Northern Oklahoma College
Policy for Institutional Review Board for Research Proposals

OVERVIEW:

Because Northern Oklahoma College wishes to encourage academic scholarship while providing a safe environment that protects all rights of research participants, an Institutional Review Board (IRB) will be responsible for reviewing all requests for research studies that involve Northern Oklahoma faculty, staff, or students. Research projects must be approved whether conducted by a Northern Oklahoma College employee or an external agent. (Student research, as part of a graded course at Northern, will normally be considered exempt from this policy, if human participants are not involved or if interview techniques for the research represent no risk to the participants.) The IRB will be an institutional committee chaired by the Vice President of Academic Affairs (or his or her designee) and staffed by NOC faculty and administrative staff who currently hold terminal degrees.

As part of the approval process, research investigators are asked to review the application for IRB approval (see attached) and determine if the proposal qualifies for an exempt, expedited, or full review.

1. If the investigator determines that the proposal qualifies for an "exempt" review (that is, there is no risk to human subjects), an application will be submitted to and reviewed by the IRB Chair. If the Chair agrees that the proposal qualifies as "exempt," the proposal may be approved with the Chair's signature. If the Chair cannot verify that the proposal qualifies as exempt, the application may be reviewed by two other members of the IRB Committee and/or may be returned to the investigator for further clarification through a revised application and, if needed, a reclassification as an expedited or full review.

2. If the investigator determines that the proposal qualifies for an "expedited" review (that is, there is minimal risk to human subjects), an application will be submitted to the IRB Chair and will be reviewed by two members of the IRB Committee, at least one of whom should have subject matter background. The application may be approved, denied, or returned to the investigator for further clarification through a revised application and, if needed, a reclassification as a full review.

3. If the investigator determines that the proposal qualifies for a "full" review (that is, there is a possibility of a higher level of risk to the participants), the application will be reviewed by a minimum of four members of the IRB Committee. If they determine that the appropriate precautions have been put in place to manage participant risk, they will approve the research study contingent upon the approval of the President; however, Northern Oklahoma College does not support research projects involving participants under the age of 18 in any category other than "exempt" status, in which there is no risk evident for the participants. If they determine that there are insufficient precautions in

place, the application will be denied, and the investigator will have the opportunity to submit one revised version after a 30-day waiting period.

All applications, regardless of classification, must be submitted a minimum of two weeks prior to the date on which the investigator would like to begin the study if approved. While the IRB will review all submissions within two weeks, for expedited and full reviews it is recommended that the application be submitted one month prior to allow for revisions or clarifications.

Approved applications are valid only for the academic year in which the proposal is submitted. Research that extends beyond one academic year will require a reapproval by the IRB.

For more information, please contact
Dr. Pam Stinson
Vice President for Academic Affairs
Pamela.stinson@noc.edu
(580) 628-6431
Northern Oklahoma College
1220 East Grand, P.O. Box 310
Tonkawa, OK 74653

Northern Oklahoma College
Institutional Review Board Application for
Exempt, Expedited and Full Board Research Studies

Note: Before beginning application, please review the Exempt and Expedited Categories to determine if a full review is required or if an Exempt Review (See C) or Expedited Review (See Appendix D) is appropriate. Applications with missing required information will not be processed.

PART I – INVESTIGATOR and KEY RESEARCH PERSONNEL

1) PRINCIPAL INVESTIGATOR

(Graduate students must complete Appendix A. Undergraduate students cannot serve as Principal Investigator, but may be listed as a Co-Investigator. For student investigators, a faculty co-investigator or sponsor must be listed.)

Name:

Title:

Highest Degree Completed:

Investigator Status: ☐ Faculty ☐ Graduate Student ☐ Staff
☐ Other (Specify) _____

Email Address:

Institution:

College/Department:

Work Mailing Address:

Daytime Phone:

Cell Phone:

2) CO-INVESTIGATOR / FACULTY SPONSOR (if applicable)

Name:

Title:

Highest Degree Completed:

Investigator Status: ☐ Faculty ☐ Graduate Student ☐ Staff
☐ Undergraduate ☐ Other (Specify) _____

Email Address:

Institution:

College/Department:

Work Mailing Address:

Daytime Phone:

Cell Phone:

PART II – FUNDING INFORMATION

List all funding sources for this research and provide one complete copy of any grant proposal submitted to the funding sponsor(s) with this application; this information will be used only to confirm the IRB proposal is in compliance with funding requirements. For each funding source, include the following information: Principal investigator for the grant, funding sponsor, grant number (if applicable), grant title, and whether funding has been approved or is pending.

PART III – PRINCIPAL INVESTIGATOR ASSURANCE

- I certify that the information provided in this application is complete and correct.
- I understand that, as Principal Investigator, I have the responsibility for the conduct of the study, the ethical performance of the project, and the protection of the rights and well-being of all participants, and I agree that I am knowledgeable about the protocol for research with human subjects.
- I agree to all of the following:
  I will obtain legal informed consent from all participants in the research.
  I will follow the approved protocol as stated in this research proposal, and I will adhere to all applicable federal, state, and local laws.
  I will inform the IRB in writing should protocol need to be changed for any reason and/or if my employment status or contact information changes.
- I certify that I have obtained all approvals from entities other than NOC IRB that are necessary to conduct this research.
- I further certify that no children under 18 will be used in this study.

Principal Investigator	Date (mm/dd/yyyy)
Co-Investigator or Faculty Sponsor	Date (mm/dd/yyyy)

PART IV – ADMINISTRATIVE DATA

1) Proposed start date: _____ Proposed end date: _____
2) If this research will result in a thesis or dissertation, please check the appropriate box.
   ☐ Thesis ☐ Dissertation
3) Study Population: _____
   Age Range: _____ to _____ (includes low/high age range)
   Gender: ☐ Males ☐ Females
   Site of Subject Recruitment: _____

Inclusion Criteria:

Exclusion Criteria:

Maximum Number of Participants Proposed:

NOC Study Site (check all that apply):

☐ Tonkawa Campus ☐ Enid Campus

☐ Stillwater-Gateway Location ☐ Other-Specify_____

4) Potentially Vulnerable Populations:
Please Check any groups included in the study.

☐ Cognitively Impaired ☐ Pregnant Women

☐ Elderly (65 & older) ☐ Psychologically Impaired

☐ Students enrolled in a class in which the instructor is the investigator

5) Will medical clearance or a medical screening be necessary for participants to participate because of tissue or blood sampling, administration of substances such as food or drugs, or physical exercise conditioning?

☐ No ☐ Yes

If yes, attach an explanation on how clearance will be obtained. If a screening instrument will be used, please attach a copy to the application.

6) Conflict of Interest
Is there any potential or perceived conflict of interest (e.g. financial gain as a result of the study) between the researcher, sponsor and/or Northern Oklahoma College associated with the study?

☐ No ☐ Yes

If yes, please explain:

Additional information may be needed by the full Board.

PART V – SUMMARY OF STUDY ACTIVITIES

Please respond to each item. Incomplete forms will be returned to you.

1) Provide background information for the study including the purpose of the study, research question to be answered, and other relevant information.

2) Describe the research design of the study.

3) Describe the activities that participants will be asked to participate in. Explain the duration of the activities, how data will be collected, the setting used for collecting data (e.g. telephone, mail, face-to-face interviews, etc.) Provide a copy of each study instrument, including all questionnaires, surveys, protocols for the interviews, etc.

4) Describe the procedures you will use to recruit research participants, and attach any materials used to advertise.

PART VI – PRIVACY PROCEDURES

1) Will data be recorded by audiotape? ☐ No ☐ Yes

Will data be recorded by videotape? ☐ No ☐ Yes

Will photographs be taken? ☐ No ☐ Yes

If yes,

Will tapes and photographs be destroyed after the study is complete?

☐ No ☐ Yes

If no, explain why not and how the location of the data will be secure.

2) Who will have access to data during the research and, if applicable, after the study? (Please give title and need for information.)

3) Please clarify how subjects will be identified in audio or videotaped responses.

4) Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, etc.? ☐No ☐Yes
If yes, explain why these identifiers are necessary to the study.

5) Will you retain a link between the study code numbers and direct identifiers after the data collection is complete? ☐No ☐Yes
If yes, explain why this is necessary and state how long you will keep this link.

6) Will you provide a link or identifier to anyone outside the research team (e.g. the participant's employer)? ☐No ☐Yes
If yes, explain why and to whom.

7) Will you place a copy of the consent form or other research study information in the participant's record such as medical, personal, or educational? (This information should be clearly explained in the consent document and/or process) ☐No ☐Yes
If yes, explain why this is necessary.

8) Will you obtain a Federal Certificate of Confidentiality for the research? ☐No ☐Yes
If yes, submit documentation of application (and a copy of the Certificate of Confidentiality award if granted) with this application form.
If the data collected contains information about illegal behavior, visit the NIH Certificates of Confidentiality Kiosk http://grants1.nih.gov/grants/policy/coc for information about obtaining a Federal Certificate of Confidentiality.

PART VII – INFORMED CONSENT INFORMATION

1) Informed Consent: Please attach, as an appendix, an informed consent document to this application. If subject participation is anonymous, an information sheet or cover letter that contains all required elements (see appendix B) of informed consent is recommended. If subject participation is not anonymous, you must attach a consent form to this application.

2) Request for Waiver of Informed Consent: Provide a written justification for a waiver of informed consent according to Section 46.116 of 45 CFR 46 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
Are you requesting a waiver of informed consent? ☐No ☐Yes
If yes, please explain.

3) Requests for Waiver of Documentation of Consent (applies to studies that do not wish to have signatures of the participants, i.e. informed consent via a consent form cover letter: three options are included in Appendix B). Provide a written justification for a waiver of documentation of consent according to Section 46.116 of 45 CFR 46 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117
Are you requesting a waiver of documentation of consent? ☐No ☐Yes
If yes, please explain.

PART VIII – RISKS AND BENEFITS

1) Does the research involve any possible risks or harms to the subjects? (see list below)

☐ No, go to Part IX.

☐ Yes. Independent scientific review may be required to determine if scientific merit justifies this risk. Check all that apply:

- ☐ Use of deception
- ☐ Use of confidential records (e.g. education or medical records)
- ☐ Manipulation of psychological or social variable such as sensory deprivation, social isolation, psychological stressors
- ☐ Presentation of materials which subjects might consider sensitive, offensive, threatening or degrading
- ☐ Physical Harm
- ☐ Possible invasion of privacy of subject or family
- ☐ Social or economic risk
- ☐ Legal risk
- ☐ Employment/occupational risk
- ☐ Other risks, specify:

2) Describe the nature and degree of the risk. Also, include the script the principal investigator will use to describe these risks to the participants as well as describing their rights to withdraw from participation

PART IX – COMPENSATION INFORMATION

1) Will any compensation or incentives, e.g. monetary award, be offered to the subjects for their participation? ☐No ☐Yes

If yes, describe those incentives and include the statement as provided to the participant in the consent form of how this compensation will be handled, as well as penalties for withdrawing from the study.

Checklist for Institutional Review Board Application Submission:

- ☐Application Form with Signatures – **3 copies required (AT LEAST ONE COPY MUST HAVE ORIGINAL SIGNATURES)**
- ☐Protocol
- ☐Curriculum vitae for all investigators
- ☐Solicitation Announcements/Recruitment Flyers
- ☐Data Collection Instruments/Research Questions/Questionnaires/Surveys
- ☐Medical Screening Instrument
- ☐Proposal and/or Contract or Grant
- ☐Appendix A: Student as Principal Investigator Worksheet (if applicable)
- ☐Appendix B: Informed Consent Checklist with consent forms
  - ☐*Anonymous/Confidential Survey*
  - ☐*Non-Tape Recorded*
  - ☐*Tape Recorded*
  - ☐*Parental/Legal Guardian Consent Form*
- ☐Appendix C: Criteria for Exempt Determination
- ☐Appendix D: Criteria for Extended Review

Submit to: **Attn: Dr. Pam Stinson**
Northern Oklahoma College
P.O. Box 310
Tonkawa, OK 74653

APPENDIX A: Student as Principal Investigator Worksheet

This project has been reviewed to determine that the scope, anticipated risks and benefits, and methodology are appropriate for this research by:

☐ Thesis/dissertation committee
☐ Other:

The student researcher is qualified to conduct independent research based on the following credentials:

☐ Has completed a graduate research method course
☐ Has experience as an independent or closely supervised research assistant
☐ Other:

FACULTY SPONSOR'S ASSURANCE

By my signature as sponsor on this research application, I certify that I have thoroughly reviewed this IRB application and agree that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accordance with the research protocol. I further agree to monitor the research study to insure research protocol is followed.

_____ _____
Faculty Sponsor Date (mm/dd/yyyy)

APPENDIX B: Informed Consent Checklist:

- ☐ Informed Consent Should:
- ☐ Use language that is clear to all prospective participants
- ☐ Identify the principal investigator & any grant sponsorship
- ☐ Describe the general objective of the study
- ☐ Estimate time required and any possible risks to participation.
- ☐ Explain what compensation will be provided to participants.
- ☐ Describe how participants' privacy will be protected if they are videotaped or recorded, and how student identifiers will be protected.
- ☐ State whether deception will be used for the purpose of the research study and how full explanation will be provided following the study
- ☐ Provide the name & contact information for the principal investigator (PI) to whom questions about the research can be directed
- ☐ Indicate that participation is voluntary and can be discontinued at any time without penalty.
- ☐ Note that the participant should keep his/her copy of the informed consent form

ANONYMOUS/CONFIDENTIAL SURVEY
CONSENT SAMPLE

Date

Dear :

I am a professor [or a graduate student under the direction of professor] in the [Enter University Department at Name of University] . I invite you to participate in a research study being conducted under the auspices of the University of [Name of University]. [Enter sponsor of study]and entitled [Enter name of study]. The purpose of this study is [Enter purpose of study].

*** If appropriate, include a statement requiring participants to be 18 years of age or older.*

Your participation will involve [Explain the procedures] and should only take about [Enter estimate of time commitment]. Your involvement in the study is voluntary, and you may choose not to participate or to stop at any time. The results of the research study may be published, but your name will not be used. In fact, the published results will be presented in summary form only. Your identity will not be associated with your responses in any published format.

The findings from this project will provide information on [Explain expected practitioner value] with no cost to you other than the time it takes for the survey.

If you have any questions about this research project, please feel free to call me [Enter your contact information and/or contact information of your faculty sponsor] at [Enter phone number including area code] or send an e-mail to [Enter email address]. Questions about your rights as a research participant or concerns about the project should be directed to the Institutional Review Board at Northern Oklahoma College, Office of Institutional Planning Research.

By returning this questionnaire in the envelope provided, you will be agreeing to participate in the above described project.

Thanks for your consideration!

Sincerely,

[Enter Researcher's Name]
[Enter Researcher's Title]

NON-TAPE RECORDED INTERVIEW CONSENT SAMPLE

Date

Dear :

I am a professor [or a graduate student under the direction of professor] in the [Enter University Department] Department at [Enter University Name}. I invite you to participate in an interview as part of a research study being conducted under the auspices of the [Enter University Name}. [Enter sponsor of study]and entitled [Enter name of study]. The purpose of this study is [Enter purpose of study].

*** If appropriate, include a statement requiring participants to be 18 years of age or older.*

Your participation will involve [Explain the procedures] and should only take about [Enter estimate of time commitment]. Your involvement in the study is voluntary, and you may choose not to participate or to stop at any time. The results of the research study may be published, but your name will not be used. In fact, the published results will be presented in summary form only. Your identity will not be associated with your responses in any published format.

The findings from this project will provide information on [Explain expected practitioner value] with no cost to you other than the time it takes for the interview.

If you have any questions about this research project, please feel free to call me [Enter your contact information and/or contact information of your faculty sponsor] at (area code) [phone number] or send an e-mail to [Enter email address]. Questions about your rights as a research participant or concerns about the project should be directed to the Institutional Review Board at Northern Oklahoma College, Office of Institutional Planning and Research.

By participating in this interview, you are agreeing to the conditions explained in this letter.

Thanks for your consideration!

Sincerely,

[Enter Researcher's Name]
[Enter Researcher's Title]

TAPE RECORDED INTERVIEW CONSENT SAMPLE

Date

Dear :

I am a professor [or a graduate student under the direction of professor] in the [Enter University Department] Department at The [Name of Institution]. I invite you to participate in an interview as part of a research study being conducted under the auspices of the [Enter University Name]. [Enter sponsor of study]and entitled [Enter name of study]. The purpose of this study is [Enter purpose of study].

** *If appropriate, include a statement requiring participants to be 18 years of age or older.*

Your participation will involve [Explain the procedures] and the interview will be audio tape recorded. It should only take about [Enter estimate of time commitment]. Your involvement in the study is voluntary, and you may choose not to participate or to stop at any time. The results of the research study may be published, but your name will not be used. In fact, the published results will be presented in summary form only. Your identity will not be associated with your responses in any published format.

The findings from this project will provide information on [Explain expected practitioner value] with no cost to you other than the time it takes for the interview.

If you have any questions about this research project, please feel free to call me [Enter your contact information and/or contact information of your faculty sponsor] at (area code) [phone number] or send an e-mail to [Enter email address]. Questions about your rights as a research participant or concerns about the project should be directed to the Institutional Review Board at Northern Oklahoma College, Office of Institutional Planning and Research.

I would like to audio-tape this interview. Do I have your permission to audio-tape the interview?

Thanks for your help!

Sincerely,

[Enter Researcher's Name]
[Enter Researcher's Title]

APPENDIX C: Criteria for Exempt Determination

Your research may qualify for exempt status if the only involvement of human subjects will be in one or more of the following categories. These categories are established by the Federal Regulations and require submission to the institutional designee to determine appropriateness. At NOC the institutional designee is the IRB Chair.

Please check all boxes that you believe may apply.

☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

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

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior on subjects 18 years of age or older, unless:

a) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
b) any disclosure of the human subjects' response outside the research could reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures or observation or public behavior that is not exempt under paragraph 2 (b) of this section, if:

a) The human subjects are elected or appointed officials or candidates for public office; or,
b) Federal statue(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ Research involving the collection or study of existing (i.e. on the shelf, already collected and/or banked prior to the date the study is to start) 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 link to the subjects. For information not publicly available, the principal investigator should obtain IRB approval before requesting data.

☐ 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:

a) public benefit or service programs;
b) procedures for obtaining benefits or service under those programs;
c) possible changes in or alternatives to those programs or procedures; or
d) possible changes in methods or levels of payment for benefits or services under those programs.

☐ Taste and food quality evaluation and consumer acceptance studies,

a) if wholesome foods without additives are consumed or
b) 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 Environment Protection Agency or Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: These categories represent minimal requirements of review by 45 CFR 46. The NOC Institutional Review Board reserves the right to require a more stringent review of any study as deemed appropriate.

APPENDIX D: Criteria for Expedited Review

Your research may qualify for an expedited review if one or more of the following criteria apply:

Please check all boxes that you believe may apply.

☐ Research will not involve animals. Note: Research involving animals requires a full review that includes a review by the Institutional Animal Care and Use Committee (IACUC). Research involving animals may also be subject to federal and state regulations under the Animal Welfare Act, and periodic review and inspection by the USDA. It is the responsibility of the PI to ensure that the research project meets all applicable state and federal regulations. Copies of all materials, such as letters of inspection and licenses, must accompany this application.

☐ Research will not involve children under 18. **Northern Oklahoma College does not support research projects involving participants under the age of 18 with the exception of proposals fitting the "exempt" status.**

☐ Research does not involve studies of drugs and medical devices unless both of the criteria below are met.

a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increase the risks or 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.

☐ Research does not involve collection of blood samples by finger stick, heel stick, ear stick, or venipuncture unless the two following criteria are met:

a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 2 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ Research may involve 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, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ Research will involve 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 age, weight, and health of the individual.

☐ Research may involve animals (data documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

☐ Research may involve collection of data from voice, video, digital, or image recordings made for research purposes.

☐ 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.

☐ 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

☐ 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 by 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.

Note: These categories represent minimal requirements of review by 45 CFR 46. The NOC Institutional Review Board reserves the right to require a more stringent review of any study as deemed appropriate.