INSTITUTIONAL REVIEW BOARD COMMITTEE HANDBOOK

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This is a working document that is updated regularly

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INTRODUCTION

Northwest Nazarene University is concerned with the protection of the rights and welfare of human and/or animal participants in all research conducted by faculty, staff, and students and by outside entities using NNU faculty, staff, and students as part of their research. This concern, which is the primary purpose of the Institutional Review Board (IRB), includes the protection of rights to privacy, the need for informed consent, protection of confidentiality of data, protection against physical, psychological, spiritual, social, or economic risks, and an appropriate demonstration of risk to benefit ratio. The safeguarding and confidentiality of records and data collected on individuals and groups, the use of such data by the investigator conducting the original research or by other investigators, and the use of the data at a later time are all considered within the scope of this policy.

PURPOSE

The purpose of the IRB is to ensure:

1. The protection of the rights of all human and/or animal participants involved in research projects carried out by NNU faculty, staff, and students or any outside entity wishing to conduct research using NNU personnel or students, including making a risk/benefit assessment of the study. Research methodology will not be evaluated so long as it does not impact risk and ethical issues.
2. The research conducted by NNU faculty, staff, and students meets the standards required by the governmental agencies (21 CFR 50, 21 CFR 56, 34 CFR 97, 34 CFR 350.3, 34 CFR 356.3).
3. Compliance with the policies of NNU as stated in these guidelines, thereby reducing risk of harm and individual or corporate liability with regard to all persons involved in research that are subject to IRB evaluation.

The secondary goal is to assist faculty and student researchers, staff, administrative personnel, and other involved university community members in avoiding errors or oversights that can result in justifiable complaints and actions, including lawsuits against the university and/or anyone acting in a university sanctioned capacity.

STRUCTURE

There is a three-level structure for the approval of research involving human and/or animal participants.

1. Exempt: Research that is exempt as defined in Guideline #2. (See page 7.)
2. Expedited: Research that presents no more than minimal risk to participants is eligible for expedited review as determined in Guideline #2, upon request. The chair of the IRB or a designee will review the protocol.
3. Full: Research which does not meet exempt or expedited status or presents more than minimal risk must be submitted to the IRB for full review.

PROCEDURE

All research involving human and/or animal subjects must be cleared through the IRB prior to commencement of data collection. The IRB will not review a research proposal unless a protocol for the research has been submitted. Protocols must follow the instructions laid out in Guidelines 1, 2, and 3 of this handbook. To submit a protocol, please go to Submittable at https://nnu.submittable.com/submit. Here you will find the forms for exempt, expedited, and full review protocols. All protocol forms must be completed and submitted online using the Submittable website. The IRB no longer accepts hard copies or email attachments. It is the responsibility of the principal investigator to complete these forms and attach all necessary documents as indicated in guidelines 1, 2, and 3 of this handbook.

Failure to comply with the IRB Guidelines of Northwest Nazarene University will be considered a serious violation. The IRB may forward to the relevant department chair, the School Dean, and the Vice President for Academic Affairs, documentation of any violations of the guidelines or specific committee requirements, especially in those cases determined to constitute serious or continuing noncompliance. The IRB may make recommendations to university officials regarding consequences and possible disciplinary measures.

INSTITUTIONAL REVIEW BOARD GUIDELINES

Guideline #1 - Protocol

The protocol, as approved by the IRB, becomes part of the agreement between Northwest Nazarene University and the researcher(s) about the way in which research will be conducted.

Therefore, the protocol must be an accurate description of the research. Any change in the approved protocol, including supporting documents, must be approved by the IRB. In order to ensure the integrity of the research, the protocol will not be available for review by the public until the research is completed.

