipate the possibility that tissues or other samples from participants might be developed into commercial products. The consent form must indicate if this might occur. The investigator must negotiate with the University and the participant to obtain an appropriate agreement. Signed contracts are part of the IRB records. This should be done before development occurs.

## Section 8. Continuing Compliance and Periodic Review

### Periodic Review and Reporting

The Principle Investigator (PI) is responsible for ensuring that the research is conducted according to the specifics in the protocol. The PI will submit to the chair of the IRB incident reports of adverse effects, unforeseen deviations in the protocol, or any changes in the protocol. Continuing reviews should be submitted to the IRB Administrator for distribution to the board. The IRB is required to monitor the project at a frequency appropriate with risk to participants in the study, but not less than annually.

Following a visit from a study monitor, the Principle Investigator should forward a copy of the monitor's report, as well as any corrective action taken, to the IRB Administrator. The IRB Administrator will present this information at the next IRB meeting for board member's review.

### Continuing Review

Every study that is approved by the IRB must be reviewed by the IRB annually in order for the study to be in compliance with federal regulations. For example, if a study is approved 5/4/06 then approval would expire 5/4/07 based on CFR46.109(2) which states "...IRB shall conduct continuing review of research ... not less than once per year. A satisfactory progress report must be received and reviewed see Appendix E. In order to facilitate the process, the investigator should anticipate the timing of this requirement and prepare the report, while the ORSP will try to send out reminders and ask for the report prior to the due date, IT IS THE PRINCIPAL INVESTIGATORS RESPONSIBILITY TO ENSURE THE CONTINUING REVIEW IS SUBMITTED ON TIME. If the due date passes and the required information has not been reviewed by the IRB, a notice to stop enrollment into the study will be sent to the investigator with a copy to the investigator's college department chair. To reinstate the research, the investigator must submit the protocol and supporting documents for rereview. **NO PARTICIPANTS MAY BE ENROLLED IF THE STUDY IS INACTIVATED.**

Appendix E contains an example of a blank Continuing Review form. The Continuing Review form may be typed or printed neatly. Each section must be completed accurately:

- **Status of Study** - Check one only.
- **Number of Participants Enrolled** - Each block should be, "NA", "0" or another number, indicating the enrollment **since the last** Continuing Review, and the enrollment total.
- **Study Results** - Summarize results since initial approval or last Continuing Review.
- **Adverse Effects** - List adverse effects with dates; if none, state "none". Do not leave blank.
- **Signature** - Investigator's original signature in ink, date and phone.

If the progress report is incomplete or appears to be inaccurate, the IRB office staff will telephone the investigator and annotate changes. If there is much missing information or no signature, the Continuing Review form will be sent back to the PI for completion.

The Board approves or disapproves the Continuing Review. If approved, the Board sends a letter approving the continuation of the research to the PI. If the Board does not approve the Continuing Review, the research is suspended and the chair of the IRB will send written notification to the PI with a copy to the investigator's college department chair.

### Amendments

It is the responsibility of the investigator to ensure that the study is conducted as approved by the IRB. Modifications to the protocol or consent form, as requested by the investigator or sponsor, must be approved by the IRB chairperson **before** the changes are implemented. Such modifications are known as amendments.

Amendment requests must be made in the form of a written memo from the investigator and addressed to the IRB chairperson. The investigator shall promptly report to the ORSP any proposed changes in the research which would result in a significantly different involvement of human participants and shall obtain the approval of the IRB prior to the changes being made, except where necessary to eliminate apparent immediate hazards to participants. Back-up documentation should be included with the memo, for example a request from the sponsor, a revised protocol, or a new consent form. It is important to note that the consent form may need to be modified when a protocol is changed. The modified consent form must be sent with the amendment request. Alternatively, if an amendment request is a substantial change to the approved study, the IRB chairperson may deny the request and ask that the revised study be submitted as a whole new study, participant to full Board review.

### **Continuing Quality Improvement**

Problems associated with research involving human participants have received a great deal of attention over the past several years. The OSU-CHS Institutional Review Board (IRB) in conjunction with The Office of Research and Sponsored Programs (ORSP) has a Continuing Quality Improvement Program(CQI). The goals of the program are to increase the availability and visibility of ORSP as a resource for investigators and research staff and to ensure compliance with federal and state regulations regarding the protection of human participants in research.

The CQI program consists of site visits from the Institutional Review Board (IRB) administrator and/or members of the IRB. Studies are chosen after they are approved by the IRB at the discretion of the IRB.

Visits may be scheduled at the time the study is ready to begin enrollment for the purpose of reviewing plans for study conduct with the investigator and the research staff.

The follow up visit will be scheduled to coincide with the enrollment of a participant. One of the purposes of this visit is to observe the informed consent discussion and ask permission from the participant to contact them later in the study for an assessment of their research experience. This visit will be scheduled once several participants are enrolled so review of study records and documentation can also be accomplished.

### **Adverse Events**

Prompt reporting of adverse events is a condition of IRB approval and so stated in the initial approval letter. The IRB definition of **Adverse Event (AE)/Serious Adverse Event (SAE)** is:

**Adverse events (AEs):** On a continuum, awareness of signs or symptoms, but easily tolerated; are of minor irritant type; causing no loss of time from normal activities; symptoms would not require medication or a medical evaluation; signs and symptoms are transient; progressing on the continuum to discomfort severe enough to cause interference with usual activities; persistent or requiring treatment.

**Serious Adverse Events (SAEs)** (21 CFR 312.32) are events that result in any of the following outcomes: death; a life threatening experience; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant disability/incapacity; or a congenital anomaly/birth defect. In addition, events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. May or may not be considered related to the study.

## Reporting AEs/SAEs

All local AEs should be reported to the IRB.

All reports at sites that do not report directly to this IRB of serious adverse events (SAEs) or any adverse events (AEs) should be submitted to and received in the Office of Research two weeks prior to the 1<sup>st</sup> Wednesday of each month. Please fill out Appendix I, as well as attaching copies of the actual reports.

In the event of a local SAE or an off site SAE that could affect the safety of local participants in the study, the IRB chairperson should be notified by telephone within 24 hours, with a follow-up written memo to include immediate actions taken as a result of the event by the PI; recommendations for further actions (e.g., suspension of participant accrual, etc.) and any necessary recommendations for further reporting (FDA or NIH officials, OHRP, Provost, etc.).

## SECTION 9. RESEARCH INVOLVING VULNERABLE POPULATIONS

Researchers have an obligation to ensure prospective participants have both legal capacity to consent and an ability to understand the process. The use of special populations in research requires additional actions to be taken, including affecting the composition of the IRB and exclusion from exempt status. In each case the requirements of 45 CFR 46 will be followed.

The Code of Federal Regulations (45CFR 46) set forth the following categories of special populations. The categories are not exclusive. The PI must anticipate conditions for consent that might be unduly coercive, or incomprehensible, or otherwise request consent that can not be given freely.

### Fetuses, Pregnant Women, and Human In Vitro Fertilization

45 CFR 46 Subpart B. 46.201-46.211; source: 40 FR 33528, Aug. 8, 1975; 43 FR 1758, Jan. 11, 1978; 43 FR 51599, Nov. 3, 1978.

### Prisoners

45 CFR 46 Subpart C. 46.301-46.306; source: 43 FR 53655, Nov. 16, 1978

### Children

45 CFR 46 Subpart D. 46.401-46.409; source: 48 FR 9818, March 8, 1983; 56 FR 28032, June 18, 1991.

### Mentally Disabled

## SECTION 10. THE PROPOSAL

The format for the investigator's proposal will vary with the project, but there are elements that the IRB and its SRC will look for, and features of organization, which over the years, people have come to recognize, make them more readable. A few points worth considering are offered to facilitate the writing of the proposal.

1. An investigator inexperienced in proposal writing, should consult several of the short books and other materials on this participant. Some materials are available from NIH (<http://www.nigms.nih.gov/nigms.nih.gov/Templates/CommonPage.aspx?NRMODE=Published&NRNODEGUID=%7b88AC187B-36C0-440D-9732-7B6162DD4344%7d&NRORIGINALURL=%2fResearch%2fApplication%2fMOREGrantWritingTips%2ehtm&NRCACHEHINT=Guest>). The Bibliography in Appendix F reflects holdings in the OSU-CHS library. These range from the design of clinical trials, grant proposal writing, to using statistics and experimental design.

2. The IRB ensures that the proposal has scientific merit (45 CFR 46). This is not an evaluation of relative merit, as a funding agency would conduct, but the investigator must make the reason for the study clear in terms that enable the IRB to see why answering this experimental question is worth the potential problems of involving human participants.
3. The experimental approach and methodology must be clear, including inclusion criteria, exclusion criteria. While every detail need not be discussed, a plausible, prudent approach consistent with good standards of care must be indicated. Indicating the needed sample size and initial statistical analysis is evidence of good planning and sound judgment by the investigator considering clinical research.
4. The IRB always includes at least one member whose primary concerns are non-scientific. Other members may have scientific but non-medical backgrounds. Write the proposal with them in mind. In the case of a protocol prepared by a pharmaceutical company, the investigator should consider preparing an Executive Summary/Introduction as a separate item in the proposal package to be included with the formal protocol. The principal investigator, or a knowledgeable person involved within the study should the PI be unable to attend, must present the study to the IRB and answer any questions generated.
5. The fact that a proposal written by someone elsewhere got a majority approval vote on some other IRB does not always mean that it is adequately written, suitable for research at this institution, or that it will be approved in its present form by any additional institution's IRB.
6. The proposal becomes the written record. This record may need to be reviewed at a substantially later date by individuals not associated with the original IRB review. Information should include how you will handle real or perceived adverse events. Thus sections which require oral explanations will need editing for clarity before IRB approval is granted.
7. Investigators engaged in projects that may be classified as "Exempt" or "Expedited Review" do not always use extramural funding, and may not have written a formal proposal to submit for funding support for the project. Nevertheless, both for planning purposes and for IRB approval, write a short plan that incorporates the standard elements of good proposal writing and complete the application form included in Appendix B.

Please include the following information in a way that makes it clear why this project will satisfy the criteria for other than full board review status.

