

**Oklahoma State University Institutional Review Board
Standard Operating Procedures**

Criteria for IRB Approval

SOP #	RR-402
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Revision #	1
Approval: IRB	02/10/2016

1. POLICY

All research proposals that intend to enroll human subjects must meet certain criteria before 1) the IRB can approve the activity, 2) recruitment of subjects can begin, and 3) study-related procedures can be initiated. The criteria are based on the principles of justice, beneficence, and respect for persons (i.e. autonomy), as discussed in the Belmont Report and specified below. In addition, other criteria that are unique to Oklahoma State University may apply and must also be met.

Specific Procedures

1.1 Minimal Criteria for Approval of Research

In order for a research project to be approved, the IRB must find that:

1.1.1 Risks to subjects are minimized:

by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate,

by using procedures already being performed on the subjects for other purposes.

1.1.2 Risks to subjects are reasonable in relation to any anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research).

The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

1.1.3 Selection of subjects is equitable.

In making this assessment the IRB should take into account the purpose of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Recruiting materials, including letters, flyers, language to be used in email and/or social media, advertisements, and posters must be provided to the IRB for review. If an advertisement is recorded for broadcast, the IRB will need to review the final audio or video

recording.

1.1.4 Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate state and federal ([§46.116](#)) regulations, as will child assent and parental/guardian permission.

1.1.5 Informed consent will be appropriately documented in accordance with and to the extent required by state and federal ([§46.117](#)) regulations, as will child assent and parental/guardian permission.

1.1.6 Where appropriate, the research plan makes adequate provision for monitoring the data collected to protect the rights and welfare of subjects.

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

1.1.8 When some or all of the subjects, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence, or for subjects found at international sites, the IRB is likely to look to confirm that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

1.1.9 The necessary resources are available, including:

sufficient time to conduct and complete the research; adequate numbers of qualified staff; adequate facilities; a process to ensure that those assisting with the research are adequately informed about the protocol and their research-related duties and functions; and adequate medical or psychological resources are made available that participants might require as a consequence of participating in the research.

For sponsored research projects, the IRB, or IRB office staff member, must review a copy of the research proposal and the terms and conditions of the grant, contract, or cooperative agreement.

1.1.10 Studies are reviewed at intervals appropriate to the degree of risk posed to research subjects, not less than once per year, and the IRB shall have authority to observe or have a third party observe the consent process and the research.

Studies may be reviewed more frequently than annually

if the IRB believes that the study population is especially vulnerable.

if the IRB believes that previous studies indicate high incidence of unanticipated problems involving risks to subjects or others and/or adverse events.

if the IRB believes close monitoring is indicated.

If the IRB determines that a study that was approved for annual review requires closer monitoring, the IRB will make a determination to review the study on a more frequent basis. The reasons for such a determination will be included in the minutes and communicated to the investigator.

1.2 Other Criteria

The IRB may require verification of information submitted by an investigator. The need to verify any information will be determined by the IRB at a convened meeting, unless the proposed research qualifies for expedited review. The purpose of this verification will be to safeguard the rights and welfare of the subjects, when deemed appropriate by the IRB.

The criteria used to determine whether third-party verification **may be** required include:

- studies that involve vulnerable populations,
- investigators who conduct studies that involve a potential high risk to subjects,
- investigators who conduct studies that involve large numbers of subjects, and
- investigators who are selected at the discretion of the IRB.

The IRB will determine at a convened meeting which projects need third-party verification from sources other than the investigator.

1.3 Reliance on Other IRBs

The Oklahoma State University IRB is able to enter into joint review arrangements known as written authorization agreements with an institution possessing a Federalwide Assurance, rely upon the review of another qualified, assured IRB, and make similar arrangements with other assured institutions in order to avoid duplication of effort,. Each institution must update its institutional Federalwide Assurance (FWA) **if deemed necessary**.

2. SCOPE

These policies and procedures apply to all IRB staff and IRB members, as well as to research proposals submitted to the IRB.

3. RESPONSIBILITY

The IRB Coordinator is responsible for ensuring that IRB reviewers have all of the tools and resources they need to complete their research study reviews.

The IRB Manager, or her or his designee, is responsible for providing IRB members with ongoing training and guidance regarding protocol review and approval.

