Procedures for Research with Human Subjects

Institutional Review Board for Research with Human Subjects (IRB)

Revised (January 8, 2019)

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Introduction

The purpose of this document is to outline procedures for processes of Diné College Institutional Review Board (IRB). The policies for the Diné College IRB are provided in the *Policies for Research with Human Subjects* document. These policies include information about the purpose, scope, and mission of the IRB, as well as details about Board Membership. IRB procedures include additional information and guidelines for IRB members and Principal Investigators about specific processes for electing a chair, scheduling meetings, submitting and reviewing IRB proposals, and managing certifications, notifications, and records. The policies and procedures of the IRB apply to any research activities that involve Diné College students, faculty, or staff either as principal investigators, co-investigators, research assistants, or participants (see Appendix A for a glossary of terms, such as 'research' and 'principal investigator'). The procedures described in this document comply with standards set by the US Department of Health and Human Services as well as the Navajo Nation Human Research Code (Title 13, Chapter 25 of the Navajo Tribal Code). When applicable, Navajo Nation tribal laws will be applied [45 CFR Part 46.101 (f)].

I. Selecting IRB Members and Electing the IRB Chair

IRB members may engage in the following selection process for new members:1) nomination of prospective IRB members by current IRB members, 2) acceptance of nomination by prospective member, 3) recommendation of prospective member to College President (who retains final appointment authority for IRB membership*).

The IRB Chair must be elected by voting members. The term for the IRB Chair is one academic year. Election of the IRB Chair for the following academic year will take place before the end of the spring semester in the preceding year. Candidates for the role of IRB Chair must be IRB members* who volunteer or who accept a nomination by another voting member. The candidate who receives the highest number of votes will become Chair. Deliverables demonstrating Chair workload for purposes of release time will include meeting agendas and minutes posted on Warrior Web. In the event that the IRB Chair is not available, the Chair may designate another Board member to temporarily assume Chair responsibilities.

**See Policies for Research with Human Subjects, Section II, for more information about Board Membership*

II. Meetings

The Diné College Institutional Review Board meets multiple times a year, as needed (3-4 annually at minimum). Emergency meetings or Focus Committee meetings may be convened, as appropriate, and require at least a notice of 48 hours. Members may attend in person or via telephone/video conference. Five (5) of the members of the full IRB must be present in order to constitute a quorum and for the meeting to be official. The Chair will vote only in the event of a tie or to establish a quorum. If necessary, voting will take place online (e.g., via email or online software such as Survey Monkey). Principal Investigators should be available to the board at meetings when their research is reviewed, either by telephone, video conference, or in person, if

needed. Minutes will be taken at every meeting and posted on the Diné College IRB Warrior webpage. Minutes will include actions and votes for each research proposal or manuscript undergoing review, votes on all board actions, rationale for changes requested of the researcher by the board, and documentation of a quorum.

III. Areas of Review

Any research activities that involve human subjects conducted by Diné College students, faculty, or staff, whether funded or unfunded, shall be under the jurisdiction of the Diné College IRB. This jurisdiction includes research that is conducted outside of the Navajo Nation. Any research activities that involve Diné College students, faculty, or staff as human subjects shall also be under the jurisdiction of the Diné College IRB. Research activities include any systematic investigation that leads to generalizable knowledge. In the event research is undertaken without the intention of involving human subjects, and subsequently an investigator wishes to involve human subjects in the research, the research must be reviewed by the Diné College IRB in accordance with the policies and procedures outlined in this manual.

The Diné College IRB will have the authority to provide final review and action decisions (Approve/Pending (i.e., conditionally approved)/Disapprove) for research in which students are Principal Investigators and are being mentored by Diné College Faculty/Staff advisors. Research in which Faculty or Staff are the Principal Investigators must be reviewed by the Diné College IRB but is also subject to the review and approval of the Navajo Nation Human Research Review Board (NNHRRB). Student investigators may not conduct any research activities without prior approval of the Diné College IRB. Other investigators may not conduct any research activities without approval of both the Diné College IRB and the NNHRRB.

The IRB Chair (or the Chair's designee) will be responsible for determining whether the research should be reviewed by the full board or by a Focus Committee of the board. If additional information/clarification is necessary, the IRB Chair must be contacted.

Research Covered by Review of Full IRB

Research which has greater than minimal risk to subjects must be reviewed by the full IRB in which a quorum is established. In order for the research to be approved, the IRB shall determine that all criteria for approval (see section IV) are satisfied and the research must receive the approval of a majority of the members present at the meeting. Research involving "greater than minimal" risk includes procedures that have the potential to cause, physical, psychological, or emotional harm that is greater than what is ordinarily encountered in daily life or during the performance of routine procedures in education and/or in the practice of psychology and medicine. Such research includes, but is not limited to:

- Research that involves a sensitive and vulnerable populations (children, prisoners, pregnant women, mentally disabled persons, educationally or economincally disadvantaged persons)
- Research which involves the administration of drugs or other substances to subjects
- Research involving subjects with life-threatening physical conditions
- Research involving physically or psychologically intrusive procedures

- Research which previous experience (by the particular investigator or other investigators) has shown to create a potential of risk to subjects
- Research which potentially could put the subject at risk for legal or civil liability or invade a subject's privacy in regard to sensitive aspects of his/her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use).