- a) the project's overall purpose and primary objectives, starting and ending points.
  - b) the participant population to be used (specifically noting if any will be from "vulnerable" categories; e.g. minors, prisoners, mentally or physically infirm). Also, describe the procedures for identifying/obtaining the participants, participant compensation (if any), and the research procedures to be used in treating or obtaining information from the participants.
  - c) the procedures to be used to assure the confidentiality of participant data, specifically addressing whether participants will be identifiable from raw and/or refined data, how such data will be protected from non-project personnel (e.g. stored in locked cabinets), whether the identifiable data will be destroyed when no longer needed, and whether project publications (theses, papers, videotapes, etc.) will allow identification of individual participants.
  - d) the level and potential risks to participants that may result from the projects.
8. Investigators writing their own materials should refer to the provided informed consent form, and add relevant information in the sections where relevant. It is particularly useful to use page numbers, and allow a place on each page of the form for the signer to initial that page. The informed consent should also contain a version date (usually located in the footer at the lower left) so that revised consents are not confused.



## **PART II ADMINISTRATIVE TOPICS**

### **SECTION 1. REGULATIONS**

1. The OSU-CHS complies with the Belmont Report (<http://ohsr.od.nih.gov/guidelines/belmont.html>) prepared by the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research, as embodying the principles OSU-CHS will apply in the discharge of its responsibilities for protecting the rights and welfare of human participants.
2. Common Rule (Federal Policy) for the Protection of Human Participants (56 FR 28003) is incorporated into 45 CFR 46, and other CFR as listed in the introduction to 45 CFR 46 (<http://www.hhs.gov/ohrp/humansubjects/guidance/statute.htm>).
3. For research likely to be conducted at OSU-CHS, it may be useful to note that two federal agencies, the OHRP and the Food and Drug Administration (FDA), have published complete sets of regulations regarding the review of research involving human participants and additional state statutes may exist which pertain to patient/participant rights. In most respects, the regulations parallel each other.
4. These regulations apply to all research involving human participants conducted; supported, or otherwise participant to regulation, by any federal department or agency that has adopted the regulations. In addition, state statutes may exist which pertain to patient/participant rights. Researchers should be aware that funding agencies, and other organizations with which they are associated in their projects may impose additional requirements.

**Thus, any research involving human participants in which OSU-CHS personnel are involved must be reviewed by this institution's Institutional Review Board and appropriate records kept to assure federal and state compliance. In order to be compliant with the OSU-CHS Institutional Review Board's requirements: all persons involved with the study must have human participant research training certification on file before final approval to begin the study is given.**

### **SECTION 2. INSTITUTIONAL REVIEW BOARD**

#### **Function**

The OSU-CHS shall have an Institutional Review Board (IRB) which shall review and have authority to approve, require changes in prior to approval, or disapprove research activities involving human participants which are conducted at or sponsored by OSU-COM, including research activities:

- performed by OSU-CHS faculty, staff, and students,
- performed in OSU-CHS facilities, or
- otherwise supported by OSU-CHS resources which are under the control of OSU-CHS officials. The IRB shall also have the responsibility and authority to adopt appropriate procedures adequate to assure compliance with the approved consent process and other requirements for the protection of human participants.

#### **Membership**

Requirements are specified in 45 CFR 46 , 46.107.

The OSU-CHS IRB shall have a minimum of five members with varying backgrounds to ensure complete and adequate review of research activities commonly conducted at OSU-CHS. There will be at least one out-side community member. The IRB 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 backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. In addition to possessing the professional competence necessary to review specific research activities, the IRB 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. No member may vote on proposals which might present a conflict of interest.

In addition to the above requirements, the IRB shall:

1. not consist entirely of men or entirely of women,
2. not consist entirely of members of one profession,
3. include at least one member whose primary concerns are in non-scientific areas,
4. include at least one member whose primary concerns are in scientific areas, and
5. include at least one member who is not otherwise affiliated with OSU-COM and who is not part of the immediate family of a person who is affiliated with the college.

When necessary or desired, the chairperson of the IRB 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. These individuals shall not have the right to vote with the IRB. The IRB shall have additional *ex officio*, non-voting members as needed to provide administrative support in carrying out its duties. Normally, such members would consist of an Administrative Officer, usually the IRB Administrator and an Administrative Assistant.

### **Members Appointments and Terms**

Faculty appointments are expected to be for four, one year renewable terms made by the usual mechanism committee assignments are made at OSU-CHS-COM. These terms shall be staggered so that not more than one-third of the IRB membership shall be appointed in the same year, excepting abnormal circumstances created by the death, resignation, discharge, or other incapacitation of members. Generally, the chairperson of the IRB shall be appointed annually by the Director of Research, from among the Board's membership.

Any member of the IRB may be removed for cause, including insufficient attendance, lack of proper preparation for meetings, disruptive or other improper conduct at meetings, or other improper conduct which would jeopardize the functionality of the IRB, as reflected in 45 CFR 46, 46.107 (a).

The chairperson may appoint consultants and ex-officio, non-voting members on a temporary basis.

Members who are unable to attend or participate in their expected capacities should be replaced.

Alternate members will be appointed in the same manner as regular members. Alternate members may only replace regular members of the same discipline. Alternate members may attend any meetings but may vote only when serving in the role of the regular member.

A roster of members must be created and maintained each year by the ORSP which lists the members, with specifics as required by 45 CFR 46: 46.103 (b)(3) and 46.107.

All IRB members (regular, community, and alternate) are appointed by the IRB Chair and receive an appointment letter from the Associate Dean of Research and the faculty senate is advised. Nominations for membership may be sent to the Chair of the IRB.

The appointment and function of alternate members is the same as that for regular IRB members, and the alternate's qualifications are comparable to those of the primary member. The IRB roster identifies the primary member(s) for whom each alternate member may substitute. When alternates substitute for a primary member, the alternate member will receive and review the same materials that the primary member received or would have received. The IRB minutes will document when an alternate member replaces a primary member.

IRB members will be appointed for a term of four (4) years. Members may serve consecutive terms

IRB members will have documentation of the same training as required for investigators.

Members may be removed from the IRB Board by a majority vote of the Board.

Committee members may identify additional conflicts of interest not previously identified by the PI, involving the research study, prior to the review of research activities and bring this to the attention of the Principal Investigator.

Committee members have an understanding of basic ethical principles, the regulatory requirements, and the mechanics of serving on the IRB.

Committee members conduct prospective and continuing review of proposed research activities according to DHHS regulations 45 CFR 46, FDA regulations 21 CFR 50 and 56 and when applicable, Federal, State and local laws, and Oklahoma State University Center for Health Science's IRB policy and procedures.

### **IRB Responsibilities**

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

1. The IRB shall have the responsibility to review and the authority to approve, require modification of, or disapprove all research activities or proposed changes in previously approved research activities covered by this policy.
2. Except when an expedited review is used (see Part I), the IRB shall review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one outside member whose primary concerns are in non-scientific 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 shall not allow any member to vote or 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.
4. The IRB is responsible for reporting through the chairman of the IRB is responsible for reporting to the Associate Dean of Research and the IRB Administrator, any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB and provision made for reporting to the Office of Human Research Protection (OHRP) as appropriate.
5. The IRB shall conduct continuing reviews of research at intervals appropriate to the degree of risk at least once per year. The IRB shall have the authority to determine which research requires IRB reviews more often than annually.
6. The IRB shall determine which research projects need verification from sources other than the research investigators that no material changes have occurred since the previous IRB review and shall have the authority to obtain that verification.

### **IRB Authority**

1. The IRB shall approve or disapprove proposed research activities using the criteria procedures detailed in Part I.

2. The IRB shall have the authority to observe or have a third party observe the consent process and the research.
3. The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with this policy and the IRB decisions, conditions, and requirements, or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of reasons for the IRB's action and shall be reported promptly to the investigator, appropriate OSU-CHS officials, and the Federal Department or Agency Head (e.g., OHRP), or other funding sponsor.

### **Procedures for Review of Research**

Except for exempt and expedited reviews (see Part I), the IRB shall use the following procedures for:

1. Conducting its initial and continuing review of research, including review by the SRC, and reporting its findings and actions to the investigator;
2. 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 review;
3. Assuring prompt reporting to the IRB of proposed changes in a research activity and assuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the participant; and
4. Assuring prompt reporting to the IRB and to the OHRP, if appropriate, or unanticipated problems involving risks to participants and others.
  - a. The IRB administrator shall review requests for proposal review, determine the level of review appropriate (exempt, expedited or a full IRB review) and process each according to these decisions.
  - b. Prior to each IRB meeting, the IRB administrator shall prepare and distribute an agenda for that meeting which shall include copies of research proposals and accompanying information to be reviewed.
  - c. When it is determined in advance that consultants or experts will be required to advise the IRB 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 chairperson or the full IRB as the chairperson elects.
  - d. The IRB shall normally meet on a monthly basis; however, meetings may be held more or less frequently as circumstances require. The IRB shall not conduct any reviews or make any determinations on projects or policies unless a quorum of members, which consists of a simple majority of voting members including a community member whose primary concerns are non-scientific, is present. If a convened meeting of the IRB meets these requirements, then the IRB shall take the following actions on proposed research before it:
    - The IRB shall review each proposed research project in accordance with the criteria for approval given in Part I and make a decision to approve, require modifications prior to approval, defer for additional information, or disapprove the use of human participants in the research. A project may be approved or disapproved only by a majority vote of the voting members present. Following

approval by the IRB contingent on changes, the principal investigator should return the corrected/changed document(s) to the IRB Administrator within 4 months. If changes are not returned within 4 months, resubmission of the study, the investigator will need to resubmit the project as new.

- The IRB Administrator, after confirming the requested changes have been made, will send a memo to the investigator informing the investigator that they may begin the study. No PI may begin a study until the IRB grants approval.
  - As a part of the approval for each project, the IRB shall require that information given to participants be in accordance with the elements of informed consent. The IRB may require that that information, in addition to any specifically mentioned in Section 7, be given to participants when in the IRB judgment the information would meaningfully add to the protection of the rights and welfare of participants. The IRB may require documentation of informed consent in accordance with 45 CFR 46.
  - For approved projects, the IRB 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.
  - For approved projects where the IRB determines that verification should be obtained from sources other than the research investigator, the IRB shall determine which sources shall be used and at what frequency the ORSP shall check those sources to ensure that no material changes have been or will be made.
5. The IRB shall notify each PI in writing of its decision to approve or disapprove his/her proposed research activity, or of any modification required to secure IRB approval of the activity. If the IRB disapproves a research activity, the notification shall include a statement of the reasons for its decision and the investigator shall be given an opportunity to respond in writing and/or in person. The IRB may, at its discretion, re-review and reconsider its decision to disapprove a research activity at any time.
6. Each notification of approval to a PI shall include a reminder that the investigator is responsible for promptly reporting to the ORSP any proposed changes in the research activity and for ensuring that those changes are reviewed and approved by the IRB prior to being made. The investigator will also be reminded that he/she is responsible for promptly reporting any injuries or unanticipated risks to participants and others resulting from the research. The notification shall state whether the IRB approval of the research is for one year or for some lesser period from the date of the notification.

