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I. INTRODUCTION

In accordance with the Federal Policy on the Protection of Human Subjects (DHHS Policy 45 CFR Part 46, effective August 19, 1991), Northwest Christian University (NCU) assumes the responsibility for the protection of the rights and welfare of human subjects who participate in research and other activity projects conducted by, or under the supervision of, faculty, staff, or students.

II. INSTITUTIONAL REVIEW BOARD

To conduct this responsibility effectively, NCU maintains an Institutional Review Board (IRB) competent to review research, training, and other activity protocols involving human subjects and to evaluate both risk and protection against risk for those subjects.

It is the function of the IRB to: (1) determine and certify that all projects reviewed by the IRB conform to the regulations and policies set forth by DHHS regarding the health, welfare, safety, rights, and privileges of human subjects; and (2) assist the investigator in complying with DHHS regulations in a way that permits accomplishment of the research activity. To this effect, the IRB will establish policies and procedures to govern the research involving human subjects, as set for in this document.

The IRB aims to provide a service to NCU and the public by facilitating ethical treatment of research subjects while at the same time supporting the investigator's endeavor to advance knowledge.

The IRB is composed of the following individuals: the Chair of the Undergraduate Research Committee as chair, the other faculty members of the Undergraduate Research Committee, one outside member, and the Vice President for Academic Affairs (VPAA) as an ex-officio member.

III. ABBREVIATIONS/DEFINITIONS

A. ABBREVIATIONS

**IRB** - NCU’s Institutional Review Board, established for the purpose of review and approval of human subjects in research, in accordance with federal regulations governing the protection of human subjects in research.

**DHHS** - U.S. Department of Health and Human Services, the federal agency which enters into agreement with institutions through a signed assurance of compliance for the protection of human subjects in biomedical or behavioral research.

NIH – National Institutes of Health, the agency that provides the free online training on ethics in human subject research.

B. DEFINITIONS

Research - "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

Human subject - "Human subject" means a living individual about whom an investigator (whether faculty, staff, or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.

Minimal risk - The risk to the subject is said to be minimal when the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Minimal risk is to be determined with regard to the state of vulnerability of the particular subject or subjects, especially if special populations are used as subjects.

Subject at risk - Any individual who is exposed to the probability of injury, physical or psychological, as a consequence of participation as a subject in a research procedure. A subject is beyond minimal risk when participating in a research endeavor in which the risks of harm are greater, considering either probability or magnitude, than those risks encountered in daily life.

Physical risk - Any strenuous or unusual physical activity or procedure required of a subject, use of compounds, which might alter the subject's biochemical milieu, exposure to strong stimulation, and placement in a situation, which could lead to violence. The investigator is responsible for anticipating circumstances which might endanger the subject's physical well-being and for bringing these circumstances to the attention of the IRB.

Psychological risk - Any experimental condition that induces personality change or intense changes in a subject's feelings or motivations, or that may induce such changes which extend beyond the experimental or debriefing period; subjection to deceit, to demeaning or dehumanizing procedures, to humiliation and embarrassment. The investigator has the responsibility to eliminate or minimize the effects of psychological risks to subjects and to bring these matters to the attention of the IRB.
Confidentiality - Right of privacy and of non-release of disclosed personal information. The investigator should protect subjects against invasion of privacy and loss of confidentiality. Lack of secure handling of completed personality tests, questionnaires, interview protocols or data, and recorded materials, augments risk and must be avoided.

Informed consent - Informed consent means "knowing consent," the exercise of a free power of choice without undue inducement, force, fraud, deceit, duress, or other form of constraint or coercion. If the subjects are minors or are not capable of giving consent, parental, guardian or other legal representative consent is required. Use of a written consent form that includes all the basic elements of informed consent must be documented by a signature of the subject or legally authorized representative.

Anonymity - exists when there are no identifiers whatsoever on project materials which could link the data with individual subjects. Even the research investigator cannot know the identity of participants.

Protocol - A protocol is the researcher's plan of a scientific experiment or treatment.

IV. REVIEW CATEGORIES
A. GENERAL

According to 45 CFR 46, there are two review categories: category I – exempt review, and category II -- expedited review and full review. At NCU, there are essentially three types of research: (1) those conducted by students to satisfy part of a course requirement; (2) those conducted by students where the primary emphasis of the course is research; for example, master’s thesis, undergraduate capstone course, or adult degree program (ADP) project; and (3) those conducted by faculty or staff as part of a research project or grant. The first type would generally fall in category I while the second and third type would fall in category II.

In general, research which involves data gathered solely for internal, on-campus use would not need to be reviewed by the IRB. If, however, the results of this research will be disseminated in any way, then the research must receive prior approval from the IRB. If no dissemination is planned at the time the data are gathered, but the possibility of future dissemination exists, the investigator would be advised to submit the project for approval prior to initiating the research.

Some projects assigned to students in a class may have a research component or constitute training in research methodology. If such projects may contribute to generalizable knowledge (e.g., through publication or dissemination of the findings), they are subject to the regulations and must undergo review. The IRB is unable to give post facto approval. Classroom projects that are exclusively for instructional purposes need not undergo review by the IRB; however, it is important that instructors and students discuss the guidelines and ethics for protection of research subjects and incorporate these into their methodology. In particular, obtaining informed consent is essential as well as informing subjects of the risks involved.
Graduate students conducting human subject research as part of their thesis requirements are required to submit such research to the IRB prior to starting the research project. Undergraduate students taking a class whose sole purpose is a research project (such as a capstone course or management project) that involves human subjects are required to submit such research to the IRB prior to starting the research project.