IRB members are responsible for conducting thorough reviews and for making appropriate approval decisions for research reviewed and for making appropriate approval recommendations for consideration by the IRB at convened meetings.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

RR 402-A	IRB Reviewer Guide
RR 402-B	IRB Review Sheet
RR 402-C	IRB Review Sheet — Waiver/Alteration of Informed Consent
RR-402-D	IRB Review Sheet — Waiver of Documentation of Informed Consent

RR-402-E
RR-402-F
RR-402-G

Review Sheet — Expedited Review of Research Involving Children
IRB Review Sheet - Review of Research Involving Children
IRB Review Sheet — Review of Research Involving Prisoners

7. IMPLEMENTATION OF PROCEDURES

Who	Task	Tool
<i>IRB Coordinator</i>	Provide reviewers with IRB Reviewer Guide and appropriate IRB Review Sheet(s).	IRB Reviewer Guide-RR-402A IRB Review Sheet(s) RR-402-B-G
<i>IRB Manager</i>	Provide training in research review and approval to IRB members.	
<i>IRB Manager</i>	Develop review guidance materials as needed.	
<i>IRB Member</i>	Review research protocols, summarize findings, and make appropriate approval decisions and recommendations.	IRB Review Sheet(s)

This guide is prepared to assist IRB members with the review of research involving human subjects as presented in the OSU IRB application form.

1. Purpose

The purpose of the research should be thorough enough that a reader not familiar with the discipline can still understand the basic elements of what the subjects are to be doing and the purpose for subjecting them to being subjects in research. This sets the context for evaluating the risks posed to subjects compared with the benefits expected to result from the research.

2. Subject Description and Selection

The investigator is responsible for providing the following information:

- Description of the population from which the subjects will be selected. If the subject population is one covered by “special population” regulations (children, prisoners, pregnant women, and fetuses), then the relevant subcode of the regulations (45 CFR 46) applies.
- Description of the sampling methodology (random, snowball, etc).
- Description of how the subjects will be solicited. Copies of any scripts (including those to be used in email and/or social media), flyers, advertisements, posters, or letters that may be used to recruit subjects must be attached. Researchers can find guidance on what these should and should not contain on the IRB website at <http://compliance.okstate.edu/irb/irb-index> or in the IRB Member Handbook.
- An estimate of the maximum number of subjects that are to be enrolled in the study.
- The length of time the subjects will be actively involved in the study, including the number of individual interactions.
- The calendar time frame during which active data collection will occur. The IRB can approve an application for a maximum of one year. Research studies requiring more than one year to collect data will need to apply to the IRB for continuation review each year the study is to remain active.
- Any follow-up procedures (if YES, then look very carefully at how the investigator is protecting data, whether she or he has informed subjects of follow-up, and how she or he intends to accomplish this.)

3. Methodology

The application should include a description of where the study will take place. **The IRB requires documentation of approval from appropriate authorities for research to be conducted at any location outside of OSU (i.e., schools, clinics, prisons, other universities, etc).** The description should detail exactly what each subject will be asked to do, including:

- the topic areas of any instruments or tests (copies of all questionnaires, tests, surveys,

instructions or scripts to be used must be provided);

- interviews (including a description of the topic areas to be covered in the interviews);
- medical procedures;
- physical exercises;
- any other activities that the subjects will be asked to complete;
- audio or video recording;
- identification of any procedures or products that are experimental;
- any possible discomforts or inconveniences that the subject might experience.

For observational studies, the description should include any manipulations of the subjects and the behaviors to be recorded.

4. Additional Personnel

List any undergraduate or graduate research assistants, and/or any members of the community who will be involved in the recruitment, consent process, data collection and/or analysis. Names are not necessary. Include a description of the training and the protection of human research that these individuals will be required to complete.

5. Possibility of stress to subjects

There is nothing wrong with stating that there is a possibility of stress. However, the investigator is required to state how she or he will respond to any issues that could arise from that, how the subject is informed of the possibility of stress, and why stress may occur, etc. This is to ensure that subjects are protected from undue risk from participating in a study.

If there is a possibility of an adverse reaction to the research of any kind (physical, emotional, or psychological), then this possibility should be discussed in this section as well as how the investigator plans to address these issues.

6. Medical clearance required?

If yes, the investigator must clarify how this clearance will be obtained. The IRB will rely on the members from the medical profession to ensure that the process is satisfactory.

7. Deception

If subjects are to be deceived or misled in any way for purposes of the research, the PI should explain and justify why the methodology requires deception. If subjects have been deceived, there must be a debriefing upon the completion of the study clarifying the true or complete intent of the research. The debriefing procedures should be included. For more information on this issue, please consult the IRB Member Handbook.