### **IRB Records**

The IRB with clerical support provided by the ORSP, shall prepare and maintain adequate documentation of IRB activities, including the following:

1. copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants.
2. minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
3. records of continuing review activities.
4. copies of all correspondence between the IRB and the investigators filed in the ORSP.
5. a list of IRB members in the same detail as described in 45 CFR 46 § 46.103(b)(3).

6. written procedures for the IRB in the same detail as described in 45 CFR 46 § 46.103(b)(4) and 45 CFR 46 § 46.103(b)(5).
7. statements of significant new findings provided to participants, as required by 45 CFR 46 § 46.116(b)(5).

The records required by this policy shall be retained in the ORSP for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

#### **Routine Duties of the IRB Administrative Assistant**

include the following:

- Prepares agenda for IRB meetings.
- Schedules meetings
- Mails proposals, minutes of the preceding meeting, and agenda to members in a timely fashion before meetings.
- Maintains a file of all correspondence and documents.
- Maintains minutes of IRB minutes including attendance and voting on each proposal, and has a copy of approved minutes. (See Appendix H for example of minutes)
- Provides reference material and assistance as needed to newly appointed IRB members.
- Requests/assigns members to conduct an Expedited Review

#### **Routine Duties of the IRB Administrator**

- Conducts initial administrative examination of proposals and schedules proposals for appropriate level of review.
- Conducts the meetings in the absence of the IRB chair.
- Assists investigators in preparing applications.
- Provides reference material and assistance as needed to newly appointed IRB members.
- Requests/assigns members to conduct an Expedited Review

#### **Routine Duties of the IRB Chairperson**

- Appoints *ad hoc* IRB members, and members to other subcommittees, as needed.
- Appoints a committee member for signature authority in the chair's absence.
- Conducts IRB meeting
- Serves as the spokesperson of the IRB

#### **Conduct of Meetings**

The chairperson is responsible for the conduct of the IRB meetings. In the absence of the chairperson, the IRB Administrator or ORSP Director may chair the meeting. Individuals who are not members of the IRB are welcome only during those parts of the meeting in which they have business. Other discussions, including all deliberations, are held in closed session to respect the other investigators and to allow IRB members the needed freedom of discussion to evaluate proposals. Minutes of meetings are on file in the ORSP and may be viewed upon presentation of a need to know.

A quorum as defined by 45 CFR 46 requires "a majority of the members of the IRB are present including at least one member whose primary concerns are in nonscientific areas", (outside/lay person). "In order for research to be approved, it shall receive the approval of a majority of those members present at the meeting".

### **Section 3. Office of Research and Sponsored Programs**

The Office of Research and Sponsored Programs (ORSP) is responsible for coordinating the use of human participants with other research requirements, providing administrative support services for the IRB, and maintaining IRB records. To meet these requirements, the ORSP will provide a staff.

### **Administrative Actions**

The ORSP will:

1. Receive information submitted by research investigators on proposed research involving human participants and determine whether that information is sufficient for review under IRB guidelines and this policy. If it is not, the ORSP will request additional information from the investigators. The ORSP will also assist investigators in determining whether proposed research may be exempt from review under 45 CFR 46 and this policy, and as needed may refer the investigator's questions to the IRB chairperson.
2. Submit proposals to the IRB administrator.
3. Provide support for the IRB chairperson to schedule meetings and distribute the agenda for the IRB meetings.
4. Transmit to research investigators IRB requests and decisions concerning their proposed research projects. If the IRB approves a project contingent upon the investigator making modifications, the IRB chairperson will so inform the investigator in writing and obtain revisions from the investigator prior to the involvement of participants. Copies of all correspondence must be kept on file in the ORSP.
5. Certify to the FDA, or to sponsors as appropriate, that a research proposal has been reviewed and approved by the IRB, that the research was reviewed and approved by an IRB established under a federal wide assurance, or that the research was determined to be exempted from review and approval under 45 CFR 46 and this policy.
6. Make recommendations in a manner consistent with OSU-CHS policies, on appointment of new members to the IRB and appointment of its chairperson; identify and appoint outside members to the IRB.

### **Reports**

The ORSP is responsible for reporting the following types of information to the party indicated.

1. The ORSP will promptly report, as appropriate, any information received concerning noncompliance by investigators, instances of injuries to participants, unanticipated problems involving risks, changes proposed in research activities, and the progress of research to the IRB and to the OHRP and/or FDA.
2. The ORSP will maintain information concerning the IRB's reasons for the termination or suspension of its approval for any research and will report these reasons to the OHRP and/or FDA or other sponsors as required.

### **Documentation**

The ORSP will prepare and/or maintain the following documentation of IRB activities:

1. Copies of all research summaries and proposals reviewed, scientific evaluations (if any) that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants.
2. Minutes of IRB meetings prepared by the administrative assistant which show, at a minimum, attendance at those meetings, actions taken by the IRB, the vote on those actions (including the number of members for, against, and abstaining), the basis for requiring changes in or

disapproving research, and a written summary of the discussion of disputed issues and their resolution.

3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and investigators.
5. A list of IRB members as required by 45 CFR 46.103(b)(3).
6. Written procedures for the IRB as required by 43 CFR 46.103(b)(4).
7. Statements of significant new findings provided to participants, as required by 45 CFR 46.116(b)(5).

These records will be retained for at least three years after completion of the research, and the records will be accessible for inspection and copying by authorized representatives of the FEDERAL at reasonable times and in a reasonable manner. The documentation of IRB activities will be the responsibility of the IRB chairperson and the Director of Research.

### **Format for the Roster of Members**

45 CFR 46 requires the following information to appear on the roster of members:

- name and earned degrees
- representative capacity
- affiliation with the institution or nonaffiliation by themselves or immediate family member
- indications of experience, e.g., board certifications, licenses

The following example and format is useful:

<u>Name and degrees</u>	<u>Capacity</u>	<u>OSU Association</u>	<u>Experience/Certifications</u>
Wm. Smith, B.S.	Non scientist	None	College graduate.

### **Resources Available in the Office of Research and Sponsored Programs**

Copies of the following are on file and available from the Office of Research and Sponsored Programs:

Federal Register Vol. 59, No. 59, March 28, 1994: FEDERAL NIH RIN 0905-ZA18, "NIH Guidelines on the Inclusion of Women and Minorities as Participants in Clinical Research".

Federal Register, Vol. 56, No. 117, June 18, 1991: FEDERAL, Food and Drug Administration, 21 CFR Parts 50 and 56 RIN 0905-AC52, "Protection of Human Participants; Informed Consent; Standards for Institutional Review Boards for Clinical Investigations".

Oklahoma State Statues, Chapter 54. Health Services for Minors. Sections 2601-2606.

OHRP Reports, "Protection of Human Participants": Title 45 CFR 46, Revised June 18, 1991.

Belmont Report found at <http://ohsr.od.nih.gov/guidelines/belmont.html>

Code of Federal Regulations (45 CFR 46) can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/statute.htm>

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**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.

FOR ORSP USE ONLY: RECEIPT DATE: \_\_\_\_\_  
This and other ORSP forms are available electronically.

IRB #: \_\_\_\_\_

## APPENDIX B APPLICATION FOR IRB REVIEW

### I. THE RESEARCH PROPOSAL

Principal Investigator [*the person responsible for the overall conduct of the project*]: (Name, Degree, Department, Address, Phone, Human Participant Research Certification)

Collaborating Investigators: (*for each: Name, Degree, Department, University, Address, Phone, Human Participant Research Certification*)

Study Sites:  
(Attach Other IRB Approval if initiated elsewhere)

Project Title:

Sponsor: (funding agency or department):

Proposed Starting and Ending Dates:

Financial Disclosure filed with the Office of Research \_\_\_\_yes \_\_\_\_no  
(You may use sponsor or college disclosure form)

### II. REQUEST FOR EXEMPT STATUS OR EXPEDITED REVIEW

I request this application be considered for: Exempt Status \_\_\_\_\_; Expedited Review \_\_\_\_\_  
The reasons this project qualifies are included on an attached page.

I understand that the IRB chairperson may grant exempt or expedited review, but, reserves the right to require full Board review of any IRB application.

### III. STUDY POPULATION

Age Range: \_\_\_\_\_ Gender: (Please check one) Males: \_\_\_\_\_ Females: \_\_\_\_\_ Both: \_\_\_\_\_  
Special Qualifications: \_\_\_\_\_  
Source of Participants: \_\_\_\_\_  
Number of Healthy Volunteers: \_\_\_\_\_ Number of Patients: \_\_\_\_\_

Will placebos be used?

IV. **PROTECTED GROUPS:** Please check any protected groups included in this study.

_____	Children	_____	Mentally Disabled
_____	Pregnant Women	_____	Prisoners
_____	Fetuses		

If the protocol involves children as research participants (not including emancipated minors), read the following:

The consent of both parents is required by regulation where the research involves greater than minimal risk and will not directly benefit the individual child research participant unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. If both parents' consent is not going to be obtained, please explain why:

The assent of the child is required by regulation, if the child is capable of providing such assent (typically age 7-17). If the child's assent is not going to be obtained, please explain why:

If this protocol involves children who are wards of the state or any other agency, entity or institution, advocates must be assigned. Will such children be research participant? \_\_\_\_\_ YES \_\_\_\_\_ NO

## V. PROTOCOL/CONSENT FORM REFERENCES

Please indicate the page numbers of the protocol and consent form on which the following topics are addressed:

<u>PROTOCOL</u>		<u>CONSENT FORM</u>	
Page No.	Topic	Page No.	Topic
_____	Purpose	_____	Purpose
STUDY POPULATION		_____	Status of Drug/Device/Procedure
_____	Inclusion/Exclusion	_____	Description of Study
_____	Criteria	_____	Costs
_____	Duration of Participation	_____	Risks
_____	Early Termination Criteria	_____	Benefits
METHODS/PROCEDURES		_____	Alternative to Participation
_____	Drugs and Dosages	_____	Compensation and Injury
_____	Devices	_____	Participant's Assurance
_____	Surgical Procedures	_____	Contact for Questions about Rights as a Research Participant
DATA			
_____	Collection		
_____	Analysis		
_____	Confidentiality		

## VI. INVESTIGATIONAL DRUGS AND DEVICES

Please list any investigational drugs or devices that will be used in this study:

IND/IDE Number(s): \_\_\_\_\_

IND/IDE Name(s): \_\_\_\_\_

IND/IDE Sponsor(s)/Manufacturer(s): \_\_\_\_\_

## VII. IONIZING RADIATION

Does this study involve the use of ionizing radiation? \_\_\_\_\_ Yes \_\_\_\_\_ No

If "Yes" please submit one copy of the application form, consent and protocol for approval by the Radiation Safety Committee.