Research Covered by Review of the IRB Focus Committee (Expedited Review)

Expedited review may occur for minor changes in approved research and for research involving no more than minimal risk in which subjects' identities are easily identifiable. Expedited research includes but is not limited to the following:

- Research involving minimal risk in which subjects include children in educational research or individuals from vulnerable populations in public benefit studies
- Research involving broad consent
- The following types of studies if subjects' identities are easily identifiable:
    i. Research on individual or group behavior, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects,
    ii. Research using educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior
    iii. Research involving benign behavioral interventions (such as studies of perception, cognition, game theory, or test development in which the investigator has no reason to think the subjects will find the interventions offensive or embarrassing) in conjunction with the collection of information from an adult subject (including written or verbal responses or audiovisual recording) as long as informed consent is obtained and identification would not put subjects at risk of criminal, work, financial, or other harm.
    iv. Research involving the collection or study of existing data, documents, records, specimens, or other products (i.e., secondary data).

    **Note that items i-iv may qualify as exempt from review if subjects' identities cannot be readily ascertained, either directly or indirectly. Research may also qualify as exempt if the research activities occur in schools or other educational settings, involves normal educational practices, includes evaluations of curricula, or includes educational interventions, as long as these activities do not interfere with students' ability to learn educational content or educators' assessment activities. Submission to the IRB is still required for exempt human subjects research.*

Additionally, a Focus Committee review may be used when there are minor changes in previously approved research during the period (one year or less) for which approval is authorized. The IRB will have responsibility for determining what does or does not meet the criteria for a Focus Committee review. The Focus Committee review may be carried out by the IRB Chair or by one or more reviewers designated by the Chair from among members of the IRB. When conducting this review, IRB members may exercise all of the authorities of the IRB, except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after a full IRB review has been conducted.

All IRB members must be advised of research proposals that have been approved using the Focus Committee procedures at the next regularly scheduled meeting.

Continuation/Renewal

Continuing review is not required for projects that qualify for expedited review or for research that is limited to data analysis. Continuing review of research that qualifies for full review must be conducted at intervals appropriate to the degree of risk, but not less than once per year. The IRB cannot approve a research project for more than 12 months. All reviews for continuation will be conducted by the Focus Committee review, if no changes have been made to the research protocol and/or no adverse or unexpected reactions or side effects have occurred or are expected (i.e., minimal risk). The full IRB will be given the opportunity to review the continuation/renewal report.. In all other instances, continuing review will be conducted by the full IRB.

Revision

If the investigator, during the course of conducting the research, revises the research protocol (e.g., makes changes to the informed consent form, survey instruments used, or number and nature of subjects), he/she will notify the IRB Chair immediately. The Chair will determine the need for additional review as well as the type of review and then notify the IRB members. Researchers must report any unanticipated problems involving risks to participants or others or any non-compliance with IRB policies and procedures.

IV. Criteria for Approval of Research

In order to approve research, the IRB will determine that all of the following requirements are satisfied:

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable and reasonable. In making this assessment, IRB will take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of special problems of research involving vulnerable populations, such as children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged individuals.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative and, if necessary, interpreted in the primary language of the subject.
- Informed consent will be appropriately documented
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects
- When appropriate, adequate provisions exist to protect the privacy of subjects and to maintain the confidentiality of data
- Additional safeguards have been included in the study to protect the rights and welfare of vulnerable populations, such as children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged.
- All appropriate cultural protections are in place

- Research activities are feasible and possess scientific merit
- All researchers are required to complete "Human Subjects Research Training." To access the training, click on the link below, click "Register," and choose NAU (Northern Arizona University) when asked for your affiliation (NAU has agreed to partner with Diné College to offer this training).
  https://about.citiprogram.org/en/course/human-subjects-research-2/

Conduct and Responsibility of a Researcher

The Diné College IRB expects all researchers to understand the basic principles of ethical research, which includes the following, at a minimum:

- Design research that has potential to directly or indirectly benefit human beings
- Use fair subject selection/recruitment methods for study subjects
- Plan experimental procedures with consideration for the physical and psychological safety of subjects
- Disseminate results to the impacted community and subjects.
- Understand the definitions of "research" and "human subjects" from The Research Act of 1974, 45 CFR 46.102, the Diné College Procedures for Research for Human Subjects and the Navajo Nation IRB procedures.
- Understand reasons for federal regulations about human subjects research
- Understand the Belmont Report principles of respect for persons, beneficence, and justice
- Describe at least three historical examples of the abuse of human subjects that led to legislation designed to protect the rights of human research participants
- Recognize the requirement for human research protection training for every investigator
- Understand investigator responsibilities associated with IRB approval of research involving human subjects
- Understand the consequences for students, staff and faculty for failing to obtain IRB approval before initiating research involving human subjects

V. Types of IRB Actions

The IRB shall review and have the authority to approve, tentatively approve pending receipt of additional information, or disapprove research involving human subjects for research projects in which a Diné College student is the Principle Investigator (see definitions below). For all other research activities, the IRB shall review and provide recommendations regarding final decisions to the NNHHRB.

Approve
The protocol is approved as submitted.

Pending (Conditionally Approve)
A protocol is considered pending when the problems identified in the protocol are not serious and generally fall into two categories: 1) the investigator needs to clarify an aspect of the study or provide additional information, or 2) minor changes need to be made in the informed consent document. In these cases, approval can be given after the

investigator rewrites the informed consent and/or submits to the Chair a written response to the IRB's questions and concerns.

Disapprove
The IRB will disapprove the proposed research if it places the subjects at risks, which far outweigh the benefit or value of the knowledge to be gained, or it raises such serious ethical questions as to be unacceptable. In the event a disapproval is foreseen, the investigator will be invited to attend the meeting of the IRB to discuss the protocol. A research activity may be disapproved only after a full IRB review has been conducted.

Suspension or Termination of Research

The IRB shall have authority to suspend or terminate research that is not being conducted in accordance with the IRB's requirements, other institutional and federal requirements, or has been associated with any serious harm to subjects. Concerns regarding the conduct of research must be reported immediately to the Chair of the IRB by any individual having such knowledge. Any suspension or termination of research must include a statement of the IRB's action and the Chair must report its decision promptly to the principal investigator and the funding agency, in the case of a sponsored project.

Appeals

Researchers have the right to submit an appeal regarding any IRB decision or action. To complete an appeal, a Principal Investigator must resubmit a complete proposal, including any and all changes required by the IRB, and must submit a cover letter that summarizes the original IRB decision/action, all changes that have occurred in the research plan/proposal, and the rationale for requesting reconsideration by the IRB.

VI. Preparing and Submitting Proposals to the IRB

The Institutional Grants and Sponsored Projects Office (IGO) will be responsible for coordinating the submission of required documentation to the IRB for review at its next scheduled meeting. All applications will be submitted to either the IGO Compliance Officer or the IRB Chair. All applications received by the IGO Compliance Officer will be immediately forwarded to the IRB Chair, who is then responsible for coordinating the review process among the IRB members.

The principal investigator must submit the following:

- The original Submission Form (see Appendix B)
- One copy of the IRB Protocol (see Appendix C), including all research instruments (questionnaires, interviews, etc.)
- An Informed Consent Form (see Appendix D)
- When applicable, documentation related to research activities involving special populations (see Section VII below)
- "Human Subjects Research Training" certificate demonstrating that training has been completed within the last 3 years. To access the training, click on the link below, click "Register," and choose NAU (Northern Arizona University) when asked for your

affiliation (NAU has agreed to partner with Diné College to offer this training). https://about.citiprogram.org/en/course/human-subjects-research-2/

- Student PIs must also submit a description of their roles and responsibilities in the project, the roles and responsibilities of their instructor(s), mentor(s), or advisor(s), and the procedures that are in place to ensure proper mentorship. If the student-lead project is funded or is part of a mentor/advisor's larger program of research and scholarship, the student PI must also describe the contribution that the student-lead project makes to the larger program of research.

Once an application is received by the IRB Chair, the IRB Chair (or the Chair's designee) will review for completeness and determine whether a Full Review or an Expedited Review (see Section III in this manual) is warranted. Upon receipt of all required paperwork, the IRB Chair will log the IRB submission, assign a protocol number, and forward copies to IRB members. Insufficient information may delay processing and IRB approval.

VII. Special Populations

The federal government has extensively regulated and provided additional safeguards with respect to research, development, and related activities involving "special populations"; these include children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged. The following are guidelines for the inclusion of these special populations as subjects in research. If investigators need additional information and/or clarification regarding special populations, they are to contact the IRB Chair or the Chair's designee.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards must be included in the study to protect the rights and welfare of these subjects. Projects must include a plan that protects subjects' privacy and ensures confidentiality of data.

Neonates

Research involving neonates will be submitted to a special review process in which the rationale for conducting such research will be assessed.

Prisoners

Inasmuch as prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision about whether or not to participate as subjects in research, additional safeguards for their protection must be adhered to. With respect to research involving prisoners, the IRB shall also meet the following specific requirements:

- A majority of the Board (exclusive of prison members) shall have no association with the prison(s) involved, apart from their membership on the Board
- At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a

particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

The following research involving prisoners is permitted:
Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if 1) the institution has certified to DHHS that the IRB has approved the research, and 2) and in the judgment of the agency, the research involves solely the following:

- study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) only after the Secretary of the DHHS has consulted with appropriate experts, and published in the *Federal Register* his or her intent to approve such research; or
- research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups that may not benefit from the research, the research may proceed only after the Secretary of the DHHS has consulted with appropriate experts, and published in the Federal Register his/her intent to approve such research.

Children

Research involving children is permitted in the following instances when/if

- the IRB finds that no greater than minimal risk to children is presented, and adequate provisions are made for soliciting the assent of the children and the permission of parents or guardians, as outlined below.
- the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds:
    1. the risk is justified by the anticipated benefit to the subjects;
    2. the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
    3. adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as outlined below.
- the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:
    1. the risk represents a minor increase over minimal risk;

2. the intervention or procedure presents experiences that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
3. the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for understanding or amelioration of the subjects' disorder or condition; and
4. adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as outlined below.

Wards. Children who are wards of the state of any other agency, institution, or entity can be included in the research only if such research is:

- related to their status as wards, or
- conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the IRB approves the research, it shall require the appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in *loco parentis (in place of the parent)*. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way with the research, the investigator(s), or the guardian organization.

Individuals with Impaired Decision-making Capacity

Informed consent will be sought from each prospective subject's legally authorized representative or guardian, if necessary.

Requirements for Parental/Guardian Permission and for Assent by Children

The IRB shall require that adequate provisions be made for soliciting the permission of each child's parents or guardians. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient if the research does not involve greater than minimal risk, or does involve greater than minimal risk, but presents the prospect of direct benefit to the individual subjects. If the research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizing knowledge about the subject's disorder or condition, the IRB will require both parents' permission. Exceptions would include: 1) one parent is deceased, unknown, incompetent, or not reasonably available, or 2) when one parent has legal responsibility for the care and custody of the child.

Permission by parents or guardians shall be documented in accordance with and to the extent required under the Informed Consent section of this manual (see Appendix D).

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages,

maturity, and psychological state of the children involved. This judgment may be made for all children to be involved or for each child, as the IRB deems appropriate.
If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.
When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

VIII. Notification, Certification, and Records

Notification of IRB Actions to the Investigator

An IRB Chair shall provide written notification to the IGO Compliance Office (or his/her designee) and to the PI. The notification will include the IRB's decision to approve or disapprove the proposed research activity, any modifications required to secure IRB approval of the research activity, and information about key personnel who must be informed of the research, including the College President, the Provost, the Deans, and any other individuals who might be impacted by the research (e.g., faculty who may be contacted for recruitment and/or data collection during class time, etc). If an IRB decides to disapprove a research activity, the IRB Chair shall include a statement of the reasons for its decision in the written notification and give the investigator an opportunity to respond in writing. All information provided in notifications to investigators will be determined by the IRB.

Certification of IRB Review (for Funded Projects only)

Certification of IRB review involves official notification by the College to the DHHS that the research activity or project involving human subjects has been reviewed by the IRB.

Records

It will be the responsibility of the Chair or the Chair's designee, in coordination with the Office of the IGO, to prepare and/or maintain adequate documentation of IRB activities regarding research involving human subjects, including the following:

- Copies of all research proposals reviewed and actions taken, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects
- Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of issues of dispute and their resolution
- Records of continuing review of research activities
- Copies of all correspondence between the IRB and investigators

- A list of all IRB members, including their name, race, ethnicity, and gender; earned degrees; affiliation, indications of experience, such as board certifications, licenses, etc.
- Written policies and procedures governing the IRB.
- Statements of significant new findings

Copies of all documentation will be maintained in the IGO's Office. All records shall be retained for at least three (3) years. Records relating to funded research conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representative of the department or agency at reasonable times and in a reasonable manner.

The IGO Compliance Officer (or his/her designee) will provide an annual report summarizing highlights of all research activity to the Office of the President by the last working day of the academic year.

IX. Sharing Results of the Research

Principal investigators are required to share the results of their research with Diné College. A research paper, short report, poster, or powerpoint presentation that summarizes preliminary results and/or final results should be presented to the IGO Compliance Officer (or his/her designee), who will distribute to the Diné College IRB Chair and to the Diné College President. All research papers submitted to academic journals and other venues will require Diné College IRB approval before submission. Manuscripts will be submitted to the IGO, who will then forward to the IRB Chair. Written summaries of conference presentations will be submitted to the IGO Compliance Officer for distribution to the IRB Chair. For student investigators, IRB review of conference presentations is not required before presenting at conferences. The IRB Chair will coordinate distribution of all summaries and manuscripts to the IRB members.

X. Cooperative Research

Cooperative research projects are those that involve more than one institution and can be designed to be both multi-site and multi-protocol in nature. In the conduct of such projects, each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations.

- **Institutional Approval**: In cases where the research project will be housed and conducted at another institution with participation by Diné College faculty, staff, or research participants, it is required that documentation of the primary institution's IRB approval and a copy of the research protocol and consent forms be obtained and made part of the Diné College IRB records. The proposed research project must then go through an additional review by and receive approval from Diné College's IRB. All cooperative research projects involving Diné College faculty, staff, or research participants, whether conducted at Diné College or off-site, must have Diné College IRB approval as well as the approval of the Navajo Nation Human Research Review Board. Diné College maintains the right to review all cooperative research projects that are

associated with Diné College faculty, staff, or students (45 CFR 46.114 Cooperative Research, section b, 2, i).

- **Assurances**: It is the responsibility of the lead institution to file the required assurances and certifications with the Office for Protection from Research Risk (OPRR).

XI. Assurance of Compliance

Institutions that engage in research funded by the Department of Health and Human Services (DHHS) must file for Federal Wide Assurance as an assurance of compliance with the agency's regulations governing the protection of human subjects. The assurance is a written agreement, which includes the following:

- A statement of ethical principles and institutional policies governing research involving human subjects
- IRB, institution, and investigator compliance with 45 CFR Part 46
- Certification of IRB approval and institutional endorsement
- A list of IRB members and their qualifications
- Written procedures which the IRB will follow for conducting its initial and continuing review of research and for reporting its findings and actions to the the institution, for determining which projects require review more often than annually, for ensuring prompt reporting to the IRB of proposed changes in a research activity
- Written procedures for ensuring prompt reporting to the IRB of any anticipated problems involving risks to subjects or any noncompliance with this policy and any suspension or termination of IRB approval

XII. Changes in Policies and Procedures

Any procedures governing the IRB may be changed at a regularly convened IRB meeting by a vote of the majority of the Board members present, based on all members present. Any changes made will be to facilitate the effective and efficient operation of the IRB and in no way shall be in conflict with the rules and regulations set forth in federal statutes and regulations relating to the protection of human subjects or by the Navajo Nation Human Research Code. Substantive changes will be submitted to the President for review and approval. Any changes in procedures shall be distributed to all members and shall be included as (an) amendment(s) to this manual. The IRB Chair will make changes to these procedures and will be responsible for completing and distributing any amendments to this manual. The IRB will review at six-month intervals the federal guidelines governing research with human subjects, and update, as necessary. An updated copy of the IRB policies and procedures will be provided to the Institutional Grants and Sponsored Projects Office (IGO) on an annual basis.

All changes in IRB policies must be approved by the IRB, the College President, and the Diné College Board of Regents.

References

Angal, J. & Andalcio, T. (2015). CRCAIH Tribal IRB Toolkit. *Collaborative Research Center for American Indian Health.*

Revised Common Rule Regulatory Text (2018). *Office for Human Research Protection*, Retrieved from https://www.hhs.gov/ohrp/

Appendix A

Glossary of Terms

Assent
A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Assurance
A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

Authorized Institutional Official
An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

Certification
The official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Children
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.

Contract
An agreement; as used here, an agreement that a specific research activity will be performed at the request, and under the direction, of the agency providing the funds. Research performed under contract is more closely controlled by the agency than research performed under a grant.

DHHS
Department of Health and Human Services

Fetus
The product of conception from implantation until delivery.

IRB Focus Committee Review
Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than the entire IRB. Federal rules permit this type of review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

Full Board Review
Review of proposed research at a convened meeting at which five of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

Grant
Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

Guardian
An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Human Subjects
Individuals whose physiologic or behavioral characteristics or whose understanding of their lived experiences and responses are the object of study of a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

Informed Consent
A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

Institutional Review Board (IRB)
A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. Under the federal regulations, an IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

IRB Approval
The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

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. 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 a routine physical examination.

Neonate
A newborn.

Office for Protection from Research Risks (OPRR)
The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.

Parent
A child’s biological or adoptive parent.

Permission
The agreement of parent(s) or guardian to the participation of their child or ward in research.

Pregnancy
The period of time from implantation until delivery.

Principal Investigator
The scientist or scholar with responsibility for the design and conduct of a research project.

Prisoner
Any individual involuntarily confined or detained in a penal institution.

Protocol
The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description

of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Risk

The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. (See Minimal Risk)

Appendix B

Institutional Review Board for Research with Human Subjects (IRB)
Submission Form

Instructions: In order to comply with federal regulations as well as to conform with guidelines of the College's Institutional Review Board (IRB), the principal investigator is required to complete all of the following items contained in the Submission Form and the IRB Protocol. Upon completion of all information, the principal investigator must submit the original Submission Form and one copy of the IRB Protocol, including all consent forms and research instruments (questionnaires, interviews, etc.) to the Institutional Grants and Sponsored Projects Office (IGO). Incomplete forms may delay review by the IRB. For further information, refer to the **Policy Manual for Research with Human Subjects and the Procedure Manual for Research with Human Subjects**.

I. General Information

A. Project Title_____

New_____ Continuation/Renewal_____ Revision_____

Proposed Start Date_____
Proposed Duration of Research_____
Performance Site(s)_____

B. Principal Investigator_____
Student _____ Faculty _____ Staff _____
**Please note that all research in which a Faculty/Staff member is the Principal Investigator is also subject to review and approval by the Navajo Nation Human Research Review Board (NNHRRB)*
College/Center _____
Home Mailing Address_____
City_____ State_____ Zip_____
Home Phone Number _____
Office Phone Number_____
Email Address: _____
Co-Investigator(s) *Please Note: For Student PIs, Co-Investigators include instructor(s), mentor(s), and/or advisor(s):* _____

Principal Investigator's Signature_____Date_____

II. Funding Information

If this protocol is part of an application to an outside agency, please provide:

A. Source of Funding _____
B. Project Title (if different from above)_____
C. Principal Investigator (if different from above)_____

D. Type of Application:
E. Grant_____ Subcontract_____ Contract_____ Fellowship_____
F. Date of Submission _____

III. Cooperative Research

Cooperative research projects are those that involve more than one institution and can be designed to be both multi-site and multi-protocol in nature. Each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations. Diné College maintains the right to review all cooperative research projects that are associated with Diné College faculty, staff, or students. If this proposal has been submitted to another Institutional Review Board please provide:

Name of Institution _____
Date of Review _____ Contact Person _____
IRB Recommendation _____

IV. Subject/Patient Information

A. Types of Subjects/Patients (check all that apply)
Fetus in Utero/non-viable fetues/abortuses
Newborns/Infants
Children (aged 2-12)
Adolescents (aged 13-18)
Adults (over 18)
Pregnant Women
Special populations (e.g., prisoners, mentally disabled)
Specify _____
B. Other (Check all that apply)
Use of investigational drugs or devices
Information to be collected may require special sensitivity
(e.g. substance abuse, sexual behavior)
C. Number of Subjects/Patients _____
D. Approximate time commitment for each subject/patient _____
E. Compensation to subjects/patients : Yes_____ No_____
F. Form (e.g. cash, meals) _____ Amount_____

V. Continuation or Renewals

A. Attach a copy of the original IRB protocol
B. Indicate all proposed changes in the IRB protocol affecting subjects
C. Progress Report

- Indicate the number of subjects entered in the study, including their group status, whether they are active or completed, the number of subjects still pending, and the time frame of subject participation.
- Indicate adverse or unexpected reactions or side effects that have occurred or are expected. If none, state none.
- Summarize the results of the investigation to date (in terms of subjects entered, in process, completed, and pending).
- Attach consent form(s) to be used and indicate if any changes have been made.

VI. Protecting Human Participants Training

- "Human Subjects Research Training" is completed within the last 3 years. To access the training, click on the link below, click "Register," and choose NAU (Northern Arizona University) when asked for your affiliation (NAU has agreed to partner with Diné College to offer this training).

  https://about.citiprogram.org/en/course/human-subjects-research-2/

  Yes ____ No _____

  Date of Completion: _____

  Certificate demonstrating completion is included in proposal: Yes ____ No _____

Appendix C

Protocol

The IRB protocol is the formal design or plan for the proposed experiment or research activity; specifically, it is the plan submitted to the IRB for review and subsequently, to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data. The following format should be used in developing the research protocol.

Description of Study

Purpose and Potential Benefits

Summarize the background, rationale, nature, and significance of the proposed research.

Location of Study

Identify all sites at which research will be conducted.

Dates of study

Include month/day/year of start and end dates of study.

Subjects

Include estimated number and description of types of subjects (e.g., normal volunteers, pregnant women, students), age, sex, inclusion and exclusion criteria, and source of subjects.

Methods and Procedures

Provide details on subject recruitment, nature and type of evaluation, subject's time commitment, proposed follow-up, debriefings when indicated, and any other information necessary to evaluate the involvement of subjects in the research. Any media, including flyers, brochures, or other advertisements used to recruit human subject participation in a research study, must be submitted to the IRB for review and approval and must be included as part of the IRB submission package.

Participant Payments or Costs

Indicate whether the subjects will be offered an incentive to participate in the study and if so, in what form (e.g., cash, meals, taxi fare, etc.) and in what amount.

Subject Confidentiality

Indicate the extent to which confidentiality of records identifying subjects will be maintained. Be specific where will the records be maintained? Who will have access to the records? How records will be maintained, i.e., hardcopy or electronic? Etc.

Potential Risks to Subjects

Specify any risks (physical, social, psychological, legal), indicate precautions instituted to minimize risks, and describe procedures to be followed in the event of problems. Specify the results of pilot work or the work of others with similar procedures.

Risk/Benefit Ratio

Specify the level of risk in relation to anticipated benefits.

Informed Consent

A copy of all proposed informed consent forms must be attached to the research protocol. Refer to the Appendix D for all information pertaining to development of Informed Consent forms.

Student PIs

Student PIs must also submit a description of their roles and responsibilities in the project, the roles and responsibilities of their instructor(s), mentor(s), or advisor(s), and the procedures that are in place to ensure proper mentorship. If the student-lead project is funded or is part of a mentor/advisor's larger program of research and scholarship, the student PI must also describe the contribution that the student-lead project makes to the larger program of research.

Appendix D

Informed Consent

One significant outcome of the Nuremberg medical trials was the establishment in 1947 of the Nuremberg Code, which set forth ten principles for conducting research involving human subjects. The first of those principles states, "the voluntary consent of the human subject is absolutely essential." The Belmont Report states that an autonomous agent is “an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.” Respect for persons requires that prospective research subjects “be given the opportunity to choose what shall or shall not happen to them” and thus necessitates adequate standards for informed consent. Thus, no investigator may involve a human being as a subject in research, as defined in this policy and procedure manual, unless the investigator has obtained the subject's informed consent. The process of *informed consent* is constituted by two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced, i.e. his or her consent is voluntary. Once informed consent is obtained, documentation to that effect shall follow the procedures outlined in this manual in the "Documentation" section below.

Additionally, the researcher should be aware that litigation against the College is always a possibility. From this perspective, even an ethical informed consent is not sufficient. Rather, we need an ethical informed consent which is legally valid and the legal validity of which can be demonstrated (should such a need arise), and which does not include any exculpatory language that either diminishes the legal rights of participants or releases researchers and organizations from liability for negligence.

General Requirements

The process of obtaining informed consent shall contain the following elements:

1. It should be obtained from the subject or the subject's legally authorized representative
2. It should be in language understandable to the subject or his or her legal representative
3. It should only be obtained under circumstances that provide the subject with sufficient opportunity to discuss study procedures, to consider whether or not to participate, and that minimizes the possibility of coercion or undue influence.
4. It should ***begin*** with key information that is most critical for understanding the reasons to participate or not to participate.
5. It must present research-related information in sufficient detail and in a way that facilitates understanding of the reasons why one might or might not want to participate.

Basic Elements

- A statement that the study involves research
- The purpose of the research
- The expected duration of subject’s participation
- A description of the procedures to be followed
- Identification of any procedures that are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject

- A description of any benefits to the subject or to others that may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- For research involving more than minimal risk:
    - A description of any compensation to the subject
    - A description of any treatments available if injury occurs, what they consist of, and where additional information can be obtained
- Contact information if there are any questions about the research and the subject's rights or if there are any research-related injuries
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits, and that the subject may discontinue participation at any time without penalty or loss of benefits
- A statement describing the process by which confidentiality of records identifying the subject will be maintained, including a description of procedures for protecting privacy and specific information regarding how data will be stored to ensure security and confidentiality
- A statement about whether information obtained through the study procedures might be used for future research studies after removal of identifying information

Additional Elements

When appropriate, one or more of the following elements shall be provided to each subject:

- Statement that procedure may involve unforeseeable risks to the subject
- Description of circumstances under which the subject's participation may be terminated by the investigator without the subject's consent
- Additional costs to the subject resulting from participation in the research
- Consequences of the subject's decision to withdraw from the research and procedures for termination of participation by the subject
- Statement that significant new findings developed during research which may relate to subject's willingness to continue will be provided to the subject
- Approximate number of subjects involved in the study.
- A statement regarding whether clinically relevant research results will be disclosed to subjects, and if so, under what conditions
- If applicable, statements about the use of a subject's information for commercial profit or genetic research

Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information (including identifiable biospecimens)

Broad consent for the storage, maintenance, and secondary research use of identifiable private information is permitted as an alternative to informed consent requirements. If the subject or legally authorized representative is asked to provide broad consent, the following shall be provided:

- A description of any reasonably foreseeable risks or discomforts to the subject

- A description of any benefits to the subject or to others that may reasonably be expected from the research
- A statement describing the process by which confidentiality of records identifying the subject will be maintained
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits, and that the subject may discontinue participation at any time without penalty or loss of benefits
- If applicable, statements about the use of a subject's information for commercial profit or genetic research
- A general description of the types of research that might be conducted with sufficient detail such that a reasonable person would expect that broad consent would apply to those research activities
- A description of identifiable private information that might be used in research, whether it will be shared, and the types of institutions or researchers that might conduct research with this information
- A statement that subjects or legally authorized representatives will not be informed of the details or purpose of any specific research studies that might be conducted using the subject's identifiable private information and that, by providing broad consent, they might have chosen not to consent to those research studies
- A statement that results from the research will not be disclosed to the subject (unless it is known that clinically relevant research results and individual results will be disclosed)
- Contact information if there are any questions about the research, the subject's rights, or storage and use of the subject's identifiable private information or if there are any research-related injuries

Additional Instructions

Written Consent forms should contain the basic elements or additional elements outlined above, as appropriate, and follow the format outlined below:

- Each page of the consent form should be on Diné College letterhead, except in cases of collaborative projects when the letterhead from a College, agency, etc. is acceptable.
- If the research is externally funded, the funding agency should be listed on the consent form.
- The title of the study and the name, address, and telephone number of the investigator(s). The Principal Investigator's address and phone number, and the telephone number of the IRB Chairperson must appear on the consent form. For a student principal investigator, the address and phone number of his/her mentor/advisor(s)/clinical supervisor(s) must also appear on the form.
- Voluntary Consent by the Participant and signature - The following voluntary consent paragraph must be used in all consent forms and must appear in boldface type: "I have read this consent form (or it has been read to me) and I fully understand the contents of this document and voluntarily consent to participate. All of my questions concerning this research have been answered. If I have any questions in the future about this study they will be answered by the investigator listed above or his/her staff. A copy of this form has been given to me." Consent forms must provide space for the subject's signature, the date,

and the signature of a witness, generally the member of the research staff obtaining the consent.

Documentation (see below for more detailed Instructions for Completion)

- Informed consent will be documented by using a written consent form approved by the IRB. The form will be signed by the subject or the subject's authorized representative. A copy will be given to the person signing the form.
- Researchers must only distribute informed consent forms with current IRB approval dates on them.
- Two types of consent forms are permissible:
    - A written **consent document** that includes all of the requirements stated above (this form made be read to the subject or the subject's legally authorized representative):
    - A short written form which states that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative, and that the key information that is most critical for understanding the reasons to participate or not to participate was presented first before any other information was provided. When using the short form the following conditions must be met:
        1. the written summary of what is to be said receives prior approval of the IRB
        2. a witness must be present at the oral presentation
        3. the short form is signed by the subject or his or her representative
        4. the witness signs both the short form and the written summary is given to the person signing the form, and
        5. a copy of both the short form and the written summary is given to the person signing the form.

Exceptions from Requirements for Informed Consent (Waiver of Informed Consent)

DHHS Exceptions

There are only certain conditions under which documentation of informed consent and its required elements can be waived (see below). In order to approve research involving collection of new data, IRB applicants will need to either: a) include a copy of the informed consent document including all requirements, or b) provide a justification for passive consent or modification of requirements that aligns with HHS.gov guidelines.

Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials

Under 45 CFR 46.116(e), an IRB may waive the requirement for obtaining informed consent or parental permission or approve a consent or parental permission procedure that leaves out or alters some or all of the elements of informed consent, provided that the IRB finds and documents that the following two criteria are satisfied:

1. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    - public benefit or service programs;
    - procedures for obtaining benefits or services under those programs;
    - possible changes in or alternatives to those programs or procedures; or
    - possible changes in methods or levels of payment for benefits or services under those programs

    Note that this criterion means that only public benefit or service program research activities that are under state or local authority meet this criterion.

2. the research could not practicably be carried out without the waiver or alteration.

    This criterion means that the practical circumstances of the research are such that the research is not feasible if the informed consent of the subjects must be obtained.

If a broad consent procedure is used, an IRB may not omit or alter any of the required elements. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, an IRB cannot waive consent.

General waiver or alteration of consent

Under the IRB may waive the requirement for obtaining informed consent or approve a consent procedure that leaves out or alters some or all of the elements of informed consent, provided that the IRB finds and documents that all of the following four criteria are met:

1. the research involves no more than minimal risk to the subjects;
2. the research could not practicably be carried out without the waiver or alteration;
3. If the research involves using identifiable private information or biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
5. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

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

Screening, recruiting, or determining eligibility

An IRB may approve a research proposal in which an investigator will obtain information for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or subject's legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

Posting of clinical trial consent form

For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms. The informed consent form must be posted after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject.

Preemption

The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws that require additional information to be disclosed in order for informed consent to be legally effective, including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe [45 CFR 46.116 (j)].