A protocol, in writing and suitably titled or identified, must contain the following information:

1. Title, faculty supervisor information and approval, and principal investigator information.
2. A summary of the nature and purpose of the research.
3. A full description of the human and/or participants involved, their characteristics, the total number anticipated, and how they will be selected. Indicate explicitly whether any human participants are minors (under age 18 years) or are otherwise members of "vulnerable" populations (e.g. prisoners, hospital patients, or inpatients in state hospitals, such as the cognitively impaired, or others whose ability or competence to give voluntary informed consent may be questioned). Participants subject to "undue influence" (e.g. college classes, interest groups, clubs, Sunday School classes and/or Bible study groups) should also be considered "vulnerable." The reason for using minors or members of "vulnerable" populations as participants should be stated clearly.
4. A description of exactly how the participants will join in the research.
5. A full description and assessment of the potential benefits, if any, to the individual human and/or animal participant, and/or to the group or class of which the participant is a member, and/or to society in general as a result of the research.
6. A description and assessment of the potential risks, if any, to the individual participant, and/or group or class of which the participant is a member, and/or to society in general as a result of the research. Such risk may be physical, psychological, spiritual, economic, or social. The likelihood, severity, and duration of such risks is to be assessed. If the <u>research methods</u> create potential risk provide:

    a. A description of other less risky methods, if any, which were considered, and explain why they will not be used. See Guideline #2 and complete the form entitled "Risk Level Determination" which should be included with your protocol.

    b. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant and the name and telephone number of the investigator and research supervisor.

c. When relevant, a statement that describes the plan for medical care in the case that an untoward event occurs.

7. A description of the means to be taken to minimize such risks, including the means by which the participant's personal privacy is to be protected and the confidentiality of the information obtained from the participant maintained. Assess the likely effectiveness of such precautionary measures.

8. A description of the procedures to be used in obtaining and documenting the prior informed consent of the participant. If participants are minors, participant "assent" must be obtained as well as parental/guardian informed "consent." Whether written consent or electronic consent will be used, a copy of the consent form (and/or a verbatim copy of any accompanying oral instructions) should be attached to the protocol. For more information concerning elements included in informed consent, see Guideline #3. Copies of suggested consent forms for adults and for minors are attached to these guidelines.

9. Studies designated to have greater than minimal risk must include a description of medical services available if the participant suffers adverse health effects as a result of the research.

10. A waiver of written informed consent must be requested from the IRB if the researcher does not wish to use a written informed consent. If a waiver of the requirement for written informed consent is sought, the justifications for the waiver must be specified. See Guideline #3.

11. If cover letters, questionnaires, interview schedules, or follow up communications are to be used in the research, a copy of each must be attached with the protocol. If such are not available at the time of submission, an informative description of their content and manner of administration must be included in the protocol. The completed versions must be approved by the IRB or designee prior to use.

12. An explanation of any special or unusual circumstances regarding the research that the principal investigator believes could be relevant to the IRB's decision in reviewing the protocol.

13. When required by the nature of the research, a copy of state and/or federal documents which permit the investigator to proceed if a new drug or device is to be tested or used in the research.

14. A protocol signed by the principal investigator (the on-line form asks for a check mark to be given instead of a signature) and the immediate supervisor (e.g. department chair, research director, or research supervisor). The signature (on-line check mark and ID#) of the immediate supervisor indicates acceptance of responsibility that the research will be

conducted in accordance with ethical principles concerning the protection of participants. No protocol will be accepted without these signatures (checked boxes and ID#).

Guideline #2 – Risk & Status

Risk is defined as the probability of harm or injury (physical, psychological, social, spiritual, or economic) occurring as a result of participation in research (adaptation of Federal Guidelines in the IRB Guidebook – http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm . Both the probability and magnitude of possible harm may vary from less than minimal risk to greater than minimal risk. Research determined to have substantially significant risk to participants will not be approved by the IRB at NNU. The level of risk must be evaluated and designated by the researcher.

Risk level determination:

1. *Less than minimal risk.* Research in which there is no known physical, emotional, psychological, spiritual or economical risk. Research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.) and falls in an exempt category. Research involves no risk to participants when it includes only:

    a. Observation of public behavior or the use of information available to the public, and/or

    b. Data used in a manner that is strictly statistical and anonymous at the point of data collection – information cannot be traced to a specific participant.