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**APPENDIX C INFORMED CONSENT FORM MODEL**

This is an approved informed consent format. Use this to prepare your own form. The IRB will expect to see this language and these sections included in your form.

Please include a header and footer. The header should have the protocol number (example: IRB # 2007006 Informed Consent). The footer should have the version, page # of total pages, and place for patient 's initials (example: Version 7/11/01 page 1 of 5 Patient's initials \_\_\_\_). Each time the informed consent is changed, the version should reflect the change.

**OKLAHOMA STATE UNIVERSITY  
Center of Health Sciences  
PATIENT INFORMATION AND CONSENT FORM**

Title of Project: **BOLD** \_\_\_\_\_

Investigator(s): **BOLD**

*(Give name(s), title(s), department(s), and telephone number(s)).*

Sub-Investigator(s): **BOLD**

*(Give name(s), title(s), department(s), and telephone number(s)).*

You are being asked to take part in a research study. If this consent form contains any words you do not understand, please ask you doctor or the staff to explain these words so that you understand them. This consent form contains important facts to help you decide if it is in your best interest to take part in this study.

The purpose of this research is to:

The approximate number of participants involved in the study.

The procedures to be followed are:

*(This section must include a fair and understandable explanation of the nature of the activity, its purpose, the duration of the participant's participation, and the procedures to be followed, including identification of any procedures which are experimental.)*

You may expect the following (physical and/or mental) discomforts during the course of this research:

By participating in this research, you may be exposed to the following (physical, mental, and/or social) risks:

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

This research may result in the following benefits to you:

Tissues or other materials from experimental participants will be used only for research and destroyed at the conclusion of the experiments, except when it may be discovered that these may have potential long term value. When and if that occurs and before commercial development, the principle investigator,

University, and experimental participant will negotiate a contract as to details of ownership. I understand that my participation in this study does not forfeit any rights to these materials, which I would otherwise possess.

OR

Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the Oklahoma State University Center for Health Sciences. Once you have provided the specimens you will not have access to them. The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol

The following are alternative investigative procedures or treatments, which might be more advantageous to you:

The information obtained from or about me will be kept confidential to the following extent:

*(If participant information is not to be kept fully confidential, indicate the extent to which it will be protected. It should note the possibility that the Food and Drug Administration may inspect the records..)*

**By state statute the following paragraph must be included in each Informed Consent. The bolded sentence must remain bolded.**

By signing this form, you agree to allow the use and disclosure of your medical information for the purposes described above. **The information you authorize for release may include records which may indicate the presence of a communicable or noncommunicable disease.** With this knowledge you give your authorization and consent to the use and disclosure of information as described in this document to the people identified in this form. A copy of this authorization form will be given to you.

Your participation in this research study is voluntary. You are free to refuse to participate in any procedure and to refuse to answer any question at any time, and are free to withdraw your consent, and to withdraw from the research at any time without penalty.

A statement should be included with anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. *(example: Your doctor, the sponsor company, or the FDA also has the right to stop the study at any time, with or without your consent for any of the following reasons: if you have an adverse or serious effect from the study medications, if you need a treatment not allowed in this study, if you do not keep appointments, etc .....)*

If you have any questions about your rights while in this research study, please contact Dr. Stephen Eddy at (918) 561-8287.

If you have questions about your medical treatment or if you feel you have an injury from participation, you may call \_\_\_\_\_ (name of contact) at \_\_\_\_\_ (telephone number) for assistance or advice.

*(For projects containing physical risks to participants only)*

Oklahoma State University-Center for Health Sciences will not provide compensation and will not provide medical treatment without charge for any injury as a result of and during the course of this research investigation.

If either compensation or medical treatment is provided, also provide a source where additional information on the limits and restrictions can be obtained by the participant.

By agreeing to participate in this research and signing this form, you do not waive any of your legal rights, nor is the investigator(s), sponsor, the institution or its agents free from liability for negligence.

As the person changes to first person in the following paragraph, please bold this paragraph:

**I have read and been given information about this research study and the risks involved have been explained to me. Any questions I may have had were answered to my satisfaction and I have been told who to contact should additional questions arise. As a result, I give my informed consent to participate in this research. I will receive a copy of this consent form.**

\_\_\_\_\_  
Participant or Parent/Guardian Signature

\_\_\_\_\_  
Date

**NOTE:**

The informed consent should be written at a 8<sup>th</sup> grade rural level.

All elements of this consent form must be explained to the participant or legal representative. Actually reading the consent to them IS A VERY GOOD IDEA to assure they have received the information. The study participant must be given an opportunity to ask any questions. All questions asked must be answered before they sign the consent.

The informed consent form signed by the patient must have a stamped approval by the IRB on each page. Once approved, the principal investigator will be sent an original stamped with the approval. He/she may use this original to make copies for participant signature.

The patient must receive a copy of the signed informed consent form to take home.

**ASSENT FORM**

FDA guidelines now require studies involving children to include an assent form. The purpose of this form is to make sure this group of patients understands the study, what their participation will mean to them, and that they agree to participate. This form should be written in language they can understand. This may mean several forms (*example: the explanation would be different for a 5 year old versus a 15 year old*). There are currently no specific guidelines about what information must be included. The OSRP recommends you include as much of the above information as deemed applicable.

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## APPENDIX D EXAMPLES OF LANGUAGE USEFUL IN INFORMED CONSENT FORMS

Because projects can vary so widely, particular language may vary considerably to reflect the needs of the investigator. A series of examples are included which may be helpful.

### **The Consent Form - Purpose**

This paragraph should tell participants why they are being asked to participate and what the purpose of the study is, relative to the participant. This purpose should match the purpose outlined in the protocol of the study. There may be some circumstances, primarily in surveys or psychological studies, where giving the specific purpose will prejudice the answers given by the participants or will eliminate part of the target population. An example would be a study examining the psychological impact of childhood sexual abuse. In such an instance, a cover letter is necessary explaining why the study's purpose is not precisely the consent's purpose.

#### **Example #1:**

*You have been asked to participate in this research study because you have been recently found to have a cancer in the kidney called renal cell carcinoma. It had spread outside the boundaries of the kidney and so the surgery was not able to remove all the cancer. This form of cancer does not respond to any standard drugs used for chemotherapy and thus no cure is possible with them. It also does not respond to radiation treatment. This study will examine the effect of an experimental drug called [name of drug] in combination with the drugs \_\_\_\_\_ and \_\_\_\_\_, to see if this combination of drugs lengthens the life of patients with your disease. Both the response to the drugs and their side effects will be studied.*

#### **Example #2:**

*You are giving consent for your child and this research study is designed to gather information about the effects of the legal process on children who have been involved in the legal process as witnesses or potential witnesses in cases of child physical abuse or sexual abuse. There is wide spread belief that the legal process is difficult for children and may even traumatize them. The investigators hope to obtain information about the child's view of the process, what caused problems and what was or could have been helpful.*

#### **Example #3:**

*The purpose of this research study is to evaluate how diet and exercise affect hypertension. You are invited to participate because you have been diagnosed with hypertension or you are serving as a healthy volunteer.*

### **The Consent Form - Status of the Drugs, Devices and/or Procedures**

This section is appropriate for many but not all studies. Its purpose is to tell the participant whether the drug(s), device(s), or procedure(s) in the study are experimental or investigational for the purposes for which they will be used in the study. It may be that it is the combination or the dosage which is experimental, or the combination with other modalities of treatment. Remember in this section that FDA stands for Food and Drug Administration, not Federal Drug Administration. Also, it may be confusing to say that the FDA has approved the investigational use of a drug; it would be better to state that the drug is not approved by the FDA for this use. If the study does not involve any drugs, devices or procedures, omit this section.

#### **Example #1:**

*All the drugs to be used in this research study are approved by the Food and Drug Administration for treatment of some forms of cancer. However, the combination of the drugs, plus the use of a relatively low dose of Cisplatin, is not standard therapy for my kind of cancer.*

#### **Example #2:**

*This procedure is commonly used in the treatment of patients with irregular heart rhythms which start in the lower part of the heart. However, its use in patients like you, with the irregular heart rhythm starting in the upper part of the heart, is not accepted therapy.*

**Example #3:**

*[Name of drug] is an investigational drug not approved by the Food and Drug Administration. [Drug] is a new type of antihypertensive which is used to lower blood pressure.*

**The Consent Form - Description of Study**

This section of the protocol is very important, as it tells the participant what will happen. It should be complete but optimally will be concise. In order to make it easier to read, divide the description into paragraphs. If there are separate phases to the study, each phase should be described in a separate paragraph. The participant's participation should be described in chronological sequence. The description of study must be written in lay language, with complex medical terminology explained in simple terms. It should specifically address if hospitalization will be required and for how long; if procedures will be done on an outpatient basis, that should be stated with the expected duration.

It should address whether participants will be divided into groups and how that will be done (e.g., *randomly, like the flip of a coin; randomly, like the roll of a die, into \_\_\_ number of groups*). It should also include any use of placebo (*inactive medication tablet or capsule*) and whether it will be single blind (*your doctor but not you will know*) or double blind (*neither you nor your doctor will know which medication you are receiving, but if that becomes important for your care, the code can be broken to find out*) in design. The use of the following terms is irrelevant for the participant: blind, placebo-controlled, parallel design, crossover. If the study involves standard therapy of the disease with addition of new drugs/procedures or with changes in doses of current medication, that should be stated. If the main thrust of the study is testing blood or doing blood levels, the amount of blood to be drawn should be included (5cc = 1 teaspoon, 15 cc = 1 tablespoon, 4 tablespoons = 1/4 cup).