B. CATEGORY I – EXEMPT

This category includes research that includes one or more of the following:
(1) anonymous, mail, or telephone surveys on innocuous topics;
(2) anonymous, non-interactive, non-participating observation of public behavior;
(3) secondary analysis of existing data;
(4) educational research involving no interaction with students; e.g. classroom activity;
(5) research involving the use of educational records if information taken from these sources is provided to the researcher in such a manner that subjects cannot be identified;
(6) interviews and interactive surveys on non-sensitive topics.
Generally, the chair of the IRB will determine if a protocol is exempt from review or not.

C. CATEGORY II – EXPEDITED AND FULL REVIEW

This category includes research that includes one or more of the following:
(1) research that might put subjects at risk;
(2) research involving psychological or physiological intervention;
(3) non-curricular, interactive research in schools;
(4) research involving deception;
(5) interviews or surveys on sensitive topics;
(6) research on special populations; e.g. minors, mentally disabled individuals, pregnant women and fetuses, prisoners,
(7) collection of data from voice, video, digital, or image recordings made for research purposes;
(8) research involving survey or interview procedures of children or mentally disabled individuals.
Generally, expedited review will be handled by the chair of the IRB while full review will involve all board members.

V. OVERVIEW OF PROCESS

STEP 1 -- Design the Research

Although scientific concerns are primary in the design of research involving human subjects, the rights of human subjects should be considered from the outset. The principles, policies, and procedures explained in this document should be kept in mind throughout the design of any research project.
STEP 2 -- Determine Whether the Project Needs to Be Reviewed

All research projects in which human subjects participate are subject to the federal regulations governing such research, and to the policies and procedures outlined in this document. In addition, state and local laws may exist which govern the use of special populations, existing data or documents, or other activities in research. As mentioned in the previous section, research projects that are simply one small part of a course requirement do not need to be reviewed by the IRB. Those research projects that are the focus of the course do require IRB approval.

STEP 3 -- Complete the Required Training

All investigators must provide proof (a certificate) of having completed a training program involving the ethical standards for conducting research on human subjects. The National Institutes of Health (NIH) provides such ethics training free online at http://phrp.nihtraining.com/users/login.php?l=3.

STEP 4 -- Complete the Protocol

The protocol provides the IRB with the information that it needs to approve the proposed research. The protocol consists of the following documents:

1. for graduate students, the Thesis Approval Form signed by the thesis committee,
   for undergraduate students, a form signed by the faculty advisor,
   for faculty, a form signed by the academic department associate dean,
   for staff, a form signed by the appropriate department head;
2. a copy of the thesis or research proposal;
3. a copy of any grant proposal, if applicable;
4. a copy of any survey instrument, if applicable; and
5. a sample informed consent form

STEP 5 -- Review and Signature of Faculty Supervisor (Student Research Only)

All student initiated research involving human subjects, whether thesis or other research projects, must be supervised by a faculty member to assure that human subjects are protected. For thesis research, the signatures of the thesis committee are required. For student research other than thesis projects, a faculty supervisor’s signature is required and the student must be enrolled for at least one credit hour of research during that period of the project when human subjects are involved. Graduate students must meet the College requirements of continuous enrollment. The faculty signature on student research attests that the research procedures comply with federal and College policies with regard to the protection of human subjects and is approved. The faculty supervisor also is expected to monitor the research to assure that the approved protocol with human subjects is followed. Appendix A contains a cover form for undergraduate student research.
STEP 6 -- Review and Approval by Department Head (Faculty and Staff Research Only)

This step applies to research conducted by faculty and staff. When the investigator has completed the protocol, it is submitted to the appropriate department head for review. Although the process varies according to the department, it will either approve the protocol as described or will consult and negotiate with the investigator until the protocol is acceptable. When the protocol is acceptable, the department head signs the cover sheet. This signature indicates that the proposed project has been judged to be in compliance with federal and college regulations regarding research with human subjects. Appendix A contains a cover form for faculty and staff research.

STEP 7 -- Submit the Protocol to IRB

After the proposed project has been received by IRB, a preliminary review of the protocol is done to determine whether (a) the project is exempt under the regulations or is to undergo either expedited or full review; (b) the protocol meets the general requirements for review under the regulations; and (c) the informed consent form contains the required elements and is in satisfactory form for IRB review. The IRB will consult with the investigator (and/or faculty supervisor, if student research) when the proposal does not meet the general requirements, the informed consent form is missing required elements, or additional information or clarification is needed to determine the review category.

STEP 8 -- Review and Approval by IRB

The chair of the IRB will receive all protocols, assign them a classification number, and ensure that the protocol is complete. If the chair of the IRB determines that the protocol is exempt under the federal regulations and everything is satisfactory, he/she will approve the protocol, indicating that the research may commence. If the chair determines that the protocol involves expedited or full review, he/she will then forward it to the full IRB for their comment and review. The IRB can approve the research or disapprove the research. If the research is approved, the chair of the IRB will sign the cover sheet and the research may commence.

If there are correctable problems with the protocol, the chair of the IRB will consult with the investigators to seek revisions in the protocol. Typically, determination of whether the changes made by the investigator satisfy the conditions set forth by the IRB can be made by the chair of the IRB, obviating further discussion of the protocol by IRB. When the conditions have been satisfied, the chair of the IRB will sign the cover sheet and research may commence.