2. *Minimal risk.* A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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 [Federal Policy §46.102(i)].
   For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. Research involves at least minimal risk to human participants when:

    a. The research procedure includes non-public behavior or data and/or allows for connection of the response to the individual's identity;

    b. The research procedure includes no deception of participants, no sensitive, culturally taboo, or socially controversial material that is likely to evoke responses which could distress participants; or

    c. The research procedure is unlikely to impact or change the participants' physical, social, psychological, spiritual, or economic status.

3. *Greater than minimal risk.* Research procedures that may include risk beyond that ordinarily encountered by subjects. This research requires full review by the IRB. Research involves greater than minimal risk to human participants when:

    a. The research procedure includes deception of participants; sensitive, culturally taboo, or socially controversial material that is likely to evoke responses which could distress participants;

    b. The research procedure is physically demanding or intrusive (e.g. maximal exercise testing);

    c. The research procedure may impact the physical, social, psychological, spiritual or economic status of the participant (e.g. experimental drugs, biologics or medical devices, stressful psychological testing);

    d. The research procedure involves the use of organs, tissues, or bodily fluids may create medico-legal risks;

    e. The research procedure may expose the participant to public embarrassment or humiliation through breach of confidentiality and invasion of privacy; or

    f. The research includes use of special populations (e.g. children, pregnant women, cognitively impaired, prisoners and others).

IRB review categories:

Research that does not require IRB Review. Federal regulations allow for exemption from IRB review for certain kinds of research. They also allow for each university IRB to require that all research under all circumstances be reviewed at some level by the IRB. The Northwest Nazarene University IRB has determined that research meeting the following condition does not require IRB review:

1. Data collected as a classroom activity assigned by the instructor and involving only the students enrolled in the class as the participants. The class instructor is responsible for the ethical treatment of participants as set forth in these guidelines.

Exempt Status.

Research that is "less than minimal risk" and meets one of the following criteria may complete the EXEMPT review form at https://nnu.submittable.com/submit. All other research must be reviewed either as an expedited or full board review.

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

    a. Commonly accepted educational settings include but are not limited to K-12 schools and college classrooms. They may also include after-school programs, preschools, vocational schools, alternative education programs, and other sites where educational activities regularly occur.

    b. Normal educational practices include established or innovative teaching methods (not considered to be experimental) or curriculum, and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher. Normal educational practices are activities that could occur regardless of whether the research is conducted.

        i. A study that evaluates a new instructional strategy or curriculum, or that randomly assigns students to different instructional strategies/curricula for comparison that would create inequity, would probably not be exempt since these are not "normal educational practices."

        ii. Studies that involve surveys and interviews with minors that are outside of "normal educational practices" also do not qualify for this category of exemption.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

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

    c. Research involving surveys or interviews with children, or observation of public behavior when investigators interact with children, does not qualify for exempt status under this category. In other words, the only research activities involving children that may fall under this exemption are those involving educational tests or observation of public behavior where the investigators do not participate in the activity being observed. To be exempt, these activities must also meet the condition that the data are recorded without individual identifiers, or the condition that disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be damaging to their financial

standing, employability, or reputation. Otherwise, all the requirements of the human subjects regulations apply, or

d. The research involves a task (except when the task is part of an educational test such as an intelligence test).

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior is not exempt under paragraph (b)(2) of the code of federal regulations, if:

   a. The human subjects are elected or appointed public officials or candidates for public office; or

   b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

   a. Public benefit or service programs;

   b. Procedures for obtaining benefits or services 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.

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

Expedited Status.

An expedited review is conducted by the chair of the IRB or a designee. Research that qualifies for expedited review can submit a protocol at https://nnu.submittable.com/submit. A researcher may request an expedited review if:

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

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

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

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

5. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or full--utilized by the IRB.