**Example #1:**

*The standard therapy of your disease would be the use of [these four drugs] to induce or cause a remission. The experimental part of the study will be to add [new drug] at this time. The standard therapy would be given in 4 cycles given every 28 days, with hospitalization required for the first 4 days and taking [name of old drug] by mouth once a day once you are discharged. You will receive [new drug] once a day while you are in the hospital, but it will not lengthen your time in the hospital.*

*Once you go into remission, when the disease is no longer detectable by examining your blood or bone marrow, you will begin what is called maintenance therapy, which will try to keep the disease from coming back. At this time, you will be randomly assigned, like the flip of a coin, to either treatment with [these four drugs] or [those five drugs]. The use of [these four drugs] is standard accepted maintenance therapy. For that treatment, every 28 days you will come to the clinic for treatment into the vein with \_\_\_\_\_ and \_\_\_\_\_. You will then take \_\_\_\_\_ for the next 5 days by mouth, then begin \_\_\_\_\_, by mouth until the next cycle starts. The treatment with [those five drugs] would also be every 28 days, but you will have frequent clinic visits, x-rays, blood and urine tests to monitor the response to the therapy and also to watch for side effects.*

*You will continue this maintenance therapy until your disease recurs, until you have received a total of 15 months of maintenance therapy, or until you have side effects which make it necessary to stop. During this treatment, you will have frequent clinic visits, x-rays, blood and urine tests to monitor the response to the therapy and also to watch for side effects.*

**Example #2:**

*If you agree to participate in this research study, you will be given a questionnaire to complete. This questionnaire will ask you general questions about your background and will also ask you about pleasant and unpleasant experiences you have had when you have been ill and gone to see a doctor. You will not put your name on it, nor will there be any identifying marks on it, so that the*

*investigators and your doctor will not know that you were the person filling out this particular questionnaire. About 45 minutes of time will be required to complete the form. After you finish it, you will put it into the stamped addressed envelope provided. If you decide you don't want to be in the study, you will not return the form.*

**Example #3:**

*Your participation in this research study is limited to having blood drawn to be tested for these new antibodies. The investigators will attempt to have the blood drawn when you are having blood drawn for other reasons. The amount of blood will be 30 cc (2 tablespoons). For most participants, this will only be drawn once. If there are high levels of this antibody in my blood, you may be asked to give verbal permission to have more blood drawn, no more than 4 tablespoons at a time and no more often than every two months. You may however decide not to allow more blood to be drawn, if you so choose.*

**The Consent Form - Costs**

This section follows the Description of Study. The intent is to tell the participant who will be financially responsible for the costs (charges) of all parts of the study. Sometimes the participant (or his/her insurance company) bears the charges, other times the sponsor, and sometimes the charges are shared. No answer is "right", but the participant should be told in clear language.

**Example #1:**

*You or your insurance company will be responsible for charges incurred for the drugs and tests provided in this study because the drug used is commercially available and the tests done are part of the standard treatment for your disease. However, you will not be responsible for charges from the testing of the tissue from your cancer.*

**Example #2:**

*The drugs will be provided free by the sponsor. All charges for the clinic visits, blood, urine and other tests will be paid by the sponsor.*

**Example #3:**

*The drug will be provided free by the sponsor, but you or your insurance company or other carrier will be responsible for the other charges incurred in this study. In addition, should the drug become commercially available during the study, you will then become responsible for its purchase.*

**The Consent Form - Risks**

Risks may be physical or mental. Any reasonably foreseeable risks or side effects should be included, as well as any inconvenience the study would add. Any measures which will be taken to minimize the risk should be included. Adverse effects which have occurred in the past only once or twice need not be mentioned. If there is enough clinical experience with the drug to be able to define common, infrequent, uncommon and rare side effects, the risks can be divided in this way. Sometimes percentages are available and very useful. (*These side effects are common and occur in 30-50% of patients.... The following occur less often, 5-10%.... The following occur in 1-5%..... Rarely (fewer than 1 in 500 patients) the following are seen....*) If more than one drug or procedure is involved, they should be addressed individually. If several chemotherapy drugs are to be given, however, please have a general chemotherapy paragraph (e.g., *nausea, vomiting, decreased white blood cells, decreased platelets, loss of hair, mouth ulcers*), then list the other side effects that are specific to each drug. Alternately, the side effects can be listed and the drugs which could cause them listed.

The risks of procedures that are part of standard therapy or evaluation should either not be included (e.g., bone marrow aspiration, CT scans) or should be mentioned with the statement that a separate consent will be obtained for them (e.g., placement of infusion catheters, operations to evaluate the completeness of response to the therapy). If a central part of the study is to draw blood for testing, the risks of venipuncture should be included (i.e., *"The risks of drawing blood are pain, bruising or feeling faint. Infrequently infection*

or clotting in the vein may occur”). In some studies the risks of pregnancy may require attention, as well as the risk of sterility. In such cases, it must be stated that an effective means of birth control is necessary to prevent pregnancy. It is preferable to specify what are considered to be acceptable forms of birth control. The risk section should also mention that there is the possibility that the participant will have side effects which have not been recognized before.

It may be appropriate to add a statement that the participant may be removed from the study without his/her consent if side effects become severe, or under any other circumstances which may be predictable. Another helpful statement is that the participant will be made aware of significant new findings which might affect his/her decision to remain in the study.

**Example #1:**

*The primary risk of participating in this research study is the development of side effects from the medications. A rash has been seen in 10-20% of patients. Other side effects have occurred in less than 1% of patients and include constipation, nausea, swelling of the ankles and insomnia. If you have any side effects, you should report them promptly to your physician. If side effects become severe, you may be removed from the study.*

**Example #2:**

*The potential effects of these drugs on the growing fetus are not known but would be expected to include serious birth defects. If you are a woman and you suspect or know that you have become pregnant, you will contact the physician immediately. You also understand that the effect on developing sperm is also not known and if you are a man, you should take precautions not to father a child during the study.*

**Example #3:**

*The primary risk for this research study is that your child will relive the unpleasant experiences while completing the questionnaires and having the interview. In order to see how to help children who have testified in court, it is necessary to talk with them and see how they thought at the time and what effects it had over time. If the amount of anxiety seems exaggerated or abnormal, you will be informed and also referral for counseling will be provided.*

**Example #4:**

*The only risk in the study is that of drawing blood. A bruise may occur at the site and there may be minor pain at the time. Fainting occasionally occurs and infection rarely occurs.*

**The Consent Form - Benefits**

There may be no direct benefit. The IRB does not allow the benefit to society or advancement of medical science to be included in this section. If there are no direct benefits, so state.

**The Consent Form - Alternative to Participation**

In this section, the alternative to signing up for the study is addressed. In most cases, the alternative would be the standard treatment or therapy, e.g., a specific drug, chemotherapy, radiation. But sometimes this concept is difficult to describe, as it may be that standard therapy is one of the options in the study. For example, it may be that observation (which is standard) is one arm and aggressive adjunct therapy (to prevent disease recurrence) is the other. In this case, although the study may provide more aggressive therapy, it may not be effective and may have serious side effects. There are occasional protocols which state that the “control group” will be composed of participants who refused to be randomized. The participants should be informed of this use of their data and must be given the opportunity to refuse such use.

The alternative for the typical non-risk study is simply not to participate.

**Example #1:**

*If you choose not to participate in this research study, your physician will probably recommend the standard therapy, which is the use of cisplatin, vincristine and bleomycin, as used in the first arm of the study. Another choice is no treatment at all.*

**Example #2:**

*Surgery and radiation therapy are not useful in patients with your disease and/or they have already failed for me. There are no other alternative treatments which are accepted as effective or that are experimental and offer any greater chance of success than the treatment in this study. You may choose to not have any further therapy.*

**Example #3:**

*The alternative is not to participate.*

**The Consent Form - Compensation and Injury**

This section has two purposes: 1) to define what medical care is available if injury is incurred and 2) to define what compensation is available in that instance. Both should be described as fully as possible. In the vast majority of instances, there is no compensation (payment over and above the coverage of medical costs) and that fact should be stated. The options for medical care are more varied. It may be that the medical care will be provided, with the sponsor paying anything not covered by third party coverage. Another more common circumstance is that the medical care will be available but the patient, and any coverage sources he/she has available, will be responsible for the charges. In rare circumstances, the patient must seek his/her own medical care and is responsible for payment.

**Example #1: No coverage for injury; no compensation**

*If you are injured, medical treatment for the injury will be available to you, but you or your insurance carrier will be required to pay the usual fees for that treatment. You understand that no compensation will be available to you from the [hospital(s)], Oklahoma State University College of Osteopathic Medicine, or [the pharmaceutical company] unless you otherwise are covered by their health insurance or other employee health benefits. If you have questions or want further information about compensation or medical care, You may contact the Chief of Staff of [hospital](s) at [phone number(s)].*

**Example #2: Company coverage for injury; no compensation**

*If you are injured, emergency medical treatment for the injury will be available to you. Furthermore, the sponsor [company name] will pay for any charges not covered by your insurance company. These charges may cover laboratory tests, examination, procedures like X-rays, or hospitalization. This coverage is limited to injury resulting from the administration of the drugs involved with the study and does not apply to complications from any drugs or procedures not directly related to the study performance. It also does not apply if I was not taking the medication properly. No other compensation is available to you from [hospital(s)], Oklahoma State University College of Osteopathic Medicine, or [the pharmaceutical company] unless you otherwise are covered by their health insurance or other employee health benefits. If you have questions or want further information about compensation or medical care, you may contact the Chief of Staff of [hospital(s)] at [phone number(s)].*

**Example #3: Physician coverage for injury; no compensation**

*If you are injured, emergency medical treatment for the injury will be provided at no charge by Dr. [the study physician(s)]. This treatment may in addition involve other charges, from hospitals, laboratories or clinics, which will be billed to you and my insurance company. No other compensation is available to you from [hospital(s)], Oklahoma State University College of*

Osteopathic Medicine, or [the pharmaceutical company] unless you otherwise are covered by their health insurance or other employee health benefits. If you have questions or want further information about compensation or medical care, you may contact the Chief of Staff of [hospital(s)] at [phone number(s)].