If the protocol is disapproved, the researcher may not conduct the research and the IRB will provide, in writing, the reason for its decision. Furthermore, the researcher will have the right to appeal the decision. The chair of the IRB will report concerns and outcomes of the IRB to the investigator, the unit reviewer or review committee, and to the faculty member supervising the research when the investigator is a student.
STEP 9 -- Research Commences or Decision is Appealed

Once the protocol is approved, research with human subjects may commence. It is the responsibility of the investigator (and faculty supervisor if investigator is a student) to monitor the research to insure that the approved procedures are being followed. Any harm to subjects should be reported to the IRB immediately.

If for some reason an investigator is not satisfied with the decision of the IRB or with the process by which a decision is rendered, the right to an appeal is maintained.

STEP 10 -- Changes in Approved Procedures (Amendments/Modifications)

Any changes in previously approved research must be approved by the IRB. Minor changes may be submitted to the IRB in a memorandum describing those changes and the effects of the requested modifications on risks, benefits and consent procedures. If the changes are determined to be substantial, the investigator will be informed that a new protocol must be submitted. All modifications must be reviewed and approved by the faculty advisor if the researcher is a student.

STEP 11 -- Continuing Projects and Termination of Projects

At regular intervals (and at least once a year), the IRB will conduct continuing reviews of projects in progress. When the current approval period is nearing an end, the IRB will send the investigator a notification. If there are no problems, adverse reactions, or changes in activities by the investigator, continuing review will be handled administratively. If any of these conditions are present, review of the project will be conducted by the IRB and a revised protocol must be submitted.

An investigator may be granted up to two one-year renewals on each individual human subjects protocol. If the investigator wishes to continue conducting the research in question after the expiration of the second renewal, he/she will submit a new protocol application for Committee review.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to subjects. Any such termination will include a statement of the reason for action and shall be reported promptly to the investigator, to the faculty advisor if the investigator is a student, to the appropriate College officials, and to the appropriate federal officials. Furthermore, the IRB has the authority to observe or have a third party observe the consent process and the research.

If the project is terminated normally (i.e., procedures involving human subjects are completed), the investigator should inform the IRB.
VI. CRITERIA FOR APPROVAL

A. IRB REVIEW AND APPROVAL

The IRB may approve research when the following conditions are satisfied:

1. risks to subjects are minimized by using procedures which 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 subjects for diagnostic or treatment purposes;
2. risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result;
3. selection of subjects is equitable;
4. informed consent will be sought from each prospective subject or the subject's legally authorized representative and will be appropriately documented, unless informed consent or documentation is specifically waived by the IRB;
5. the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects where appropriate;
6. there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data where appropriate;
7. where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with severe physical or mental disabilities or illness, appropriate safeguards have been included in the study to protect the rights and welfare of these subjects.

B. APPEAL PROCESS

In the event that a protocol is disapproved by the IRB, the investigator may appeal the decision as follows:

1. The investigator submits the grievance in writing to the chair of the IRB;
2. The chair discusses the grievance with members of the IRB in an attempt to provide resolution;
3. If the grievance cannot be resolved at step 2, the investigator may request a meeting with the IRB, and may be accompanied by counsel or other persons with expertise or knowledge of research related to the procedures in question;
4. The IRB may invite a faculty member who is not a member of the IRB to act as an observer to the proceedings;
5. Based on the findings of the IRB, a final decision regarding the grievance will be made by a majority vote of the IRB.
VII. RISKS TO SUBJECTS

A. GENERAL

NCU accepts as a basic principle that it has an ethical and moral obligation to safeguard the rights and welfare of all subjects involved in research, training, educational development and other activities where subjects are exposed to a risk that could be detrimental to their health or well-being. In those cases where risk may exist, even with informed consent, approval of a research project will be made only if the risk to the individual is outweighed by a clear explanation of the potential benefit to the person (as in the case where an activity involves therapy, diagnosis, management, etc.). In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies the subjects would receive even if not participating in the research), and shall not consider long-range effects of applying knowledge gained in the research as among those risks that fall within the IRB’s purview of responsibility.

NCU shall be responsible for physical or psychological injury to human subjects attributable to University-sponsored research, development, and related activities, to the extent that NCU may be found liable under federal and state laws. Therefore, the obligation of researchers to conduct activities in a manner and at such locations as will assure the proximity of adequate medical attention if warranted, and to provide appropriate referrals to subjects for adequate facilities and professional attention should subjects suffer physical, psychological or other injury, is of paramount importance when designing research involving human subjects.

The seriousness of a risk to subjects is a function of the magnitude of the harm and the probability of the harm. A risk may be serious or significant because it has a probability (even a low probability) of great harm (e.g., a low probability of death), or because it has a high probability of slight harm (e.g., a near certainty of physical discomfort or psychological distress).

The risks of participation in research may be part of the research design or may be a consequence of the research procedures, or both. Risks may be a consequence of the methods of recording, maintaining, or reporting data, and they may be a consequence of methods of obtaining informed consent.

B. EXAMPLES OF RISKS

Physical risks include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research.

Psychological risks include the production of negative affective states such as anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock and loss of self-esteem, and altered behavior. Occasionally, some degree of deception is involved in a research study. Minor deception, such as failing to tell the subject what the specific points of interest are in an attempt to prevent biasing the results, can be acceptable provided the subject is fully debriefed after participating. Risks stemming from major deceptions, such as leading a subject to believe that s/he has committed a crime or has a disease, must be clearly counterbalanced by the benefits of
the research. Withholding information cannot be used as a means to secure the participation of subjects in research.