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

<u>Research Categories for Expedited Review.</u>

If the protocol is no more than minimal risk and meets one or more of the research categories below, it meets the criteria for expedited review. Please fill out the appropriate forms.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

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

decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

   b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

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

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the

subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

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

8. Continuing review of research previously approved by the convened IRB as follows:

    a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

    b. Where no subjects have been enrolled and no additional risks have been identified; or

    c. Where the remaining research activities are limited to data analysis.

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

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

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

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

Full Status. At their discretion, the IRB chair or a designee may determine that the study must have a full committee review.

Guideline #3 – Informed Consent

Informed consent means the knowing consent of an individual (or his/her legally authorized representative such as parent, guardian, conservator, etc.) to participate in research. An investigator shall provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

The basic elements of informed consent are: (*See sample of consent form)*

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

2. A description of any reasonably foreseeable factors that may be expected to influence a participant's willingness to participate such as potential risks, discomfort, or adverse effects.

3. A description of any benefits to the participant or to others, which may reasonably be expected from the research.

4. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained, and any limitations to confidentiality.

5. 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. This should include information such as an explanation of whom to contact for answers to pertinent questions about the

research and research participants' rights, and whom to contact in the event of a research-related injury to the participant and the name and telephone number of the investigator.

6. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

When appropriate, the following information shall also be provided to each participant:

1. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant.
2. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
3. Any additional costs to the participant that may result from participation in the research.
4. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
5. Details regarding authorization for access to the participant's personal records (school, university, hospital, employment, or others).
6. Details regarding any recording of their voices or images for data collection unless the research consists solely of naturalistic observations in public places, and it is not anticipated that the recording will be used in a manner that could cause personal identification or harm.
7. The amounts and terms of any proposed payments or other form of remuneration to participants.
8. When experimental treatments are used, clarify to participants at the outset of the research
    a. The experimental nature of the treatment;
    b. The services that will or will not be available to the control group(s) if appropriate;
    c. The means by which assignment to treatment and control groups will be made;
    d. Available treatment alternatives if an individual does not wish to participate in the research or wishes to withdraw once a study has begun; and
    e. Compensation for or monetary costs of participating including whether reimbursement from the participant or a third-party payer will be sought if appropriate.

A more complete description can be found in the Code of Federal Regulations Title 45 Part 46 section 116-117.

Waiver of Informed Consent

A waiver of the requirements for informed consent is granted only where research would not reasonably be assumed to create distress or harm and involves:

1. The study of normal educational practices, curricula, or classroom management methods conducted in educational settings.
2. Anonymous questionnaires, naturalistic observations, or archival research for which disclosure of responses would not place participants at risk for criminal or civil liability or damage their financial standing, employability, or reputation, and confidentiality is protected.
3. The study of factors related to job or organization effectiveness conducted in organizational settings for which there is no risk to participants' employability, and confidentiality is protected.
4. The study of situations in which the usual procedure for obtaining written informed consent would surely invalidate objectives of considerable, immediate importance. In this case, verbal instructions should assure the fully informed and voluntary consent of each participant to participate in the research.

The IRB typically honors requests for waiver of written informed consent when:

1. The participants of the investigation are illiterate;
2. The risks, usually psychological risks, inherent in asking participants for their signatures outweigh the risks of not obtaining the signatures; or
3. Requests for signatures demonstrably violate or distort the participants' perceptions of the nature and purpose of the investigation.

A more complete description can be found in the Code of Federal Regulations Title 45 Part 46 section 116-117.

PROPOSED SCHEDULE OF IRB DEADLINES AND MEETINGS

All research protocols are due by the 1st of the month in which the researcher wishes the protocol to be reviewed. For example for a protocol to be reviewed in the November meeting, the completed protocol must be submitted to Submittable at https://nnu.submittable.com/submit by November 1st.

All levels of review, exempt, expedited, and full, are due the 1st of the month. See Guideline #2 for a full explanation of the different levels of review.