**Example #4: Required verbatim for all studies at TRMC**

*Emergency medical care will be provided to you, but that its location may be either at TRMC (if you are eligible for care and/or hospitalization there) or at another hospital (if you are not eligible for care and/or hospitalization at the TRMC for this condition). If life-threatening injury occurs while you are at the TRMC, emergency care will be provided, regardless of whether you would be otherwise eligible for the treatment, until you can be transferred to another hospital if I am not eligible for care there. If I have any questions about your eligibility or your compensation for any injury, you may take them to the Director of Research, OSU-COM, 1111 West 17th, Tulsa OK or telephone number (918) 561-8241. My signature at the bottom of this form confirms that the physician explaining the study to you has discussed with you your care eligibility.*

**APPENDIX E CONTINUING REVIEW**

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

**IRB** \_\_\_\_\_

**CONTINUING REVIEW OF APPROVED RESEARCH FOR THE STUDY:**

All IRB approved research is participant to continuing review

Investigator:

Protocol # :

Title:

**ALL IRB APPROVED RESEARCH IS PARTICIPANT TO CONTINUING REVIEW**

Please provide the following documents:

1. A summary of your project experience.
2. If you are currently recruiting participants, did you provide a copy of the informed consent form(s)?
3. If you are currently recruiting participants, include the last signed copy of the Informed consent with the participants name blacked out.
4. List any abstracts or new publications published within the last year that might be germane to this study.

1. Circle the status of this study:

Recruiting Participants      Following Participants      Data Analysis only  
Study Not Begun      Study on Hold      Completed/Discontinued

---

(Please Explain if you have circled Study Not Begun, Study on Hold or Discontinued)

2. Are participants currently being recruited?  
No \_\_\_\_\_ Yes \_\_\_\_\_ Please enclose a copy of the consent form(s) currently used in this study (even if unchanged from previous submission)
3. Number of participants enrolled since last year's review: \_\_\_\_\_  
Female \_\_\_\_\_ Male \_\_\_\_\_
4. Total number of participants enrolled in the study *to date*: \_\_\_\_\_
5. Is this project funded: No \_\_\_\_\_ Yes \_\_\_\_\_  
If yes, please provide current funding agency name(s) and grant number(s)
6. Is this research a clinical investigation of a new drug or medical device:  
No \_\_\_\_\_ Yes \_\_\_\_\_ If yes, please provide IND/IDE# and expiration date.
7. Is ionizing radiation (e.g., x-rays, radioactive materials) used in this project:

No \_\_\_\_\_ Yes \_\_\_\_\_ If yes, has the portion of the study involving ionizing radiation been completed?

No \_\_\_\_\_ Yes \_\_\_\_\_ If no, list any changes in radiation dosimetry and radiation dose to the study population (show assumption and calculation)

8. Any changes in Principal or Co-Investigators:

No \_\_\_\_\_ Yes \_\_\_\_\_ If yes, please explain.

9. On a separate sheet, please provide a summary of the following as applicable:

- Preliminary information about any results and/or trends
- Adverse events and dates reported to the IRB. Do adverse event trends indicate that changes are needed in the consent form or in the study?
- Changes in protocol and dates approved by the IRB
- Difficulties in recruitment or retention of participants. The number of participants who withdrew from the study

10. The PRINCIPAL INVESTIGATOR'S ORIGINAL signature is required. By signing below, the PI assures that the information contained on this form is true and accurate.

\_\_\_\_\_  
Original Signature of Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Phone

\_\_\_\_\_  
Fax

Please complete and return this form ASAP

To: Teri Bycroft, R.N., M.S.N., CIP  
Assistant Director of Research  
Department of Research  
OSU-CHS-COM  
1111 W. 17<sup>th</sup> Street  
Tulsa, OK 74107

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COLLEGE OF OSTEOPATHIC MEDICINE

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## **APPENDIX F RESEARCH BIBLIOGRAPHY**

The following are some of the many materials available from the OSU-COM library to help investigators learn more about various topics useful to their research endeavors. These lists are grouped by major topic. Since the library holdings change with time, the investigator should use this as a starting point, and examine the most current wider range of holdings by electronic search. Librarians are available to help.

Office for Human Research Protections, slide show presentation  
<http://ohrp.osophs.Federal.gov/humanparticipants/assurance/sbirsttr/sld001.htm>

NIH Protection of Human Research Participants computer based training module (MPA and SPA and Human Participants protection)  
<http://helix.nih.gov:8001/ohsr/newcbt/>

Office for Human Research Protections Web page  
<http://ohrp.osophs.Federal.gov>

The Belmont Report (Human Research ethical principles)  
<http://ohrp.osophs.Federal.gov/humanparticipants/guidance/belmont.htm>

The Nuremberg code  
[http://www.usmmm.org/research/doctors/Nuremberg\\_Code.htm](http://www.usmmm.org/research/doctors/Nuremberg_Code.htm)

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**APPENDIX G STANDARD OPERATING PROCEDURES FOR HUMAN PARTICIPANT RESEARCH  
OSU-COM Office of Research and Sponsored Programs (ORSP)**

1. **ALL** activities, which includes the collection of information or data on human participants, must be reviewed by the Office of Research. If you have questions about what information you need to submit and the extent of the review process required, consult the OSU-COM Institutional Review Board (IRB) application packets or call the Office of Research at (918) 561-8452. Typically, the determination made will call for an Expedited Review or Full Review by the IRB.
2. Support provided by the ORSP includes:
  - i. Aid/consultation in preparing documents for review contained within the IRB application packet.
  - ii. Initial review of Informed Consent documents for compliance to institutional, state and federal regulations. **Note:** Not all states require the same components to an informed consent, so if you are working on a multi-site (international or national trial) the informed consent provided by the funding agency may not meet Oklahoma state law requirements and will require changes that must be approved by the funding agency. Submit this form as early as possible.
  - iii. **Data Collection Support** for a limited number of projects is available. If you want or need support, be sure to include the ORSP in the budget preparation to assure recovery of cost from the funding agency.
  - iv. **Notification of Continuing Review.** All approved projects must submit to the IRB a report for review of progress through the ORSP, annually, unless required more frequently by the IRB. While it is the PI's responsibility to ensure the Continuing Review is submitted the appropriate time for review, the ORSP will try and provide PIs with reminder notices.
  - v. **Training.** Staff in the ORSP can offer assistance in organization and training of departmental staff in program operations, consenting of patients, data collection, etc.
  - vi. **Internal Audits.** In addition to the above support, the ORSP will perform internal audits of all ongoing projects as needed to assure compliance by the principal investigators (PI) and their support staff. Issues typically looked for include, but are not limited to:
    - a. prior consent of participants
    - b. adverse event documentation/reporting and adherence to procedures
    - c. confidentiality

vii. **External Audits Support.** When or if external agencies come on site to audit protocols such as FEDERAL, FDA, Contracted Site Management Organization, etc., the ORSP will work with you to provide support for a successful audit.

3. IRB: Function and Process

Completed applications for IRB review are submitted to the ORSP for transmittal to the IRB. The IRB meets monthly and PI's are required to submit complete applications at least 10 working days before the regularly scheduled meeting to be included on the agenda. In addition, the PI or a knowledgeable representative should plan to attend the meeting to respond to questions from board members.

i. Initial IRB Review includes, but is not necessarily restricted to the following:

- a. Basic scientific review
- b. Risk: benefit analysis
- c. Special/Vulnerable Participant Inclusion
- d. Informed Consent Review
- e. Participant Compensation
- f. Project advertisements when applicable

ii. Ongoing IRB Review Includes:

a. **Change in Protocol Notification**

Any change in the protocol made by a PI or outside agency must be submitted to the IRB for review before implementation.

b. **Adverse Event Review:** Adverse event (AE) reports and in particular serious adverse events (SAE) will be submitted to the appropriate outside organizations and copied to the IRB via the ORSP.

c. **Annual Progress Report Review:** Reports are submitted for on-going review as required by the responsible outside agency or IRB. These reports will occur annually unless required more often by the IRB. This IRB Policy and Procedure Manual includes forms for this purpose, Appendix C. Typical information included in this progress report are:

- Number of patients enrolled
- Review of AE/SAE's
- Review of changes to protocol
- Current Informed Consent Form

d. **Notification of Termination:** If a PI terminates a protocol for cause prematurely or receives notice from an outside agency of "intent to" or "notice of immediate termination" he/she will transmit that information to the ORSP and IRB immediately.

Note: The IRB and the ORSP have the authority to halt enrollment of participants in any protocol if conditions warrant. Typical situations which could result in this action are: continued failure of PI to act responsibly in the management of the study after initial warning by the ORSP/IRB or a judgment that multiple AE's or a SAE warrants such action.

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**APPENDIX H IRB MEETING MINUTES FORMAT**

FORMAT FOR ALL OSU-COM IRB MINUTES

(The order in which agenda items are reviewed is at the discretion of IRB Chairs)

Minutes of the OSU-COM IRB Meeting Held on (First Wednesday of the month)

Members Present: \_\_\_\_\_ (Chair) \_\_\_\_\_  
(indicate who is \_\_\_\_\_  
a non-scientist, \_\_\_\_\_  
non-OSU-COM, \_\_\_\_\_  
affiliated etc.) \_\_\_\_\_  
\_\_\_\_\_

Members Absent: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Guests: \_\_\_\_\_  
(include \_\_\_\_\_  
affiliation) \_\_\_\_\_  
\_\_\_\_\_

The meeting convened at --:-- (a.m./p.m.) with a quorum present.

1. MINUTES OF THE MEETING HELD ON (DATE). (The minutes must be voted on and any changes documented.)
2. ANNOUNCEMENTS
3. INITIAL REVIEWS.

A. Principal Investigator:

Protocol Title:

Protocol precise or summary:

a. Discussion:

General:

Specific: (include the following headings)

Scientific design (discuss and note that pre-scientific review has been done)

Risks/benefits (assign a level of risk here [or at the time of the IRB decision and vote, (d) below] consistent with OSU-COM IRB

Protocol Review Standards form.

Participant selection (discuss populations to be studied & recruitment plan)

Additional safeguards for vulnerable participants.

Minimization of risks to participants

Privacy & confidentiality.

Consent document (document that all required elements are present)

Additional considerations (e.g., ionizing radiation; collaborative research; IND, other.  
State if these considerations do not apply)

b. Stipulations (number the stipulations)

c. Recommendations (number the recommendations)

d. IRB Decision and Vote

State whether the vote is unanimous; if not, state how many members voted for, against or abstained. Document in or attach to the minutes the reason(s) for the minority opinion(s). Members who are affiliated with the protocol must recuse themselves from the IRB discussion and vote, and leave the room during the discussion and when the vote is taken. The minutes should state which member(s) left the room. If a quorum is lost because members recuse themselves, no action may be taken on the protocol.

If the protocol is approved with stipulations and/or recommendations, the minutes must state whether the IRB votes that the stipulations and/or recommendations are to be reviewed by the Chair, by a subcommittee of the IRB, or by the full IRB.

B. (Follow same format as above for additional new protocols)

C. (Follow same format as above for additional new protocols)

#### 4. EXPEDITED INITIAL REVIEWS, EXPEDITED CONTINUING REVIEWS OR EXPEDITED AMENDMENTS

A. Principal Investigator:

Title and type of expedited action:

Date approved by IRB Chair or designee:

Description of expedited action: (Expedited actions must be listed separately in the minutes. The Chair should provide a brief explanation of any expedited actions. A vote is not required but the IRB has the prerogative to discuss, rescind or amend expedited actions.)

B. (List additional expedited actions following above format)

C. (List additional expedited actions following above format)

D. (List additional expedited actions following above format)

#### 5. CONTINUING REVIEWS (coordinator to have the entire protocol file available for reference at the meeting)

A. Principal Investigator:

Protocol Title:

Protocol Number:

Expiration Date:

Protocol Precise or Summary (if not provided in discussion at (a) below):

a. Discussion:

b. Stipulations (number the stipulations)

c. Recommendations (number the recommendations)

d. IRB Decision and Vote (Include IRB's reaffirmation of the level of risk or establishment of a new risk level consistent with the OSU-COM IRB)

B. (Follow the same format as above for additional continuing reviews)

C. (Follow the same format as above for additional continuing reviews)

## 6. AMENDMENTS

A. Principal Investigator:

Protocol Title:

Protocol Number:

Expiration Date:

Description of the amendment:

a. Discussion:

b. Stipulations (number the stipulations)

c. Recommendations (number the recommendations)

d. IRB Decision and Vote (include a statement indicating whether or not the protocol's level of risk is altered by the amendment)

B. (Follow the same format as above for additional amendments)

C. (Follow the same format as above for additional amendments)

## 7. REPORT OF ADVERSE EVENT(S)

Principal Investigator:

Protocol Title:

Protocol Number:

Date of Adverse Event(s):

Description of the adverse event(s):

Document IRB's acknowledgement of receipt of the adverse event report(s) and discussion. Discussion of serious adverse events occurring on a protocol should include immediate actions taken as a result of the event

by the PI; recommendations for further actions, if any, by the IRB (e.g., suspension of participant accrual, etc.), and any necessary recommendations for further reporting (FDA or NIH officials, OHRP, Provost, etc.).

If the adverse events are reported from non-OSU-CHSsites for the IRB's information only, and no action is required on the IRB's part, acknowledgement of the report(s) should be documented.

8. INFORMATION ITEMS

A. Single Patient Exemption(s)

B. Other

9. ADJOURNMENT

The meeting adjourned at --:-- (a.m./p.m.).

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APPENDIX I SAE and AE Report Form

TO: Oklahoma State University College of Osteopathic Medicine  
Institutional Review Board Chair and Members

Attached, please find copies of Serious Adverse Event and Adverse Event reports on:

Protocol #: \_\_\_\_\_

Titled: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

A summary of each report is listed below and copies of the full event reports are attached.

<b>Date of Event &amp; #</b> (00/00/00) (SAE or AE #)	<b>Description (3-5 words)</b> (GI bleed)	<b>Associated w/Study Drug</b> (yes/no/unknown)
--	--	--

Signature \_\_\_\_\_

\_\_\_\_\_ Date

\_\_\_\_\_ P.I.

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## APPENDIX J Continuing Quality Improvement

Date \_\_\_\_\_

Investigator's name/address \_\_\_\_\_

Dear \_\_\_\_\_,

As you are aware, problems associated with research involving human participants have received a great deal of attention over the past several years. The OSU- Center for Health Sciences Institutional Review Board (IRB) in conjunction with The Office of Research and Sponsored Programs (ORSP) will begin a new Continuing Quality Improvement (CQI) Program in 2003. The goals of the program are to increase the availability and visibility of ORSP as a resource for investigators and research staff and to ensure compliance with federal and state regulations regarding the protection of human participants in research.

The CQI program will consist of site visits from the Institutional Review Board (IRB) administrator and/or members of the IRB. Studies will be chosen after they are approved by the IRB.

The initial visit will be scheduled at the time the study is ready to begin enrollment. The purpose of this visit is to review the plans for study conduct with the investigator and the research staff.

The follow up visit will be scheduled to coincide with the enrollment of a participant. One of the purposes of this visit is to observe the informed consent discussion and ask permission from the participant to contact them later in the study for an assessment of their research experience. This visit will be scheduled once several participants are enrolled so review of study records and documentation can also be accomplished.

You and your research staff have been chosen to participate in the program through the study titled,

Please call Teri Bycroft at 699-8643 to schedule the initial site visit. The subsequent audits of your research may be scheduled or unscheduled.

Sincerely,

Teri Bycroft, Certified IRB Manager  
OSU-CHS IRB Administrator

Adapted from the Scripps Clinic and San Diego State University's CQI programs

NAME OF INVESTIGATOR: \_\_\_\_\_ IRB # \_\_\_\_\_  
NAME OF COORDINATOR(S): \_\_\_\_\_

### Research and Sponsored Programs (ORSP) CQI Program

**Second Visit Worksheet**

**Date:** \_\_\_\_\_

*Study Questionnaires:*

- Type of data recorded: reviewer verified that data recorded included variables approved by the IRB e.g. names, addresses, phone numbers, income, SS#, etc. Yes No

*Participant Characteristics and Eligibility Criteria:*

- Number of participants enrolled: reviewer asked to see documentation of the number of enrolled participants. Yes No

Number of participants enrolled \_\_\_\_\_

- Inclusion/Exclusion criteria: reviewer looked at documentation verifying that enrolled participants met the study selection criteria. Yes No

*Informed Consent Process and Procedures:*

- Obtaining informed consent: reviewer obtained a description of how consent is obtained from the investigator. Yes No
- Clinical Coordinator witnessed the consent process with an actual participant. Yes No
- Reviewer looked at consents to verify that valid [IRB approved] consents are being used. Yes No
- Consent documentation: reviewer looked at consents to verify that they are signed and dated by the participant and a witness. Yes No
- Reviewer verified that participants are given a copy of the consent. Yes No

Adapted from the Scripps Clinic and San Diego State University's CQI programs

NAME OF INVESTIGATOR: \_\_\_\_\_ IRB # \_\_\_\_\_

NAME OF COORDINATOR(S): \_\_\_\_\_

**Research and Sponsored Programs (ORSP) CQI Program**

**Second Visit Worksheet continued**

*IRB Documentation:*

- Reviewer verified that IRB approved protocol and consents are on file. Yes No

- Reviewer verified IRB correspondence is on file of initial approved letter, conditional approval letters and modification letters. Yes No

*Data Management and Record Keeping:*

- Data coding system: reviewer looked at and discussed system of coding information to protect confidentiality. Yes No
- General confidentiality procedures: reviewer assessed where data is stored and who has access to the data once recorded to ensure confidentiality procedures are being followed. Yes No

Signature(s) of person(s) conducting second visit:

Signature \_\_\_\_\_ Date \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Adapted from the Scripps Clinic and San Diego State University's CQI programs

NAME OF INVESTIGATOR: \_\_\_\_\_ IRB # \_\_\_\_\_

NAME OF COORDINATOR(S): \_\_\_\_\_

**Research and Sponsored Programs (ORSP) CQI Program**

***Evaluation from Investigator***

Was the process of IRB review satisfactory? Yes No

If not, why not? \_\_\_\_\_

What could ORSP do to improve the process? \_\_\_\_\_

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General Comments: \_\_\_\_\_

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Adapted from the Scripps Clinic and San Diego State University's CQI programs

NAME OF INVESTIGATOR: \_\_\_\_\_

IRB # \_\_\_\_\_

NAME OF COORDINATOR(S): \_\_\_\_\_

## Research and Sponsored Programs (ORSP) CQI Program

### **Initial Visit Worksheet**

**Date:** \_\_\_\_\_

*For sponsored clinical trials:*

- Did the Principal Investigator attend the start-up meeting?  Yes  No  N/A

If not, does the PI's knowledge of the protocol seem adequate?  Yes  No

- Did the Coordinator attend the start-up meeting?  Yes  No  N/A

If not, does the Coordinator's knowledge of the protocol seem adequate?  Yes  No

- Is the study drug/ device stored in a limited access area inside a locked cabinet?  Yes  No

If No, comment: \_\_\_\_\_

- Are the drug/ device accountability records adequate?  Yes  No

Comments: \_\_\_\_\_

*For all studies:*

- Who will obtain and return Medical Records? \_\_\_\_\_

- Record-keeping procedures (documentation in Medical Record, filing consent forms, initial IRB application, modifications to protocol, etc.) were reviewed.  Yes  No

- Recruitment methods reviewed with PI.  Yes  No

Comments: \_\_\_\_\_

- Recruitment materials reviewed with PI.  Yes  No

Comments: \_\_\_\_\_

Adapted from the Scripps Clinic and San Diego State University's CQI programs

NAME OF INVESTIGATOR: \_\_\_\_\_

IRB # \_\_\_\_\_

NAME OF COORDINATOR(S): \_\_\_\_\_

# Research and Sponsored Programs (ORSP) CQI Program

**Initial Visit Worksheet continued**

- The plan for obtaining informed consent (who, when, where) was reviewed.  Yes  No

Comments: \_\_\_\_\_

- A process is in place for ensuring that only currently approved informed consent form(s) will be used.  Yes  No

Describe: \_\_\_\_\_  
\_\_\_\_\_

- Continuing Review Process reviewed.  Yes  No  
With: \_\_\_\_\_

- Adverse Event Reporting reviewed.  Yes  No  
With: \_\_\_\_\_

- Procedures for reporting Serious Adverse Events and protocol violations were reviewed.  Yes  No  
With: \_\_\_\_\_

- The requirement to forward monitoring reports from the sponsor or CRO to ORSP was reviewed.  Yes  No

- Was the Study Coordinator prepared to initiate the study, including preparing adequate resource documents?  Yes  No

Signature(s) of person(s) conducting initial visit:

Signature _____	Date _____
Signature _____	Date _____
Signature _____	Date _____

Adapted from the Scripps Clinic and San Diego State University's CQI programs

NAME OF INVESTIGATOR: \_\_\_\_\_ IRB # \_\_\_\_\_

NAME OF COORDINATOR(S): \_\_\_\_\_

## Research and Sponsored Programs (ORSP) CQI Program

**Participant Follow-up**

**Date:** \_\_\_\_\_

**Follow-Up Interview with Research Participant**

**Date:** \_\_\_\_\_

Check method used for interview:

