Oklahoma City University

Institutional Review Board

Procedures and Guidelines

The authority for evaluating research involving human subjects conducted on the Oklahoma City University campus or by Oklahoma City University employees or students is vested in the Institutional Review Board (IRB). Members of the IRB are appointed by the Provost. (Effective date January 26, 2005).

Overview

Prior to initiation of any research project that involves the use of human subjects and is conducted by Oklahoma City University (OCU) faculty, staff, or students, the project must be reviewed and approved by the OCU Institutional Review Board (IRB)[1].

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

Human Subject means a living individual about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information[2].

The IRB performs the review to protect the rights and welfare of human subjects involved in research and to assist the investigator and the University in the mutual obligation to comply with all federal, state and OCU policies with respect to these subjects. IRB approval must be obtained if any of the following circumstances apply:

- The research is sponsored by OCU;
- The research is conducted by or under the direction of any OCU employee or student in connection with his or her responsibilities;
- The research is conducted by or under the direction of any OCU employee or student using any subjects, property or facility at OCU or any location identified with the University; and
- The research involves the use of OCU's non-public information to identify or contact human research subjects or prospective subjects.

Graduate student research involving human subjects conducted in conjunction with a thesis or other graduation requirement must be reviewed by this committee. Graduate and undergraduate student research projects that are for educational purposes only and that involve human subjects **may** require IRB review. Such classroom projects that involve human participants are not subject to review **if and only if**: (1) the research does not include topics of a sensitive or personal nature; (2) the participants in the study will be limited to OCU students who volunteer to participate; (3) no minors (individuals under 18 years of age) or other protected groups are involved in the research; **and** (4) the project will not involve dissemination of any kind (including but not limited to public presentation outside of the classroom, publication, posting of findings on a webpage, etc. are ordinarily exempt from this process. When IRB review is not required it is recommended that faculty members who assign such projects require the students to complete a similar application and serve as the review board for the students' projects, in order to educate students about the process of completing and submitting an application to the IRB.

PHRP Course refers to the Protecting Human Research Participants course offered by the National Institutes of Health (NIH). This is an online course that is offered free of charge. The training program requires 1-2 hours to complete. Upon completion of the course requirements the user may print out a certificate of completion. This certificate of completion must be attached to the IRB application, and is required of all persons named on the application as a Project Director or Co-Project Director. This course will not need to be repeated unless updated information is released through the program. The PHRP course is available online at https://rit.sr.unh.edu/training/rcr-training/human-subjects.html . Users must

register online to take the course and are responsible for maintaining their username and password themselves.

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[1] This document is based on Title 45 Code of Federal Regulations Part 46 Protection of Human Subjects. The text of these regulations is available from a National Institutes of Health website (Re*gulations and Ethical Guidelines-Title 45 CFR Part 46-Protection of Human Subjects*. Retrieved 12-21-2004 from National Institutes of Health Office of Human Subjects Research Website: http://ohsr.od.nih.gov/guidelines/45cfr46.html).

[2] Non-identifiable private information used in research must be reviewed under the exempt process and therefore must also be submitted to the IRB.

The Application and Approval Process

A completed Institutional Review Board Application Form along with a complete copy of the protocol and consent form (if necessary), and any supporting documents must be delivered to the chairperson of the IRB in MS Word format on disc or as an e-mail attachment, along with one signed paper copy. The application must include the following:

1. Institutional Review Board Application Form
2. Research Protocol
3. Consent Form
4. Questionnaires/surveys (required if used)
5. Advertisements (required if used)
6. Copy of certificate(s) of completion of Protecting Human Research Participants (PHRP) course for each Project Director and Co-Project Director named on the application form.

The chairperson of the IRB will perform the initial review of the application to see if there are problems easily found and corrected, and to determine whether the proposed research meets the criteria for exempt or expedited review status (see the following sections), or whether the proposed research must be reviewed by the full IRB. After this review the chairperson of the IRB will notify the Project Director (PD) of any action, or of any need for revision.

For any proposed research that requires full IRB review the appropriateness of the protocol will be examined in relationship to the research question. The risks to the subjects will be compared to the direct benefit. The involvement of protected groups will be assessed. The consent form will be assessed in detail to ensure that the purpose is conveyed accurately, the study is described in sufficient detail for the subject to decide what is involved, and the risks and benefits are outlined. The PD may be invited to attend the IRB meeting. Four outcomes are possible:

- Approval
- Approval contingent upon changes or clarifications
- Deferral with the protocol and/or consent form needing significant revision before submission can be reviewed again by the Committee.
- Disapproval.

Following full IRB review a letter to the PD outlining the IRB's decision concerning the study will be prepared. If applicable, the letter will address the steps and changes needed to re-submit the study to the IRB. The letter will be ordinarily be available 48 hours after the IRB's meeting.

The PD should review the letter to be sure any changes recommended will not misrepresent the study to the subject. If such problems exist, the PD should request an appeal to the IRB. If the study was approved contingent upon changes, timely submission of revisions will be followed by review by the chairperson of the IRB. If adequate changes have been made and all questions answered, immediate approval may be granted. If the study was deferred or disapproved, resubmission to the entire IRB is required. The chairperson cannot overrule the deferral or disapproval. In the case of a deferral or disapproval, the chairperson may also speak with the PD personally to facilitate the resubmission process.

Approval is granted for a period of one year. Once initial approval is granted, continued contact with the IRB is required. These contacts are listed and covered in detail in the Continuing Compliance section.

The chairperson of the IRB determines whether studies meet the criteria for exemption or for expedited review. In these cases, the PD is notified by letter. Exempt and expedited studies, as well as studies that required approval by the convened IRB, are filed with the Office the Vice President for Academic Affairs with all other active studies. The PD is responsible for immediately reporting all amendments to the protocol as well as closure of the study to the IRB Chair.

Criteria for EXEMPT Status

The chairperson of the IRB may exempt from convened IRB review research activities in which the only involvement of human subjects will be in one or more of the following six categories.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Source: The Federal Policy (Common Rule) for the Protection of Human Subjects, which was published in the Federal Register on June 18, 1991 (56 FR 28003).

Criteria for EXPEDITED Review[1]

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

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

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

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

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

8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998

Instructions for IRB Application Form

The IRB Application Form requests information that is central to the protocol. It serves as a "cover sheet," providing a summary of the protocol for those who will be reviewing it. Since it is the central information source for the study ALL QUESTIONS MUST HAVE AN ENTRY, even if that entry is "not applicable" or "none". As most of the entries are self-explanatory, only those that require some explanation are listed below. A copy of the application form is provided in the appendix.

Project Title: The entry should match verbatim the title of the protocol and the title on the consent form. Only in special circumstances should it be different from the consent form, and then only if including the title would affect the enrollment of subjects or prejudice the research to be done.

Project Director: The PD must be an OCU faculty member. This person does not necessarily have to be the first author on the manuscript that is published later, but must be responsible for overseeing all aspects of the research and communicating with the IRB. An individual in a student status, such as a graduate student, may NOT be listed as the PD, but may serve as Co-PD. List the telephone number, fax number, e-mail address and campus address where the PD wishes to be contacted.

Co-Project Director(s): The individuals(s) who are directly involved in the design and management of the research project. If research is being done for degree requirements, the Co-PD is the graduate student.

Certificate(s) of Completion: Each person listed as PD and Co-PD must separately complete the Protecting Human Research Participants Course. Their certificates of completion must be attached to the application.

Collaborating Investigator(s): The investigators who are involved in enrolling subjects and conducting the study at various locations are considered collaborating investigators. Typically these individuals are not involved in the design and management of the study.

Sponsor: If the proposed project will be supported wholly or in part by any external funding agency or through internal (institutional) resources list all sources of support.

Study Sites: Specify the location(s) on the OCU campus the proposed research will be completed.

Off-Campus Sites: List any and all off-campus sites to be utilized in carrying out the proposed research. In many cases those sites may have their own requirement for IRB review. In those cases a copy(ies) of the IRB approval for those sites must be included in the application.

Study Population: Complete each section.

> **Age Range**: This should be the actual age range with a beginning and end point, for example 18-65, not a general statement such as children, adults. Children are defined as less than 18 years, while elderly are considered 65 years old and older.
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> **Gender:** Please mark appropriately. Be aware that many funding agencies require women and minorities of all ages be included for participation in research projects unless reasons for exclusion are specifically justified in the protocol.
>
> **Special Qualifications**: These are typically the inclusion criteria. Please condense if very lengthy or attach an inclusion criteria page. Do not merely state the page in the protocol.
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> **Number of Subjects/Healthy Volunteers**: Please include the number of participants anticipated. This should be a realistic estimate expected for the duration of the study in order to answer the research question.

Exclusions: These are typically the exclusion criteria. Please condense if necessary, attach a page, or state "none".

Protected Groups: These individuals are ones specifically named as protected in the federal regulations governing research. These include children, pregnant women and fetuses, prisoners, and mentally disabled. If you plan to use any subjects from these groups, please contact the IRB Chairperson for the criteria and policies governing the specific group.

Protocol/Consent Form References: Specify where in the protocol and the consent form the listed categories of information may be found.

Request for Exempt or Expedited Review: Upon review of the criteria, the PD may request that an application be considered for exempt or expedited review. The PD should indicate on the application form the number corresponding to the category under which exemption or expedited review is being sought. The Committee Chair will determine whether it meets the criteria for exempt or expedited review. Under appropriate circumstances the Committee reserves the right to require full Committee review of any application.

Signatures: All signatures must be original (not a stamp) of the person listed as PD. It specifically attests that this person accepts the responsibilities of the PD, as outlined above, and has the complete agreement of the other investigators in the protocol and consent process.

The Research Protocol

The required sections of the research protocol are provided below. If the application submission is in conjunction with a grant application, the PD should submit the pertinent sections of the grant application; the entire grant application is not required because much of it does not pertain to this review.

Purpose and Objectives: Explain the purpose of the research project, including the importance of the knowledge that may reasonably be expected to result. The IRB must have sufficient information to determine that risks associated with the research are reasonable in relation to anticipated benefits.

Background Information: Include a paragraph that describes the importance of the study to the IRB.

Research Design: Limit this section of the protocol to those aspects of the research project that deal specifically with human subjects.

- Study Population – Describe the manner in which subjects will be selected. The Committee must have sufficient information to determine that selection of subjects is equitable and that adequate consideration has been given to potential consequences of participation for each subject. This section should verify that all appropriate populations are included in this study. This includes minorities, women and children as appropriate to the research being conducted. The study population must be chosen in accordance with all federal guidelines.

- If subjects are to be solicited through advertising, a copy of the ad must be submitted for approval. Description of the study population should include the following: (1) Inclusion/Exclusion Criteria; (2) Duration of Participation, and (3) Early Termination Criteria.

- Methods and Procedures – Describe, in detail, research procedures involving human subjects. The Committee must have sufficient information to determine that procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Data Collection, Analysis, and Confidentiality – Describe procedures for data collection and analysis. The Committee must have sufficient information to determine that safety and privacy of subjects will be protected, and that procedures will yield meaningful research findings to justify the use of human subjects.

References – Provide a list of references that support the protocol.

Appendices – Include as appendices the survey instrument, proposed advertisements, data collection forms or any other supplemental material that will facilitate the review process.

Informed Consent Form

Remember that informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provisions of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. The informed consent document should be written in lay language that is understandable to the study population.

In writing the document, think of it as a teaching tool. Although either first (I) or second (you) person is acceptable, second person appears less coercive and more reader friendly. The "person" used should be consistent throughout the document. The only exceptions are the introduction and the final paragraph prior to signature, which should always be in first person.

Federal Regulations require that certain information be included in all research consent documents. These informational items are as follows:

- Statement that the study involves research
- Explanation of the purpose(s) of the research
- Duration of the subject's participation
- Identification of any experimental procedures and/or drugs
- Description of procedures to be followed
- Reasonable foreseeable risks or discomforts
- Direct benefits reasonably expected
- Appropriate alternative procedures or treatments
- Extent of confidentiality of records
- Availability of compensation
- Information regarding availability of medical treatment
- Who to contact with questions about the research project
- Who to contact with questions about rights as a research subject
- Statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits otherwise entitled
- Statement that subject may discontinue participation at any time without penalty or loss of benefits.

Other issues to be addressed if appropriate to the research proposal are:

- Statement that participation may involve other unforeseeable risks
- Circumstances under which participation may be terminated by the PI
- Additional costs to the subject
- Consequences of early withdrawal
- Statement that significant new findings will be provided to subject.

The final paragraph and signature lines should not be alone on the final page of the consent as it could appear that the consent was not attached.

Continuing Compliance

All correspondence, including progress reports and amendment requests, should be delivered to the chairperson of the IRB. Provide the PD name and Application Number on all correspondence relating to an existing study.

When a study is approved by the IRB, an approval letter is sent to the PD. This letter states that the approval is for a specified period, usually one year. In some cases, approval will be less than one year or will be for a specific enrollment of subjects. To maintain the study in active status, a Periodic Progress Report (PPR) is required each year.

The PPR must be reviewed by the chairperson of the IRB and approved by the IRB during the anniversary month in order for the study to be in compliance with federal regulations. To facilitate this process, the chairperson of the IRB will notify the PD 10 weeks prior to the due date. If no response to the first notice is received, a second notice is sent. The study is inactivated if the IRB does not receive the PPR before the due date. Notification of this action is sent to the PD.

The PPR must contain the following:

- Status of the Study
- Number of Study Subjects
- Study Results
- Adverse Effects, if any
- Signature of the PD

After review of the complete PPR, the Committee may extend the study for another year. Upon completion of the study, a PPR is forwarded to the Committee with the final study results.

Amendments or Modifications to the Approved Study

It is the responsibility of the PD to ensure that the study is conducted as approved by the IRB. The chairperson of the IRB must approve modification to the protocol or consent form, requested by the investigator or sponsor, before changes are implemented. Such modifications are known as amendments. This could include an increase in numbers enrolled, change in age range, change in risks from study drug or procedure or any form of new recruitment tool that is to be used to attract subjects.

Amendment requests must be made in writing by the PD and be submitted to the chairperson of the IRB. Supporting documentation must be included with the request. The chairperson of the IRB reviews the request and, if approved, the PD is informed through a letter. The chairperson of the IRB has the authority to present the amendment request to the convened IRB for approval. If the proposed amendments significantly alter the original study protocol, the chairperson of the IRB may request that a revised study be submitted as a new study, subject to IRB approval.

Advertisements/Recruitment Material

Any document which is to be used as an advertisement or recruitment tool must be reviewed and approved by the IRB prior to its use. This includes, but is not limited to, flyers, media (newspaper, radio, TV) advertisements, press releases, internet advertisements and brochures. The IRB must review the final advertisement as well as the draft copy. In addition, all publicity related to University sponsored activities must be approved by the OCU University Relations office. This approval process is IN ADDITION to the IRB review of advertisement and does not take the place of IRB approval.

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