The IRB will meet no later than the third week of each month starting in September through June to review protocols. Researchers submitting full review protocols can expect to receive feedback no later than the end of the month. If you have not received feedback by the end of the month, please contact the IRB directly at irb@nnu.edu. For exempt and expedited protocols, researchers can expect to hear back from the IRB within the first two weeks of the month. If no protocols are received by the 1st of the month, there will be no IRB meeting that month.

DECISION LEVELS AND RESUBMISSION REQUIREMENTS

Decisions are made on one of three levels: Approved, Conditional Approval, and Denied.

Approved. The reader or committee has determined from the information provided that the proposed study has been all ethical guidelines. The researcher may proceed with data collection. The chair of the IRB will notify the researcher via email and an official letter will follow containing the IRB research number.

Conditional Approval. The reader or committee has determined from the information provided that the proposed study has not meet all the ethical guidelines but the adjustments are minor. The researcher will be notified via email of the changed that must be made or the information that was lacking. The researcher will work directly with her or his reader or in the case of full-review will be assigned an IRB member to whom the researcher must report. The researcher will be given 3 months to make the corrections and complete this process. If this is not done and the committee does not receive a request for an extension, the case will be closed and the researcher will be to resubmit her or his full protocol. When the additional tasks have been completed, the reader or assigned researcher will sign the protocol as approved. The researcher will be notified and the chair will send the official letter.

Denied. The reader or committee has determined from the information provided, that the protocol is sufficiently lacking in its completeness or does not meet ethical standards. The

researcher will be sent an email from the reader or the chair of the IRB listing the reasons for the denial. A follow-up letter will be sent. The researcher must resubmit her or his protocol in its entirety with a letter of explanations directing the committee or reader how the researcher has addressed the deficiencies of the protocol. A new IRB number is assigned.

EXAMPLES OF APPROVED FORMS

The following pages contain examples of the following forms: confidentiality agreement, informed consent form, informed consent for a minor, and electronic informed consent.

Refer to GUIDELINE #3 to assure that all elements of informed consent relevant to the specific proposed research are covered, since only the basic articles are shown in the example below. The informed consent form should include the contact information for the research supervisor (NNU email, office phone number, etc.) but it should exclude any personal information of the researcher such as address, home phone numbers, etc., to minimize risk to yourself.

CONFIDENTIALITY AGREEMENT

[Insert Title of Study]

I, _____ [name of research assistant], agree to assist the primary investigator with this study by _____[list research tasks]. I agree to maintain full confidentiality when performing these tasks.

Specifically, I agree to:

1. keep all research information shared with me confidential by not discussing or sharing the information in any form or format (e.g., disks, tapes, transcripts) with anyone other than the primary investigator;

2. hold in strictest confidence the identification of any individual that may be revealed during the course of performing the research tasks;

3. not make copies of any raw data in any form or format (e.g., disks, tapes, transcripts), unless specifically requested to do so by the primary investigator;

4. keep all raw data that contains identifying information in any form or format (e.g., disks, tapes, transcripts) secure while it is in my possession. This includes:
   - keeping all digitized raw data in computer password-protected files and other raw data in a locked file;
   - closing any computer programs and documents of the raw data when temporarily away from the computer;
   - permanently deleting any e-mail communication containing the data; and
   - using closed headphones if transcribing recordings;

5. give, all raw data in any form or format (e.g., disks, tapes, transcripts) to the primary investigator when I have completed the research tasks;

6. destroy all research information in any form or format that is not returnable to the primary investigator (e.g., information stored on my computer hard drive) upon completion of the research tasks.

Provide the following contact information for research assistant:

Printed name of research assistant_____

Address:_____

Telephone number:_____

Signature of research assistant_____ Date _____

Printed name of primary investigator_____

Signature of primary investigator_____ Date_____

INFORMED CONSENT FORM

A. PURPOSE AND BACKGROUND

<Name of researcher>, a **<master's, doctoral, etc>** student in the Department of **<department>** at Northwest Nazarene University is conducting a research study related to **<brief statement of research topic>**.

You are being asked to participate in this study because you are a healthy volunteer, over the age of 18.