**Social/Economic risks** include alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of others, labeling with negative consequences, or diminishing the subject’s opportunities and status in relation to others. Economic risks include payment by subjects for procedures, loss of wages or other income, and damage to employability.

**Legal risks** include the risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally liable.

**Loss of Confidentiality:** confidentiality of identifiable information is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Risks include invasion of privacy, as well as the social, economic and legal risks outlined above.

**C. MINIMAL RISK**

The federal regulations governing research with human subjects define "minimal risk" as follows: "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

In broad terms, a project involves minimal risk if:

1. the participant experiences no pain or physical danger;
2. the participant experiences no emotional arousal or psychological stress beyond the levels normally to be expected in everyday life;
3. the project neither induces nor attempts to induce long-term significant change in the participant's behaviors (including attitudes toward self and others);
4. the data would not embarrass or socially disadvantage the participant, were confidentiality to be violated; and
5. if the investigator conceals information about the specific purpose of the project, there is no reason believe that the subject would choose not to participate if he/she had known that information initially.

It is difficult to develop a rule that can be applied across all disciplines and in all situations, to determine whether a project involves minimal risk or more than minimal risk. It is assumed that the researcher will apply the customs and practices associated with his/her discipline, such as outlined in a published code of ethics, in making this initial determination. The IRB will make the final determination as to the project's level of risk and the safeguards required to minimize risks for subjects.
VII. INFORMED CONSENT

A. GENERAL

Informed consent is the knowing consent of an individual or his/her legally authorized representative which is obtained without undue inducement or element of force, fraud, deceit, duress, or other forms of constraint or coercion. A consent form documents informed consent and is designed to protect the investigator and the institution against legal liability. The consent form should be a statement addressed to the subject and should read as such. Ordinarily, it is best worded in the second person. It must be in language the subject can understand. Separate forms may be required for different subject groups as well as for release of particular kinds of information. Templates for several types of informed consent forms can be found in Appendices B to F. Researchers need not copy this language verbatim, so long as all required elements are included in the informed consent form.

B. OBTAINING INFORMED CONSENT

Research investigators are responsible for obtaining informed consent and for insuring that no human subjects will be involved in the research prior to obtaining their consent. In obtaining informed consent, investigators must avoid the possibility of coercion or undue influence. Unless otherwise authorized by the IRB, investigators are responsible for insuring that legally effective informed consent shall:

1. be obtained from the subject or the subject's legally authorized representative;
2. be in language understandable to the subject or the representative;
3. be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
4. not include exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

C. REQUIRED ELEMENTS FOR ALL INFORMED CONSENT FORMS

A written consent form must include the following items:

1. a statement that the study involves research;
2. an explanation of the purposes of the research;
3. a description of the procedures to be followed;
4. the expected duration of the subjects' participation;
5. a description of any reasonably foreseeable risks or discomforts to the subject;
6. a description of any benefits to the subject or to others which may reasonably be expected from the research;
7. a statement describing how confidentiality of records identifying the subject will be maintained;
8. an explanation of whom to contact for answers to pertinent questions about the research (investigator); regarding research subjects' rights (IRB); and in the event of a research-related injury to the subject (IRB);
In addition, include a statement that
(1) participation is voluntary;
(2) refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and
(3) the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

Finally, indicate that the subject may keep a copy of the consent form.

**D. ADDITIONAL ELEMENTS, IF APPROPRIATE**

For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained, and who is responsible for payment of medical expenses; The following language is suggested:

If you are physically injured because of the project, you and your insurance company will have to pay your doctor bills. If you are a NCU student or employee and are covered by a NCU medical plan, that plan might have terms that apply to your injury.

For research projects that involve videotaping, a videotape release form must be attached to the written consent form. If the investigator anticipates use of the tapes beyond the scope of the initial research project, the written consent form must indicate (a) who will view the tapes; (b) for what purpose; and (c) when the tapes will be destroyed.

In addition, the following should be provided, if appropriate to the research:

(1) if subjects will be paid, all information concerning payment, including amount and schedule of payment must be included.
(2) a statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable;
(3) identification of any procedures which are experimental;
(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
(5) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
(6) any additional costs to the subject that may result from participation in the research;
(7) the consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(8) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
(9) the approximate number of subjects involved in the study.
E. DOCUMENTATION OF INFORMED CONSENT

Investigators shall be responsible for insuring that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB. Each person signing the written consent form must be given a copy of that form. Investigators are responsible for retaining signed consent forms for three years after termination of the project.

The consent form may be (1) a written document that contains the required elements of informed consent, to be read by the subject or the subject's representative or by the investigator to the subject; or (2) a short written form stating that the basic elements of informed consent have been presented orally to the subject or representative.

F. WAIVER OF DOCUMENTATION OF INFORMED CONSENT

Under certain conditions, the IRB can waive the requirement that the subject sign the consent form. However, waiver of documentation of informed consent does not constitute waiver of informed consent. The IRB may waive the requirement to obtain a signed consent form for some or all of the subjects if one of the following conditions exists:

1. The consent document is the only record linking the subject and the research and the principle risk would be potential harm resulting from a breach of confidentiality. Subjects will be asked whether or not they want documentation linking them to the research, and their wishes will prevail.
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
3. For projects of minimal risk involving the use of questionnaires, the required elements of informed consent may be included in an introductory letter attached to the instrument, which includes a statement that completion and return of the questionnaire will constitute consent to participate.

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

G. POLICY ON PASSIVE PARENTAL CONSENT FOR RESEARCH IN ELEMENTARY AND SECONDARY EDUCATIONAL SETTINGS

Under current policy, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, if:

1. The research involves no more than minimal risk to the subjects and involves no procedures for which written consent is normally required outside of the research context;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration.
4. Subject selection is based on classroom membership and not exclusionary.
Investigators who propose the use of passive consent in a study to be conducted in an elementary or secondary school must (a) obtain permission from the relevant research review mechanism for that school (e.g., school district) and (b) provide the IRB with documentation of such approval prior to initiation or recruitment, and (c) if the research involves a change of curricula by the school or school district, provide written documentation on official letterhead from the participating school or school district indicating that the school district's procedures for adopting the curricula have been followed. The letter documenting curricula adoption must be submitted with the protocol to allow review with passive parental consent.

If the proposed study meets the conditions needed to obtain a waiver of informed consent, use of a passive consent mechanism may be granted.

H. VERBAL CONSENT

Only in special and/or unusual circumstances can the consent of the subjects be obtained orally. Waiver of prior written informed consent must be approved by the IRB. A waiver of prior written informed consent might be granted in the case where: (a) the risk to the subject is minimal; (b) use of primary procedures for obtaining consent would invalidate important research objectives; or (c) alternative means would be less advantageous to the subjects.

Oral presentation of the elements of informed consent should be used only when it is the most appropriate means of conveying relevant information to the subject, thus adapting the presentation to the subject's capacities. The presentation may be made in either of two ways: (1) a written consent document that sets forth the required basic components of informed consent may be read to the subject or the subject’s representative and the investigator will allow the subject or representative ample time to read and consider the document before it is signed; or (2) the IRB may approve a short written form describing the particulars of required informed consent that are to be presented orally to the subject or representative.

Where oral consent is allowable, investigators shall insure that:

1. a witness is present at the oral presentation;
2. the short form is signed by the subject or the representative;
3. the witness signs both the short form and a copy of the written summary of the oral presentation;
4. the person obtaining consent signs a copy of the summary;
5. a copy of both the short form and summary is given to the subject or the representative;
6. the written summary of what is to be said to the subject or the representative receives the prior approval of the IRB.

I. WAIVER OR ALTERATION OF INFORMED CONSENT

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, provided the following sets of conditions exists and is documented:

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

J. CONFIDENTIALITY/ANONYMITY

By current federal and University policies, subjects in research, evaluation, and training projects
give their informed consent to participate. In the informed consent procedure, subjects are often
given assurances of protection against loss of confidentiality or for total anonymity. Despite the
assurances and subsequent efforts, subjects may yet be identifiable. Two legal conditions are at
stake:

(1) Loss of confidentiality can occur when a court requires that research files be
submitted as evidence in a legal matter. The court decides who has access to the files and
whose identity will be revealed.
(2) Loss of confidentiality can occur under the so-called "Freedom of Information Act."
Under this Act, citizens can gain access to files of federal agencies, except as provided by
law. This usually occurs when identifying information is sent to a federal agency.

NCU is obligated to protect subjects' identities when the promise of protection is made in
obtaining their consent to participate. This obligation can be fulfilled in the following way:
If the research files are arranged so that the investigators cannot know the identity of
participants, then loss of confidentiality cannot occur by court order. This can be
accomplished by routinely destroying master code lists. Confidentiality may not be
preserved by locating the master code lists outside the jurisdiction of the court, i.e., in
another country. Anonymity may be assured when there are no identifiers whatsoever on
project materials which could link the data with individual subjects.

Investigators can be held in contempt of court for failing to submit the research files or for
destroying the master code lists only because of knowledge of the intent of the court.
Investigators will not be held in contempt of court for not revealing the identity of the subjects,
when they routinely take steps to keep the identity of subjects unknown to themselves (i.e.,
subject responses are anonymous).

VIII. SPECIAL SUBJECT POPULATIONS

A. DEFINITIONS

Child means any person younger than 18 years of age unless s/he has been legally emancipated.
(However, college or College students 15-17 years of age may be considered adults for the
purpose of participation in a research project with no more than minimal risk.)

Parent means a child's biological or adoptive parent.
**Guardian** means a person who is authorized by law to consent on behalf of a child or disabled individual to general medical care.

**Permission** means the agreement of the parent(s) or guardian to the participation of the child, disabled individual, or ward in the research.

**Assent** means an affirmative agreement to participate in research; mere failure to object does not constitute assent.

**Mentally disabled** means a person who, because of mental illness, mental retardation, emotional disturbance, or senility, is incapable of giving informed consent.

**Pregnancy** encompasses the period of time from confirmation of implantation (as evidenced by missed menses or a medically acceptable test) until expulsion or extraction of the fetus.

**Fetus** means the product of conception, from the time of implantation until a determination is made, following expulsion or extraction, that it is viable.

**Prisoner** means any individual involuntarily confined or detained in a penal institution. The term applies to those sentenced to such an institution, those detained in other facilities as alternatives to prosecution, and those detained pending arraignment, trial, or sentencing.

**B. CHILDREN**

All research involving children must be reviewed by the IRB. When research subjects are children, additional considerations must be met by the researcher. In all cases, the assent of the children, and consent of parent(s) or guardian, must be obtained prior to conducting the research.

When parents or guardians are asked for permission and children are asked for assent, they must be given the same information that is generally required when informed consent for participation in research is sought, and their permission and assent must be documented in writing. The assent form for children should, of course, be written in language appropriate to their age and understanding. If the parents are not also research subjects themselves, it may be appropriate to have them sign the same form their children sign. If the parents are also research subjects, ordinarily a separate form should be drafted for them, addressing their own participation as well as that of their children. In circumstances in which the IRB may alter or waive the usual requirements for securing and documenting informed consent when the subjects are competent adults, the IRB may waive or alter the requirements seeking permission and assent when children are subjects.

Federal regulations do not set a minimum age at which a child's assent must be solicited but instead say that assent is required whenever in the judgment of the IRB the children are capable of providing assent, taking into account their ages, maturity, and psychological state. Thus, the IRB has determined that assent must be obtained from the child if the child is 7 years old or older.
If the research involves only minimal risk, or it poses more than minimal risk but promises to benefit the child directly, permission must be obtained from at least one of the child's parents, or the child's guardian. If the research poses more than minimal risk and no direct benefit to the child, both parents or the child's guardian must give permission for the child to participate in the research.

If a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the children (for example, neglected or abused children), the IRB may waive the requirement that parental permission be sought, provided that there is an appropriate alternative mechanism for protecting the children which is not inconsistent with the law.

C. MENTALLY DISABLED INDIVIDUALS

All research involving mentally disabled individuals must be reviewed by the IRB. Most of the general requirements for approving research with human subjects apply, but with some exceptions and additions. The major exceptions are that (1) some research which would fall in the exempt category if the subjects were all competent adults is not exempt, and (2) some research involving more than minimal risk to the subjects is prohibited. Additional requirements pertain to informed consent.

Of course, some persons who have these conditions are also able to give informed consent, but the IRB cannot determine the capacity of persons with these conditions on the basis of labels alone. Therefore, whenever proposed research involves subjects who have been diagnosed with one of these conditions or who may have such a condition, the researcher should explicitly tell the IRB whether the subjects are able to give informed consent because of the condition. If the subjects are able to give informed consent, the special rules in this section do not apply, and only the general requirements for research with human subjects must be satisfied.

Ordinarily, a mentally disabled person may not be the subject of research unless the person gives assent. The IRB may waive the assent requirement if (1) the capability of some or all of the subjects is so limited that they cannot reasonably be consulted, or (2) the intervention involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the subjects that is available only in the context of the research.

Ordinarily, a mentally disabled person may not be the subject of research unless permission is obtained from the person's guardian. For purposes of these rules a guardian cannot be associated in any way with the research or the investigator(s). If the mentally disabled person is a ward of the state or any other agency, institution or entity, a person associated with the entity cannot be a guardian for purposes of these rules. The parent of a mentally disabled person below the age of 18 is presumed to be the person's guardian. If the mentally disabled person is older than 18, the parent is not automatically the guardian. If the subjects are mentally disabled adults who have not formally had legal guardians appointed for them, the researcher should propose a procedure for securing permission from a competent adult acting solely in the interests of the mentally disabled person. This procedure must be consistent with federal, state, and local law.
Mentally disabled subjects and the competent adults acting on their behalf must be given the same information that is generally required when informed consent for participation in research is sought, and their permission and assent must be documented in writing. The assent form for the mentally disabled subjects should, of course, be written in language appropriate to their level of understanding.

D. PREGNANT WOMEN AND FETUSES

All research involving pregnant women and/or fetuses must be reviewed by the IRB. No pregnant woman may be involved in a research activity unless: (a) the risk to the fetus is minimal, or (b) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs.

Research activity permitted above may be conducted only after fully informing the mother and father of any possible impact on the fetus and obtaining informed consent from the legally competent mother and father. Consent by the father need not be secured if:

1. the purpose of the study is to meet the health needs of the mother;
2. the identity or whereabouts of the father cannot be reasonably ascertained;
3. the father is not reasonably available;
4. the pregnancy resulted from rape.

E. PRISONERS

All research involving prisoners must be reviewed by the IRB. Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary decision whether or not to participate as subjects in research. Additional safeguards are required, therefore, when prisoners are proposed as subjects.

When using prisoners as subjects, only the following types of research are allowable:

1. study of possible causes, effects, or processes of incarceration or of criminal behavior;
2. study of prisons as institutional structures or of prisoners as incarcerated persons;
3. study of conditions particularly affecting prisoners as a class, including research on relevant social and psychological problems such as alcoholism, drug addiction, and sexual assault;
4. study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the prisoner subjects.

IX. SPECIAL TOPICS

A. RECRUITMENT

Voluntariness begins with recruitment. Potential subjects must not feel that they have been coerced into participating, nor must they fear the loss of some benefit to which they are otherwise entitled if they choose not to participate. Special care must be taken if the person doing the recruiting is a person who is in a position of authority (such as a teacher recruiting his or her own students) or makes decisions about the provision of services (such as a director of a
training clinic). It is the investigator's responsibility to ensure that a person's decision to participate or not will have no other effect on an existing relationship.

**Guidelines for Research Using Classroom Subjects**

Students in NCU classes are occasionally asked to participate in research. In such cases, the researcher should ask the instructor to give his/her permission to use class time to conduct a study. Because students in classrooms comprise a captive audience, care should be taken to respect their rights as subjects and as students.

If participation as a subject is part of the academic work of a student, it must not be a coercive requirement, and informed consent, if appropriate, must be obtained. Alternate means of receiving credit if a student chooses not to participate or chooses to withdraw during the course of the study should be provided. To assure that students feel free to refuse to participate without concern that the evaluation of their classroom performance will be affected, if possible, the instructor should not be present during any research activities.

When investigators wish to audiotape or videotape College classes, students have the right to refuse participation. At the same time, students should not be penalized by losing significant classroom instruction in the event they decide not to be taped. The following procedures should be used:

1. the investigator must notify students in advance that the class session will be taped;
2. taping must be stopped long enough before the end of the class to allow students to ask questions without appearing on the tape;
3. students must be given a full explanation of the project after the recording and given the option to arrange for deletion of their participation on the tape.

**Recruiting Clients of Social Service Agencies, Schools, and Other Institutions**

The researcher shall not ask institutions to directly identify potential subjects for a research study. Rather, the investigator shall ask an intermediary (doctor, case worker, school administrator) to first approach potential subjects (or their guardians, as appropriate) and inform them about the research. If a potential subject agrees to participate, the intermediary should provide him/her with the information necessary to contact the researcher, in such a way that the institution is unaware whether the subject chooses to participate in the research. The intermediary should not obtain consent from potential subjects.

The researcher shall not ask institutions to release records or anecdotal information either for the purposes of identifying subjects, or for examination by the investigator, unless this information is public. An investigator wishing to examine records must first obtain permission of the subject via an intermediary. If a potential subject agrees to release his or her records, the intermediary should provide the information necessary to contact the researcher. This provision does not apply to records with all identifiers removed.
Advertising for Subjects
If advertising for subjects, investigators must follow these guidelines:
(1) information must not be misleading to subjects, especially when a study will involve
vulnerable populations;
(2) include the name and address of the investigator, the purpose of the research and
eligibility criteria for participation as subjects, a clear description of any benefits and/or
risks of participating, the affiliation of the researcher, the location of the research, and
whom to contact for further information;
(3) a copy of the advertisement must be included with the protocol.

B. INFORMED CONSENT AND ABUSE REPORTING REQUIREMENTS

Child Abuse Reporting Requirements
According to ORS 419B.010, "Any public or private official having reasonable cause to believe
that any child with whom the official comes into contact has suffered abuse or that any person
with whom the official comes in contact has abused a child shall immediately report or cause a
report to be made..." to the Department of Human Services/Child Welfare Program of the State
of Oregon.

If the research requires subjects to respond to questions about suspected sexual abuse in the
children they observe, the respondents must be informed about the possible legal ramifications of
their answers. The following language is suggested for use in the informed consent form:
The questions you will be asked include information regarding child abuse. According to
Oregon Revised Statute 419B.010, all public or private officials are required to report any
"reasonable cause to believe that any child...has suffered abuse." In the unlikely event
that your responses to the child abuse items were disclosed and there was evidence that
you did not appropriately report child abuse, you could be subject to a fine not exceeding
$1,000.

Abuse of Elderly Persons
According to ORS 124.060, "Any public or private official having reasonable cause to believe
that any person 65 years of age or older with whom the official come into contact while acting in
an official capacity, has suffered abuse, or that any person with whom the official comes in
contact while acting in an official capacity has abused a person 65 years of age or older shall
report or cause a report to be made..." to the Senior and Disabled Services Division or to a law
enforcement agency within the county where the person making the report is at the time of
contact.

Definitions of abuse mean one or more of the following:
(1) any physical injury caused by other than accidental means, or which appears to be at
variance with the explanation given of the injury;
(2) neglect which leads to physical harm through withholding of services necessary to
maintain health and well-being;
(3) abandonment, including desertion or willful forsaking of an elderly person or the
withdrawal or neglect of duties and obligations owed an elderly person by a caretaker or
other person;
(4) willful infliction of physical pain or injury.

C. INTERNATIONAL RESEARCH

Research in foreign countries also presents special concerns regarding the rights and welfare of human subjects. In general, the IRB accepts the standards of the location in which the research is taking place; unless those standards grossly violate the basic principles of ethical human subjects research. In addition, the following issues apply to international human subject research:

(1) all materials, including consent forms must have English language translations included with the protocol; and

(2) documentation of permission from local authorities and/or research visa are generally required before approval can be granted.

X. REFERENCES


A. COVER SHEET FOR PROTOCOL SUBMISSION TO IRB

<table>
<thead>
<tr>
<th>Circle one:</th>
<th>Student</th>
<th>Faculty</th>
<th>Staff</th>
<th>Other</th>
</tr>
</thead>
</table>

Principal Investigator:________________________________________
Telephone:_________________
E-mail address: ____________________________
Mailing address ____________________________________________
Faculty Advisor (if student circled) __________________________________
Department Head (if faculty or staff circled) __________________________________
Telephone:_________________
Department:_____________________________________________________

Title of project:_____________________________________________________
_____________________________________________________

In submitting this proposed protocol and signing below, I certify that I will conduct the research involving human subjects as presented in the protocol and approved by the department and IRB; I will obtain and document informed consent and provide a copy of the consent form to each subject; I will present any proposed modifications in the research to the IRB for review prior to implementation; and I will report to the IRB any problems or injuries to subjects.

________________________________________
Signature of Principal Investigator

Date

This project has been reviewed and approved by the faculty advisor or department head.

________________________________________
Signature (Faculty Advisor or Department Head)

Date

The Institutional Review Board has reviewed this research proposal with the following action:
______Exempt from review, study may proceed
______Approved, study may proceed
______Not approved, see attached documentation for explanation

________________________________________
Signature (IRB)

Date
B. SAMPLE CONSENT FORM: WRITTEN CONSENT, ADULTS

This sample is a template from which a consent form can be developed. The language does not have to be repeated verbatim. THE CONSENT FORM SHOULD BE WRITTEN IN TERMS UNDERSTANDABLE TO THE SUBJECT (avoid or define technical terminology, adjust for educational background and ages, provide translations in other languages when subjects do not understand English). Investigators with projects involving more than minimal risk, and/or those working with special populations must consult this document for additional informed consent elements.

You are invited to participate in a research study conducted by [name of investigator], from the NCU [departmental affiliation]. I hope to learn [state what the study is designed to discover or establish. If a student, indicate that results will contribute to thesis or dissertation]. You were selected as a possible participant in this study because [state why subject was selected]. If you decide to participate, [describe procedures, including their purpose, how long they will take, their location and frequency. If activities are to be audio or videotaped, indicate this]. [Describe risks, discomforts, inconveniences, and how these will be managed. Describe any alternative procedures or courses of treatment, if applicable. Indicate costs of participating, if any.] [Describe benefits to subjects and humanity expected from the research]. However, I cannot guarantee that you personally will receive any benefits from this research. [If subject will receive compensation, describe amount and when payment is scheduled.] [If project is more than minimal risk, the standard language regarding responsibility for medical expenses and liability must be included. See additional elements if appropriate for this language. Other elements of informed consent may be required for a particular study.] Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Subject identities will be kept confidential by [describe coding procedures and plans to safeguard data]. [If information will be released to any other party for any reason, state the person/agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure.] Your participation is voluntary. Your decision whether or not to participate will not affect your relationship with [name agency, school, etc. where subject was recruited]. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without penalty. If you have any questions, please feel free to contact [provide phone number and department address. If student, also provide advisor name and phone, and identify as your advisor.] If you have questions regarding your rights as a research subject, contact the Chair of the Undergraduate Research Committee at NCU at 541-684-7256 or tbergquist@nwcu.edu. You will be given a copy of this form to keep. Your signature indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation without penalty, that you will receive a copy of this form, and that you are not waiving any legal claims, rights or remedies.

Signature ________________________ Date ___________________________
NOTE: Language may be altered to obtain parental consent for participation of their child (e.g., “If you decide to allow your child to participate in this study, the child will be asked to...”). Children may also sign this form if they understand the information provided, or a separate assent form may be given to young children (see following sample). If subjects are mentally disabled, the language should be appropriate to their understanding, and additional signatures are required (refer to informed consent). The form should indicate that the “parent/legal guardian” is the appropriate person to sign the form.

For research projects that involve videotaping, a videotape release form must be attached to the written consent form. If the investigator anticipates use of the tapes beyond the scope of the initial research project, the written consent form must indicate (a) who will view the tapes; (b) for what purpose(s); (c) when the tapes will be destroyed.

C. SAMPLE CONSENT FORM: YOUNG CHILDREN

Child's name _______________________________

I am interested in what attention is, so that one day we can try to help people who find it hard to concentrate on things, and I'd like you to help me. I'd like you to play a kind of game on a computer. All you'll have to do is press a button when some lights come on. It will take about an hour, but you can rest as much as you'd like, and you can stop the game whenever you want. If you want to rest, or stop completely, just tell me--you won't get into any trouble! In fact, if you don't want to play the game at all, you don't have to. Just say so. Also, if you have any questions about what you'll be doing, or if you can't decide whether to do it or not, just ask me if there is anything you'd like me to explain.

If you do want to try it, please sign your name on the line below. Your parent(s) have already told me that it is alright with them if you want to play the game. Remember, you don't have to, and once you start you can rest or stop whenever you like.

Signed:_____________________________________

Date________________________________________
D. SAMPLE CONSENT AGREEMENT FOR VIDEOTAPING

(to be attached to written consent form)

I have received an adequate description of the purpose and procedures for videotaping sessions during the course of the proposed research study. I give my consent to allow [ ] to be videotaped during participation in the study, and for those videotapes to be viewed by persons involved in the study, as well as for other professional purposes as described to me. I understand that all information will be kept confidential and will be reported in an anonymous fashion, and that the videotapes will be erased after an appropriate period of time after the completion of the study. I further understand that I may withdraw my consent at any time.

Signature of parent/legal guardian __________________ Date ___________
(if subject is a child)
Signature of participant __________________ Date ___________

E. SAMPLE CONSENT FORM: NON-SENSITIVE QUESTIONNAIRES

I would appreciate your assistance with this research project on [state purpose of research. If student, indicate that results will be used in thesis/dissertation]. This research will help me understand [state benefits to subjects and humanity expected from the research]. All you need to do is complete this short questionnaire, which should take approximately [state time needed to complete questionnaire]. If you do not wish to participate, simply discard the questionnaire. Responses will be completely anonymous; your name will not appear anywhere on the survey. Completing and returning the questionnaire constitutes your consent to participate. Keep this letter for your records. If you have any questions regarding the research, contact [give name, department, phone number, and department address if applicable. Include advisor name/phone if student, and identify as advisor]. If you have any questions regarding your rights as a research subject, please contact the IRB at 541-684-7256. Thank you again for your help.

F. SAMPLE CONSENT LANGUAGE FOR RESEARCH WITH POTENTIAL PSYCHOLOGICAL RISK

If you feel uncomfortable answering any of the questions, you may discontinue at any time or skip to the next question. If you experience any stress, anxiety or psychological discomfort as a result of participation in this research, you may contact my advisor _____________________________, or the College Counseling Center at 541-684-7471.

Debriefing Statement:
Answering personal questions about one's life can be a disconcerting experience. If answering any of these questions has upset you, or made you think of your own questions, or if you have experienced any stress or discomfort as a result of participation in this research, you may contact the College Counseling Center at 541-684-7471, or you can call the investigator or his/her advisor for other names and numbers that may be helpful to you.