Telephone:

In person:

Written questionnaire:

Indicate the participant's responses to the following questions or attach completed questionnaire:

1. Were you given enough information about the study to make a good decision about whether or not to participate?

Yes  No

Comments: \_\_\_\_\_  
\_\_\_\_\_

2. Did you get most of your information from reading the consent form or speaking with the research staff?

Consent form

Staff

3. Was there anything about the study procedures that you wish you had known before you agreed to participate?

Yes  No

Comments: \_\_\_\_\_  
\_\_\_\_\_

4. Did you understand that the research study was voluntary and that you could quit at any time?

Yes  No

Comments: \_\_\_\_\_  
\_\_\_\_\_

Adapted from the Scripps Clinic and San Diego State University's CQI programs

NAME OF INVESTIGATOR: \_\_\_\_\_

IRB # \_\_\_\_\_

NAME OF COORDINATOR(S): \_\_\_\_\_

## Research and Sponsored Programs (ORSP) CQI Program

### ***Participant Follow-up continued***

5. *Were you satisfied with the way you were treated in this research study?*  Yes  No

Comments: \_\_\_\_\_  
\_\_\_\_\_

6. *Would you consider participating in another research study here?*  Yes  No

*If not, why not?* \_\_\_\_\_  
\_\_\_\_\_

Signature of person conducting follow-up interview:

Signature \_\_\_\_\_ Date \_\_\_\_\_

Adapted from the Scripps Clinic and San Diego State University's CQI programs

## **APPENDIX K**

Currently there is no Appendix K

## **APPENDIX L Request for Determination of Non-Human Subject or Non-Research Explanation of Appendix L**

*Federal regulations and OSU-CHS policy require IRB review of all research involving human subjects. The IRB reviews only activities that are research and involve human subjects, as defined in federal regulations and used by the CHS-IRB.*

*Some activities that may appear to be research involving human subjects do not meet the specific definitions of “research” and “human subjects” used in federal regulations and by the CHS-IRB, and thus may not be subject to IRB review. CHS policy charges the CHS-IRB with making this determination.*

*The CHS-IRB has developed an administrative procedure to assist in making this determination. Please read the definitions below of “research” and “human subject”. **If the planned activity is either not research or does not involve human subjects (according to the definitions below), then complete and submit Appendix L.** If the IRB concurs that the activity is not research involving human subjects, the activity will not be subject to review by the IRB. (If the activity meets the definition of “research involving human subjects”, do not submit Appendix L.)*

### **Determination of “Research”:**

**45 CFR 46.102(d):** Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes.

- A. A systematic investigation is one that involves a predetermined method for studying a specific topic, answering specific questions, testing specific hypotheses, or developing theory.
- i. Examples of systematic investigations include, but are not limited to, observational studies, interview (including those that are open-ended) or survey studies, group comparison studies, test development, program evaluation, and interventional research.
  - ii. Examples of activities that would not normally be considered systematic investigations include, but are not limited to, training activities (e.g., human subjects being trained to perform a certain technique or therapy such as art therapy or psychoanalysis), classroom exercises involving human subjects or human subject data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods.
  - iii. Although, continuous quality improvement (CQI) and quality assurance (QA) activities often follow a systematic method of gathering information the findings are generally utilized for internal program improvements and do not meet the definition of “research.” However, at any point if the CQI or QA activities are intended to be extended beyond a single individual or an internal program, e.g., publications or presentations, they would be considered “research” and an IRB determination would be required.
- B. To develop or contribute to generalizable knowledge requires that the results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program, e.g., publications or presentations. Examples of activities that are typically not generalizable include biographies and service or course evaluations, unless they can be generalized to other individuals, services, courses or concepts, and there is an intention to do so. In addition, classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices would also not typically be considered generalizable. However, theses or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable.

### **Determination of “Human Subject”:**

45 CFR 46.102(f): *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

- Intervention includes both physical procedures by which data are gathered (for example, venipuncture) 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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

- A. A study does not qualify as “non-human subject” research if data or information is obtained about living individuals.
- B. The study does not qualify as “non-human subject” research if data is obtained through intervention and interaction with an individual. Interaction or intervention involves direct human contact with individuals or manipulation of an individual's environment. Examples of intervention and interaction include the performance of physical exams, obtaining blood samples, performing x-rays, altering light, temperature, or student course materials, etc.
- C. To qualify as “non-human subject” the data cannot contain any of the following 18 identifiers:
1. Names;
  2. Geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent zip codes, except for the initial three digits of a zip code;
  3. All elements of dates (except year) for dates directly related to an individual (e.g., date of birth, admission);
  4. Telephone numbers;
  5. Fax numbers;
  6. Electronic mail addresses;
  7. Social security numbers;
  8. Medical record numbers;
  9. Health plan beneficiary numbers;
  10. Account numbers;
  11. Certificate/license numbers;
  12. Vehicle identifiers and serial numbers, including license plate numbers;
  13. Device identifiers and serial numbers;
  14. Web Universal Resource Locators (URLs);
  15. Internet Protocol (IP) address numbers;
  16. Biometric identifiers, including finger and voiceprints;
  17. Full-face photographic images and any comparable images; and
  18. Any other unique identifying number, characteristic, or code.
- D. To qualify as “non-human subject”, the Investigator must receive the data or specimens without any of the 18 unique identifiers described above.
- E. To qualify as “non-human subject”, a code or link cannot exist that could allow the Investigator to establish identity.
-

## Instructions for Completing Appendix L

1. **Principal Investigator Information:** Provide all information regarding the Principal Investigator. Provide off campus address only if the PI does not have a reliable campus address.
2. **Faculty Advisor:** If the Principal Investigator is graduate student OSU-CHS IRB requires that a Faculty Advisor be appointed to oversee the conduct of human research. Provide all information regarding the appointed Faculty Advisor.
3. **Study information:**
  - A. Provide the title of the research.
  - B. Give a summary of the proposed research to include: the research question; a brief description of the methodology; and a description of any interventions.
  - C. Describe the subject population that will be studied or reviewed. This should include the age and number of the subjects and how they will be recruited. It is important to identify who your research subjects will be, as the IRB must follow specific guidance and regulations for certain populations. Also indicate the type of data or specimens. Describe the methods in which this data or specimens will be collected, stored, and how confidentiality will be maintained.
4. **Determination of "Research":**

Indicate whether the data/specimen(s) will be obtained in a systematic manner and if the intent of collection is to contribute to generalizable knowledge.
5. **Determination of "Human Subject":**

Indicate whether the activity involves obtaining information about living individuals, intervention or interaction with a human subject, or access to identifiable private information.
6. **Signatures:**
  - A. The PI must sign the form.
  - B. The Faculty Advisor must sign the form if the PI is a student.
7. **Submit to the IRB:**

Submit the original form and one copy to:

Teri Bycroft, Assistant Director of Human Subjects  
Research  
1111 West 17<sup>th</sup> Street  
Tulsa, OK 72107

**Questions? Please contact the IRB office at 918-586-4609 or [teri.bycroft@okstate.edu](mailto:teri.bycroft@okstate.edu)**

## APPENDIX L: Request for Determination of Non-Human Subject or Non-Research

*Federal regulations and OSU-CHS policy require IRB review of all "research involving human subjects". Some activities that may appear to be research involving human subjects do not meet the specific definitions of "research" and "human subjects" used in federal regulations and by the CHS-IRB, and thus may not be subject to IRB review. CHS policy charges the CHS-IRB with making this determination.*

***If, after reading the Explanation above, you believe that the planned activity is either not research or does not involve human subjects, then complete and submit Appendix L. If the IRB concurs, the activity will not be subject to review by the IRB. (If the activity meets the definition of "research involving human subjects", do not submit Appendix L. Instead, submit application for IRB review.)***

### 1. Principal Investigator Information

First Name:		Middle Initial:	Last Name:
Department/Division:		College:	
Campus Address:		Zip+4:	
Campus Phone:	Fax:	Email:	
<b>Complete if PI does not have campus address:</b>			
Address:		City:	
State:	Zip:	Phone:	

### 2. Faculty Advisor (complete if PI is a student, resident, or fellow) NA

Faculty Advisor's name:		Title:
Department/Division:		College:
Campus Address:		Zip+4:
Campus Phone:	Fax:	Email:

### 3. Study Information:

A. Title

- B. Give a brief summary of the project. (See instructions for guidance)
- C. Describe the subject population/type of data/specimens to be studied. (See instructions for guidance)

**4. Determination of “Research”.**

**45 CFR 46.102(d):** *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy whether or not they are conducted or supported under a program which is considered research for other purposes.

**One of the following must be “no” to qualify as “non-research”:**

- A. Will the data/specimen(s) be obtained in a systematic manner?  
 No  Yes
- B. Will the intent of the data/specimen collection be for the purpose of contributing to generalizable knowledge (disseminating the knowledge obtained outside of Oklahoma State University, e.g., presentation or publication)?  
 No  Yes

**5. Determination of “Human Subject”.**

**45 CFR 46.102(f):** *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example venipuncture) 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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

- A. Does the research involve obtaining information about living individuals?  
 No  Yes  
**If no, then research does not involve human subjects, no other information is required.**  
**If yes, proceed to the following questions.**

**All of the following must be “no” to qualify as “non-human subject”:**

- B. Does the study involve intervention or interaction with a “human subject”?  
 No  Yes
- C. Does the study involve access to identifiable private information?  
 No  Yes
- D. Are data/specimens received by the Investigator with identifiable private information?  
 No  Yes
- E. Are the data/specimen(s) coded such that a link exists that could allow the data/specimen(s) to be re-identified?  
 No  Yes  
 If “Yes,” is there a written agreement that prohibits the PI and his/her staff access to the link?  
 No  Yes

**6. Signatures**

Signature of PI \_\_\_\_\_ Date \_\_\_\_\_

Signature of Faculty Advisor \_\_\_\_\_ Date \_\_\_\_\_  
(If PI is a student)

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**Leave blank: To be completed by IRB**

- Based on the information provided, the OSU-CHS IRB has determined that this project **does not** qualify as human subject research as defined in 45 CFR 46.102(d) and (f) and **is not subject to oversight by the OSU IRB.**
  
- Based on the information provided, the OSU-CHS IRB has determined that this research **does** qualify as human subject research and **submission of an application for review by the IRB is required.**

\_\_\_\_\_  
Dr. Stephen Eddy, IRB Chair

\_\_\_\_\_  
Date