B. PROCEDURES (list procedures of research study)

Note: following is a list of possible procedures that could be asked of participants in a research study

If you agree to be in the study, the following will occur:

1. You will be asked to sign an Informed Consent Form, volunteering to participate in the study.

2. You will be asked to complete three surveys online.

3. You will answer a set of interview questions and engage in a discussion on your perception of the level of trust and the factors that affect the trust in the school. This discussion will be audio taped and is expected to last approximately 60 minutes.

4. You will be asked to read a debriefing statement at the conclusion of the interview.

5. You will be asked to reply to an email at the conclusion of the study asking you to confirm the data that was gathered during the research process.

These procedures will be competed at a location mutually decided upon by the participant and principal investigator and will take a total time of about 120 minutes.

C. RISKS/DISCOMFORTS

1. Some of the discussion questions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or to stop participation at any time.

2. For this research project, the researchers are requesting demographic information. Due to the make-up of Idaho's population, the combined answers to these questions may make an individual person identifiable. The researchers will make every effort to protect your confidentiality. However, if you are uncomfortable answering any of these questions, you may leave them blank.

3. Confidentiality: Participation in research may involve a loss of privacy; however, your records will be handled as confidentially as possible. No individual identities will be used in any reports or publications that may result from this study. All data from notes, audio tapes, and disks will be kept in a locked file cabinet, password protected computer or in password protected files. In compliance with the Federalwide Assurance Code, data from this study will be kept for three years, after which all data from the study will be destroyed (45 CFR 46.117).

4. Only the primary researcher and the research supervisor will be privy to data from this study. As researchers, both parties are bound to keep data as secure and confidential as possible.

D. BENEFITS

There will be no direct benefit to you from participating in this study. However, the information you provide may help educators to better understand the factors that enhance the school environment to be a place of positive staff relationships.

E. PAYMENTS

There are no payments for participating in this study.

F. QUESTIONS

If you have questions or concerns about participation in this study, you should first talk with the investigator. **<Name of researcher>** can be contacted via email at **<email address>,** via telephone at **<phone number>**. If for some reason you do not wish to do this you may contact Dr. **<name of supervisor>, <position and department>** at Northwest Nazarene University, via email at **<email address>** via telephone at **<phone number>** or by writing 623 S. University Blvd, Nampa, Idaho 83686.

Should you feel distressed due to participation in this, you should contact your own health care provider.

G. CONSENT

You will be given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You are free to decline to be in this study, or to withdraw from it at any point. Your decision as to whether or not to participate in this study will have no influence on your present or future status as a student at Northwest Nazarene University.

I give my consent to participate in this study:

_____ _____

Signature of Study Participant **Date**

I give my consent for the interview and discussion to be audio taped in this study:

_____ _____

Signature of Study Participant **Date**

I give my consent for direct quotes to be used in this study:

_____ _____

Signature of Study Participant **Date**

Signature of Person Obtaining Consent **Date**

THE NORTHWEST NAZARENE UNIVERSITY INSTITUTIONAL REVIEW BOARD HAS REVIEWED THIS PROJECT FOR THE PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH.

INFORMED CONSENT FORM

(Consent for Minor Participation)

A. PURPOSE AND BACKGROUND

<Name of researcher>, a **<master's, doctoral, etc>** student in the Department of **<department>** at Northwest Nazarene University is conducting a research study related to **<brief statement of research topic>**.

You are being asked to give consent for your child to participate in this study because **<explain rationale for minor participation>.** Their participation will help researchers **<brief explanation of significance>.**

B. PROCEDURES (list procedures of research study)

Note: following is a list of possible procedures that could be asked of participants in a research study

If you agree to be in the study, the following will occur:

6. You will be asked to sign an Informed Consent Form giving permission for your child to participate in this study.

7. Your child will be asked to participate in the **<name of survey>** no more than twice this semester.

8. Your child may be asked to participate in a short focus group with a researcher and their peers. In this focus group they will be asked to answer a set of focus group questions and engage in a discussion on **<topic>**. This discussion will be audio taped and is expected to last approximately 45-60 minutes.

These procedures will be competed at a location mutually decided upon by the participant and researcher and will take a total time of about 100 minutes.

C. RISKS/DISCOMFORTS

5. Some of the discussion questions may make your child uncomfortable or upset, but they are free to decline to answer any questions they do not wish to answer or to stop participation at any time.

6. For this research project, the researchers are requesting demographic information. Due to the make-up of Idaho's population, the combined answers to these questions may make an individual person identifiable. The researchers will make every effort to protect confidentiality. However, if you are uncomfortable answering any of these questions, your child may decline to answer them.

7. Confidentiality: Participation in research may involve a loss of privacy; however, your records will be handled as confidentially as possible. No individual identities will be used in any reports or publications that may result from this study. All data from notes, audio tapes, and disks will be kept in a locked file cabinet in the Department and the key to the cabinet will be kept in a separate location. In compliance with the Federalwide Assurance Code, data from this study will be kept for three years, after which all data from the study will be destroyed (45 CFR 46.117).

D. BENEFITS
There will be no direct benefit to your child from participating in this study. However, the information they provide may help educators to better understand how personalized learning is impacting instruction in your school district.

E. PAYMENTS
There are no payments for participating in this study.

F. QUESTIONS
If you have questions or concerns about participation in this study, you should first talk with the investigator. **<Name of researcher>** can be contacted via email at **<email address>,** via telephone at **<phone number>**. If for some reason you do not wish to do this you may contact Dr. **<name of supervisor>, <position and department>** at Northwest Nazarene University, via email at **<email address>** via telephone at **<phone number>** or by writing 623 S. University Blvd, Nampa, Idaho 83686.

Should you or your child feel distressed due to participation in this, you should contact your own health care provider.

G. CONSENT
You will be given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. Your child is free to decline to be in this study, or to withdraw from it at any point. Your decision as to whether or not to participate in this study will have no influence on their present or future status as a student in the **<Name>** District.

Name of Student: _____

I give my consent for my child to participate in this study:

_____ _____
Signature of Parent/Guardian of Participant **Date**

I give my consent for the interview and discussion to be audio taped in this study:

_____ _____
Signature of Parent/Guardian of Participant **Date**

I give my consent for direct quotes to be used in this study:

_____ _____
Signature of Parent/Guardian of Participant **Date**

Signature of Person Obtaining Consent **Date**

THE NORTHWEST NAZARENE UNIVERSITY INSTITUTIONAL REVIEW BOARD HAS REVIEWED THIS PROJECT FOR THE PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH.

SAMPLE ELECTRONIC INFORMED CONSENT

You are invited to participate in a research project about <<research topic>>. This online survey should take about <<20 to 30>> minutes to complete. Participation is voluntary, and responses will be kept confidential to the degree permitted by the technology being used. All information will be kept confidential and any identifying information will be withheld. Pseudonyms will be used for schools and school districts.

You have the option to not respond to any questions that you choose. Participation or nonparticipation will not impact your relationship with your employer. Submission of the survey will be interpreted as your informed consent to participate and that you affirm that you are at least 18 years of age.

There are risks and benefits in everything we do. The risks to the participants include a loss of time or a sense of frustration or discomfort. Your time is valuable, and you may elect to skip any questions you wish or end your participation at any time. You may also feel frustrated or uncomfortable as you examine <<research topic/focus>>. However, by participating in this survey, you will help to contribute to the body of educational research in the area of <<topic>>. Specifically, your information will contribute to research investigating << >>.

If you have any questions or concerns about the study, please contact the principal investigator, <<researcher's name>>, via email at <<researcher's email address>> or the faculty advisor, <<faculty advisor's name>> at <<faculty advisor's email address>>. If you have any questions regarding your rights as a research subject, contact the NNU Institutional Review Board at IRB@nnu.edu.

___ I affirm I am at least 18 years of age, and agree to participate in the survey.
___ I do not wish to participate in the survey.