8. Personal or sensitive information asked?

If data of a personal or sensitive nature is to be requested, the investigator should provide justification for this as well as assurance that appropriate safeguards are in place to ensure protection of confidentiality of subjects and data. The investigator must also provide assurance that subjects have an avenue for recourse in the event that they react adversely.

9. Materials that may be considered offensive, threatening or degrading

Investigators should describe any materials that might be considered offensive, threatening or degrading.

Investigators should also include steps to be taken if problems arise.

10. Inducements offered

Here the investigator should describe the inducements and ensure that there is no undue influence that could compromise a prospective subject's examination and evaluation of the risks or affect the voluntariness of her or his choice because of the inducement, and that there are equal opportunities provided for those not wishing to participate. Also it should be clarified how much of the study must be completed by subjects before they get the inducement. This is very relevant when course credit is offered.

11. Consent process

Investigators should discuss how they will go about obtaining informed consent from the subjects including how consent will be documented and how they will minimize coercion or undue influence. Consent form examples can be found on the IRB webpage, located at <http://compliance.okstate.edu/irb/irb-index> . Reviewers are responsible for ensuring that all the elements required of informed and voluntary consent are present in whatever methodology investigators propose to use. This includes:

- statement that this is a research study, conducted by whom, and the investigator's affiliation
- description of study and what subjects are to be asked to do in language that the subjects can understand (this may be done orally and/or in writing). More than one form may be appropriate when a diverse sample is used
- definition of exactly what the subjects will be expected to do in language they understand, where it will take place, how long it will take, and what investigators intend to do with the data
- how the investigators intend to protect confidentiality of the subjects and their responses. If any identifiers are to be used, subjects must give permission.
- any follow-up planned, and how subjects will be re-contacted
- what investigators plan to do with the results
- explanation of risks (real and potential), including social, economic, medical, psychological, as appropriate and any benefits to particular subject. Note differences here for special populations.
- clarification that all participation is voluntary, and subjects do not have to complete their participation
- definition of any inducements offered and what subjects have to do to get them
- contacts: IRB contact for research subjects' rights; investigator contact information

Note: parents must provide permission for minor children.

The consent form, if written, should be appropriate for the particular study, and not just reiterate the requirements above, and appropriate for the sample population. This includes the language level (we normally request a 6th grade reading level when the population is drawn from the general public). If consent is conducted orally; how, when and where the consent process is to take place must be clearly stated in the protocol. A script must be provided for IRB approval. Subjects should have ample time to ask questions during the consent process before the study takes place.

12. Waiver of Documentation of Consent

Signed consent is not always required nor always appropriate for a particular study. The IRB may waive the requirement for written documentation of consent in cases where:

1. The principle risks are those associated with a breach of confidentiality concerning the subject's participation in the research; and the consent document is the only record linking the subject with the research; or
2. The research presents no more than minimal risk and involves procedures that do not require written consent when performed outside of a research setting.

In such situations, investigators must document how their research meets one of the two criteria listed above. The IRB normally requests that subjects be provided with a "Participant Information Sheet" that contains the elements of an informed consent form, but does not require signature. Alternately, a script of proposed oral discussion can be prepared for situations where personal interaction will not occur (i.e., telephone surveys). Both of these items should be submitted for IRB review with the application.

13. Waiver of Informed Consent

There are certain research methodologies which can not be practicably carried out without a waiver of some or all of the [required elements of informed consent](#). In these special cases, investigators must demonstrate that the confidentiality of subjects will be adequately protected. The informed consent process can be modified or waived for research that is documented to meet all of the following criteria:

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

In such situations, investigators must document how their research meets the criteria listed above.

14. Identifiable Records

If investigators plan to maintain any link to the identity of the subjects for any period of time, this should be described along with how the linking information will be secured (location, who will have access, how long it will be maintained).

15. Confidentiality

If identifiers of any sort (e.g., names, ID numbers, email addresses, etc.) are to be associated with data, justification must be provided. Investigators should address how the data will be handled and stored such that the privacy of the subjects is protected. This information should include where the data will be stored, who will have access to it, how long the data will be kept and how the data will be reported. The increasing vulnerability of networked, internet accessible computers may dictate that sensitive data be stored on media that is not networked. The description should specifically address the use, storage and disposition of audio/video recordings. If recordings are to be used for future research or training purposes, this must be explained in the protocol application and specifically stated in the consent form(s). If the subjects' participation in the study will be made part of a record accessible by a supervisor, teacher, or employer, investigators must address the risk this information could pose to subjects.

16. Subject's Participation

Investigators must state if any information about the subject's involvement in the research will be revealed to a supervisor, teacher, or employer and describe what information will be made available. This is important in assessing any risks posed to the subject.

17. Translations

If any translations to languages aside from English are part of the study, the Translation Declaration Form must be included in the application.

18. Benefits

Investigators should discuss any direct benefits accruing to subjects as a result of their participation (e.g. results of testing) in the research. This should not include payments or extra credit, as these are considered compensation and should be addressed in the applicant's response to question 10. If there are no known benefits to the subjects, this should be clarified in this section. Investigators should also discuss benefits to the general class of subjects (e.g. veterans with PTSD) and/or society at large

IRB MEMBER REVIEW SHEET

THE FOLLOWING TO BE COMPLETED BY THE REVIEWER

IRB #

IRB ACTION:

- Approved**
- Approved with conditions** (the research procedures are approved; however, final approval is pending receipt of external documentation as specified, i.e. school permissions, second IRB approval, etc)
- Pending Revision**
- Designated for Full Board Review**

Comments:

Reviewer Name (typed):

Date:

IRB MEMBER REVIEW SHEET
WAIVER/ALTERATION OF INFORMED CONSENT SUPPLEMENT

IRB #: _____

All of the criteria listed below must be met before any waiver or alteration of the consent process may be allowed. Please check those that have been met.

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

COMMENTS

Reviewer Name (typed):

Date:

WAIVER OF DOCUMENTATION OF INFORMED CONSENT**THE FOLLOWING TO BE COMPLETED BY THE REVIEWER****IRB #****This application requests a waiver of documentation of informed consent.****Either of the criteria listed below must be met before the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects:**

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

Or

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

IRB ACTION:

- Approved**
- Approved with conditions** (the research procedures are approved; however, final approval is pending receipt of external documentation as specified, i.e. school permissions, second IRB approval, etc)
- Pending Revision**
- Designated for Full Board Review**

COMMENTS:

Reviewer Name (typed):

Date:

THE FOLLOWING TO BE COMPLETED BY THE REVIEWER**IRB Number:**

For expedited review of **minimal risk** research involving children, the reviewer must indicate agreement/non-agreement with the following statements:

Agree

Disagree

The proposed research does not involve greater than minimal risk

Adequate provisions are included for parent/guardian permission

Adequate provisions are included for assent of the child, when appropriate

IRB ACTION:**Approved****Approved with conditions** (the research procedures are approved; however, final approval is pending receipt of external documentation as specified, i.e. school permissions, second IRB approval, etc)**Pending Revision** (revisions are required before the research can be approved)**COMMENTS:****Reviewer Name (typed):****Date:**

IRB #:

§46.404 Research not involving greater than minimal risk. Agree Disagree

The proposed research does not involve greater than minimal risk

Adequate provisions are included for parent/guardian permission

Adequate provisions are included for assent of the child

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. Agree Disagree

The proposed research does involve greater than minimal risk

The risk is justified by the anticipated benefit to the subjects

The risk/benefit relationship is at least as favorable as that of available alternatives

Adequate provisions are included for parent/guardian permission

Adequate provisions are included for assent of the child

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Agree Disagree

The proposed research does involve greater than minimal risk

The risk represents a minor increase over minimal risk

The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations

The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition

Adequate provisions are included for parent/guardian permission

Adequate provisions are included for assent of the child

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

IRB ACTION:

- Provisionally Approved** (the research procedures are approved; however, final approval is pending receipt of external documentation as specified, i.e. school permissions, second IRB approval, etc)
- Approved**
- Pending Revision**

Comments:

Reviewer Name (typed):

Date:

IRB MEMBER REVIEW SHEET
REVIEW OF RESEARCH INVOLVING PRISONERS

IRB Application #:

All of the requirements listed below must be met before this research can be approved. Please check those that have been met.

- The research under review represents one of the categories of research allowed under [§46.306\(a\)\(2\)](#) as follow;
- Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or
 - Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.
- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- The information is presented in language which is understandable to the subject population;
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the

research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Comments:

Reviewer Name (typed):

Date: