Procedures for Research with Human Participants

Institutional Review Board for
Research with Human Participants (IRB)

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I. 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 Participants 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)].

II. IRB Membership, Leadership, and Procedures

A. Leadership

1. IRB Chair. The IRB Chair must be elected by voting members for a term of 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.
2. Vice Chair. A vice chairperson for the IRB will be nominated by a member of the IRB and voted on through the same process used to elect the chair. The role of the Vice Chair will be to lead IRB meetings in the event that the chair is unavailable.

B. Membership:

1. Core IRB. The core IRB will review proposals and materials related to social and behavioral sciences and will include at a minimum: (a) two Diné College faculty members from different departments in which human subjects' research may plausibly be conducted, (b) two community members unaffiliated with Diné College, (c) two representatives knowledgeable in the Navajo language and Navajo traditional teachings, and (d) representatives of at least two Diné College locations. The core IRB will seek equal representation by age and gender groups, and may include two DC juniors or seniors who have successfully completed at least one research course.
2. Specialty IRBs. When the research being reviewed extends beyond social and behavioral sciences, the IRB will seek representation from at least one representative

with expertise in that specialty area. Such situations might include but is not limited to the following: biomedical research, research involving animals, research involving Navajo history, or research with one of the vulnerable populations described in Section VI. In each instance, the IRB must include an individual with expertise with the type of data being analyzed or with the participants in the research. For example, research involving prisoners must have a person with firsthand knowledge of prison (e.g., a former prisoner); research involving biospecimens must have an IRB member who is knowledgeable about scientific practices with biospecimens; research involving children must have an IRB member who is an educator or otherwise experienced working with children in multiple settings.

C. Procedures:

1. Selecting new IRB members. The IRB will use the following selection process for new members: (1) a current IRB member will nominate a new member, (2) the full IRB will vote to approve new members, and (3) The IRB chair will submit the name of the prospective member to the College President (who retains final appointment authority for IRB membership).
2. Meeting schedule. The Diné College Institutional Review Board meets on twice monthly to review proposals and attend to other IRB business. The schedule will be posted on the Warrior Web IRB site. Emergency meetings or Focus Committee meetings may be convened as appropriate and require at least a notice of 48 hours.
3. Quorum. 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. Members may attend in person or via telephone/video conference. 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 utilized by the IRB). Additionally, 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.
4. Minutes. 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

A. Definition of Human Subjects' Research.

The Health and Human Services Policy for Protection of Human Research Subjects in 45 CFR Part 46 defines a human subject as: a living individual about whom an investigator (whether professional or student) conducts research. Research activities include any systematic investigation that leads to generalizable knowledge, and includes (a) obtaining, using, studying and/or analyzing information or biospecimens through intervention or interaction with the individual, or (b) obtaining, using, analyzing, or generating identifiable private information or identifiable specimens. Research involving

existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are identifiable is considered "research involving human subjects."

B. Jurisdiction of the DC IRB

Any research activities that involve human participants conducted by Diné College students, faculty, or staff, whether funded or unfunded and whether within or outside of the Navajo Nation, shall be under the jurisdiction of the Diné College IRB. Any research studies involving Diné College students, staff, or faculty as human subjects shall be under the jurisdiction of the Diné College IRB, regardless of whether or not the principal investigator is directly affiliated with Diné College. Additionally, any research involving Diné College students as part of the research team is under the jurisdiction of the DC IRB, even if such research does not fall under the category of Human Subjects Research.

C. Principal Investigators

1. Students as Principal Investigators. The Diné College IRB will have the authority to provide final review and action decisions (e.g., approval) for research in which students are Principal Investigators and are being mentored by Diné College Faculty or Staff advisors. Student investigators may not conduct any research activities without prior approval of the Diné College IRB. Student researchers need not seek approval by the Navajo Nation Research Review Board (NNRRB).
2. DC Faculty/Staff as Principal Investigators. Research in which Faculty or Staff are the Principal Investigators must be reviewed by the Diné College IRB. If this research involves Navajo people, the protocol must also be reviewed by the Navajo Nation Human Research Review Board (NNRRB). The NNRRB meets on the third Tuesday of each month, and materials must be submitted 3-4 weeks prior to the meeting. See the 2023 schedule at this link.
3. Outsiders as Principal Investigators. Outside investigators (e.g., faculty/staff at other institutions) may not conduct any research activities without approval of both the Diné College IRB and the NNRRB. If an outside institution is connected to this research, the protocol must be reviewed by the IRB at both or all institutions.

D. Types of Review

The IRB Chair or the Chair's designee will be responsible for determining whether the research will receive full review, expedited review, or consideration for exempt or non-human-participants-research (NHSR) status.

1. Full Review. Any research that involves more than minimal risk must be reviewed by the full IRB in a regular IRB meeting in which quorum has been established. The full IRB will review proposals within two weeks of their submission. In order for the research to be approved, the IRB shall determine that all criteria for approval (see section III) are satisfied and the research must receive the approval of a majority of the members present at the meeting. See definitions and examples of minimal risk at this link or in Appendix xx.

2. Expedited Review. Research involving no more than minimal risk may be reviewed through an expedited process involving a focus committee consisting of a minimum of two reviewers, one of whom is the IRB chair or the chair's designee. The decision of whether an expedited review will be conducted is the prerogative of the IRB chair or the chair's designee. Any proposals considered through expedited review must be shared with the full IRB at the next scheduled meeting. The following conditions may be considered for expedited review:
   - Submission of minor changes to an approved research proposal
   - Submission of continuation request for projects that require a time extension
   - Consideration of exempt or non-human-subjects-research status
   - Submission of a new proposal in which no more than minimal risk to participants is present.

E. Reports, Revisions, and Continuations

In addition to reviewing new proposals, the IRB requires that principal investigators on existing projects submit appropriate forms/documentation for the following:

1. Form B. Continuation/Renewal. Research that extends beyond one year must apply for continuation before the current review expires. If no changes have been made to the research protocol and if no adverse and/or unexpected reactions or side effects have occurred or are expected, the review for continuation will be conducted via the expedited review process and shared with the full IRB at the next meeting. In all other instances, continuing review will be conducted by the full IRB. Please see Form B at this link or in Appendix A – Reports, Revisions, and Continuations.
2. Form C. Revision of Submitted Proposal. If the investigator, while conducting the research, revises the research protocol (e.g., makes changes to the informed consent form, survey instruments used, or number and nature of participants), he/she will notify the IRB Chair immediately via the "Protocol Revision" form. 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 via Form E - Report of Adverse Reactions. See Form C at this link or in Appendix A – Reports, Revisions, and Continuations.
3. Form D. Final Report Submission. Principal investigators are responsible for submitting a final report within twelve weeks of the end of the project. The report may consist of an oral slide-based presentation to the IRB and/or a written report outlining research activities and findings. See Form D at this link or in Appendix A – Reports, Revisions, and Continuations.
4. Form E. Report of Adverse or Unexpected Responses. Any adverse or unexpected responses to the protocol must be reported to the IRB within two weeks of their occurrence. The report will include a description of the research activity to which the adverse response was received, the nature of the adverse or unexpected response/s, the number of participants experiencing an adverse or unexpected response, the steps

taken at that time to facilitate recovery of the affected individual/s, any follow-up steps taken to ensure that the affected individual/s fully recovered, and any changes to the protocol made to ensure that additional adverse or unexpected responses do not recur. See Form E at this link or in Appendix A – Reports, Revisions, and Continuations.

D. Criteria for Approval of Research

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

- Risks to participants and student researchers have been minimized and do not surpass anticipated benefits
- Selection of participants is equitable and reasonable based on the purposes of the research and the populations.
- 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.
- Properly documented Informed consent forms and procedures are in place to ensure and document protection for each prospective participant (or the participant's legally authorized representative) in the primary language of the participant.
- Adequate provision for ensuring the safety and privacy of participants, the confidentiality of data, and the timely destruction of data at the designated time.
- All appropriate additional protections are in place to respect and protect the unique aspects of Navajo people, traditions, land, and culture that distinguish them from non-Navajo people.
- Research activities are feasible and possess scientific merit.
- All researchers have completed "Human Participants Research Training" and submitted current certification of this training. Training is available free of charge to Diné College faculty, staff, and students. See information / instructions at this link.

IV. Informed Consent, Deception, and Debriefing

A. Informed Consent

Informed consent processes are in place to ensure that participants are (a) fully informed about risks and benefits of any study in which they are invited to participate, (b) not subject to undue coercion to elicit their participation, and (c) fully aware of their rights during and after the study. Potential participants must be fully informed before the research begins in simple, clear language in which the individual is fluent. For non-English speakers, translations must be provided. Additional protections for special populations (e.g., children, prisoners) may be found in Section VII. Informed consent must be documented via a written document or recorded oral consent, and should be viewed as an ongoing communication process rather than an isolated exchange.

The informed consent process must convey to each potential participant the following

information, at a minimum:

- Explanation of the purpose of research
- Duration or time commitment
- Description of procedures, or what the participant can expect to experience
- Description of any foreseeable risks or discomforts to the participants
- Description of any benefits to the individual or others from the research, including compensation for participation
- Disclosure of alternate treatments or experiences through which participants might gain similar benefit.
- Statement describing confidentiality procedures
- If greater than minimal risk, a explanation as to whether compensation or medical treatment are available in the event of injury
- Statement that participation is voluntary, that there is no penalty of loss of benefits if the potential participant declines to participate, and that participants may withdraw from the study at any time without penalty or loss of benefits
- Explanation of whom to contact with questions or concerns about their rights, about the research itself, or to report a research-related injury.

An example informed consent document may be found at this link. More information about the informed consent process can be found at this link from the Department of Health and Human Services.

B. Waiver of Informed Consent

In some instances, the requirement of obtaining informed consent may be waived. These instances may include minimal-risk or anonymous studies in which the research could not be carried out if informed consent procedures were followed. For example, a study examining what sort of signage elicits greatest compliance with mask requirements may rely on the number of people wearing or not wearing masks as they enter a public space in which different signs are displayed. In such an instance, seeking informed consent would hinder the possibility of gathering the needed data, and may be waived. See information related to Waiver of Informed consent at this link and the Supplement D - Waiver of Informed Consent form at this link and in Appendix B – Supplementary Forms

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 participants for research projects in which a Diné College student is the Principal Investigator (see definitions below). For all other research activities, the IRB shall review and provide recommendations regarding final decisions to the NNRRB.

A. Action Decisions.

The IRB may provide several different responses to an IRB proposal, which will be sent

to the principal investigator within 24 hours of the IRB meeting. These responses include the following:

1. Approval. An approval means that the research may proceed as described in the proposal. Approval can be granted for only one year, so the proposal must be renewed each year for multi-year projects. The IRB must be informed of any adverse reactions to the protocol through a report submitted within two weeks of the adverse event. Modifications to the protocol that affect the participants' experience or the timing of the research must be submitted for review by the IRB before implementation. All approved projects must submit a final report within eight weeks of the project end date. Additionally, multi-year projects must include an annual update along with the required renewal request.
2. Conditional Approval. Conditional approval is granted when minor changes are requested in the protocol of a project that is otherwise approved via a vote by the IRB. Such minor changes might include slight wording changes, clarifications of questions asked and answered in the IRB meeting, or other differences that do not substantially impact the study. If conditional approval is granted, the PI may submit the requested modifications via the online portal. Once the modifications are received, the chair or vice chair will review the modifications and write a formal approval letter without further review by the IRB. All such research is then participant to the requirements listed under "Full Approval" in the preceding paragraph.
3. Not Approved. The IRB may vote against approving a project in which risks to the human participants are not outweighed by the benefits of the research. The letter written from the IRB to the principal investigator will describe specific concerns about the project. In such cases, the principal investigator may substantially revise the proposal and resubmit it as a new proposal.
4. Exempt. In rare cases, research that involves no more than minimal risk to participants may be considered to be exempt from further IRB review. Principal Investigators who believe their research is exempt must submit the IRB proposal and required materials, checking the box indicating that exempt status is sought. If the IRB approves exempt status, no further review or reports will be required from the IRB. Submit Form F – Request for Exempt or NHSR Status.
5. Non-Human-Subjects-Research (NHSR). If a research project does not involve interaction with human participants for the purpose of data collection and does not rely on identifiable data previously collected from human participants, it may be determined to be non-human-subjects-research. Any researcher seeking documentation of this status (e.g., as required by funding agency) must submit the IRB Research proposal and Form C – Request for Exempt or NHSR Status. Under this designation, the researcher has no obligation for any continued interaction with the IRB unless the research protocol changes to include human participants.

B. 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 participants. 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.

C. 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. 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 participants 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 participants 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 participants. Projects must include a plan that protects participants' privacy and ensures confidentiality of data.

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

The following research involving prisoners is permitted. Read information about working with prisoners (University of Iowa). Complete Supplement B - Prisoners

- 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 participants.

- 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 participants.
- 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 if the PI has consulted with appropriate experts.
- Research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the participant.

B. Minors Under 18 Years of Age.

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

- No greater than minimal risk to children is presented, or the risk represents a minor increase over minimal risk.
- The intervention or procedure (a) holds out the prospect of direct benefit for the individual participant, or (b) contributes indirectly to the participant's well-being (e.g., through a new monitoring procedure)
- 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;
- The intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for understanding or amelioration of the participants' disorder or condition; and
- Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

Children who are 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 participants 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. Information about working with this population and the relevant form can be found at this link.

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 (a) the research does not involve greater than minimal risk, or (b) does involve greater than minimal risk but presents the prospect of direct benefit to the individual participants. If the research involves greater than minimal risk and no prospect of direct benefit to individual participants but is likely to yield generalizing knowledge about the participant's disorder or condition, the IRB will require both parents' permission. Exceptions would include: (a) one parent is deceased, unknown, incompetent, or not reasonably available, or (b) one parent has legal responsibility for the care and custody of the child.

- Example Assent Form
- Example Parent Consent Form

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 of the minors involved.

C. Individuals with Impaired Decision-making Capacity

Individuals with Impaired Decision-making Capacity include those individuals for whom legal guardianship or representation is assumed by another individual, or whose developmental disabilities, psychological conditions, or cognitive impairments (e.g., traumatic brain injury) prevent them from making Informed decisions.

D. Neonates, Fetuses, and Pregnant Women

Research involving neonates, fetuses, or pregnant women will be submitted to a special review process in which the rationale for conducting such research will be assessed. The special review process will include medical professionals as appropriate to the target population. Guidelines for working with this population and appropriate forms can be found at this link.

VII. 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. All proposals must be submitted one week prior to the next scheduled IRB meeting date, which are posted on the IRB website.

The principal investigator must submit the following via the online portal:

- Proposal for Sociocultural Research or Proposal for Biomedical Research

- Supplemental Forms required to address vulnerable populations or Waiver of Informed Consent
- Protocol: One-page description of the project and research protocols or procedures
- Materials: All scales, questionnaires, surveys, interview questions, or other materials to be used in the study
- Informed Consent/Assent forms: Appropriate Informed Consent Form/s or Assent Forms (see Appendix D)
- CITI Training: Current "Human Participants Research Training" certificate for each member of the research team

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-led 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-led project makes to the larger program of research.

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.

A. 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 participants has been reviewed by the IRB.

B. 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 participants, 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 participants
- 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. Data Retention and Storage

One of the most significant risks to study participants, aside from risks associated with the protocol itself, is the risk of a breach of confidentiality. Researchers must be cognizant of the need to protect participants' information as diligently as they protect their well-being during the study. It is the responsibility of the principal investigator to ensure that (a) appropriate security protections are in place, (b) all members of the research team are trained in security practices, and (c) requirements for data collected on the Navajo Nation are strictly followed. These responsibilities include secure practices for collection, transmission, storage, backup, and eventual destruction of identifying information linked to the data.

Identifying information defined by HIPAA include names, geographic subdivisions smaller than a state (e.g., town, street, zip code), identifying dates (e.g., birth date, admission date), contact information (e.g., telephone, fax, email addresses), identification numbers (e.g., social security numbers, medical record numbers, vehicle numbers, device numbers, etc.), URLs and IP addresses, biometric identifiers, photographs, and audio/video recordings.

The following guidelines are in place:

A. Digital materials

Much research data will be collected, transmitted, analyzed, and stored on computers or in cloud servers. The following recommendations are in place for protecting privacy and maintaining security of these data:

1. Data Collection. If possible, gather your data without any identifying information. These data would be considered anonymous data, and is the best way to ensure confidentiality. Data collected with no identifiers in studies with minimal risk may be

eligible for exempt status. If you must collect identifiers, please collect the fewest identifiers possible and justify their use.

2. Data Storage. Storage. Store all materials, including consent forms, in a special password-protected location within your OneDrive account. Use Coded Identifiers and a Master Key, as described in the following steps:
    i. Assign each study participant a random unique identifier. Avoid any number codes that could be linked to the participant through list sequencing or other methods.
    ii. Use this method to label any information connected with the individual after ensuring that no identifiable information remains within the study data.
    iii. Create an encrypted and vigorously protected master key in which the identifying information is linked with the identifier code.
    iv. Store the Master Key in a separate password-protected location from the data itself. Use the de-identified data for analysis.
    v. Once the data are organized and analyzed, or after the appropriate required time frame, destroy the master key. The remaining de-identified data can be retained indefinitely.
3. Transferring Data. If multiple individuals require access to the data, this should be done via a shared central location (e.g., access to the One Drive folder) rather than via individual copies. Transfer of information is best conducted by providing a link and unique access to the relevant file. Email transfer of information is not secure and is not acceptable. Storage and transmission of the Master Key must always be kept separate from the data itself.

B. Physical Materials

As with digital materials, physical materials must be collected and stored with a high level of caution. Researchers are advised to gather as little identifiable information as possible, to store identifying information separately from data if possible, and to designate a locked location for storage of data and a locked box or bag for transport of such data. If biospecimens are collected, identifying information should be transported and stored in separate, locked locations.

When it is time to destroy the data, precautions must be taken to ensure that the data cannot be reconstructed to identify the individual participant. For paper documents, the data must be shredded or otherwise destroyed so that it could not possibly be pieced together. For biospecimens, appropriate measures must be taken according to specifications for such data.

C. Data Retention

Minimal requirements for storage of data and consent forms differ according to the type of research being conducted. Typically, research gathered at Diné College must be stored at Diné College. Any diversion from this practice must be divulged to the IRB and participants in the informed consent documents. Students who will be graduating and may wish to use their data for additional work must (a) discuss data storage in

advance with their mentor, (b) include a plan for this work in the original IRB, and (c) disclose this possibility to participants in the informed consent.

- OHRP Requirements. Study data and consent forms be maintained securely for, at minimum, three (3) years after the completion of an IRB-approved study. After the three-year retention period, individually identifiable information (including the master key) must be destroyed. De-identified data may be retained indefinitely.
- HIPAA Requirements. Research that collects identifiable personal health information is subject to HIPAA requirements. Such data must be retained for a minimum of six years after each participant signed the authorization.
- FDA Requirements. Research involving drugs, devices, or biologics being tested in humans must retain records for two years after the data the marketing application is approved. If no marketing application is sought or if it is denied, records must be kept for a minimum of two years after the investigation is ceased.
- VA Requirements. Any research involving the Veterans' Affairs must be kept indefinitely, according to VA federal regulatory requirements. To determine whether changes have been made, seek updated information from the VA at (352) 376-1611, extension 6069.
- Navajo Nation Requirements. The Navajo Nation must be provided with all data and reports linked to data collected on the Navajo Nation. No specific requirements for storage of data have been set.

D. Dissemination 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 participants and for complying with all regulations.

A. 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).

B. 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).

C. 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 participants. The assurance is a written agreement, which includes the following:

- A statement of ethical principles and institutional policies governing research involving human participants
- 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 participants or any noncompliance with this policy and any suspension or termination of IRB approval

XI. 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 participants 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 participants, 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.

XII. 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 participants 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 participants 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 participants 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

Exempt Status
Research may be granted exempt status if it (a) presents no more than minimal risk to participants, and (b) does not involve collection of identifiable personal information.

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 Participants

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 participants are defined as: living individual(s) about whom an investigator conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human Participants Research

Data collected from human participants as defined above that is intended to be used for publication or dissemination purposes. Information gathered from human participants for educational purposes or to inform best practices in a classroom or institution is not considered to be research

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, participants 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 participants 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 participants.

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 participants 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 Participants (IRB) Submission Form

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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 Participants and the Procedure Manual for Research with Human Participants.

General Information

Project Title

New Continuation/Renewal Revision

Proposed Start Date Proposed Duration of Research Performance Site(s)

Principal Investigator Student Faculty Staff

*Please note that all research in which a Faculty/Staff member is the Principal Investigator is also participant 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

Funding Information

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

Source of Funding

Project Title (if different from above)

Principal Investigator (if different from above)

Type of Application:

Grant Subcontract Contract Fellowship

Date of Submission

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 participants 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

Participant/Patient Information

Types of Participants/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

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)

Number of Participants/Patients

Approximate time commitment for each participant/patient

Compensation to participants/patients : Yes No

Form (e.g. cash, meals) Amount

Continuation or Renewals

Attach a copy of the original IRB protocol

Indicate all proposed changes in the IRB protocol affecting participants

Progress Report

Indicate the number of participants entered in the study, including their group status, whether they are active or completed, the number of participants still pending, and the time frame of participant 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 participants entered, in process, completed, and pending).

Attach consent form(s) to be used and indicate if any changes have been made.

Protecting Human Participants Training

“Human Participants 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-participants-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 participants 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.

Participants

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

Methods and Procedures

Provide details on participant recruitment, nature and type of evaluation, participant's time commitment, proposed follow-up, debriefings when indicated, and any other information necessary to evaluate the involvement of participants in the research. Any media, including flyers, brochures, or other advertisements used to recruit human participant 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 participants 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.

Participant Confidentiality

Indicate the extent to which confidentiality of records identifying participants 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 Participants

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 participants. The first of those principles states, "the voluntary consent of the human participant 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 participants “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 participant in research, as defined in this policy and procedure manual, unless the investigator has obtained the participant's informed consent. The process of informed consent is constituted by two essential elements: (1) the participant has the information he or she requires to make an effective decision, and (2) the participant'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:

It should be obtained from the participant or the participant's legally authorized representative

It should be in language understandable to the participant or his or her legal representative

It should only be obtained under circumstances that provide the participant with sufficient opportunity to discuss study procedures, to consider whether or not to participate, and that minimizes the possibility of coercion or undue influence.

It should begin with key information that is most critical for understanding the reasons to participate or not to participate.

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 participant'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 participant

A description of any benefits to the participant 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 participant

For research involving more than minimal risk:

A description of any compensation to the participant

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 participant'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 participant may discontinue participation at any time without penalty or loss of benefits

A statement describing the process by which confidentiality of records identifying the participant 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 participant:

Statement that procedure may involve unforeseeable risks to the participant

Description of circumstances under which the participant's participation may be terminated by the investigator without the participant's consent

Additional costs to the participant resulting from participation in the research

Consequences of the participant's decision to withdraw from the research and procedures for termination of participation by the participant

Statement that significant new findings developed during research which may relate to participant's willingness to continue will be provided to the participant

Approximate number of participants involved in the study.

A statement regarding whether clinically relevant research results will be disclosed to participants, and if so, under what conditions

If applicable, statements about the use of a participant'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 participant 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 participant

A description of any benefits to the participant or to others that may reasonably be expected from the research

A statement describing the process by which confidentiality of records identifying the participant will be maintained

A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits, and that the participant may discontinue participation at any time without penalty or loss of benefits

If applicable, statements about the use of a participant'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 participants or legally authorized representatives will not be informed of the details or purpose of any specific research studies that might be conducted using the participant'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 participant (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 participant's rights, or storage and use of the participant'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 participant'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 participant or the participant'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 participant or the participant's legally authorized representative):

A short written form which states that the elements of informed consent have been presented orally to the participant or the participant'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:

the written summary of what is to be said receives prior approval of the IRB

a witness must be present at the oral presentation

the short form is signed by the participant or his or her representative

the witness signs both the short form and the written summary is given to the person signing the form, and

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 participant 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:

the research or demonstration project is to be conducted by or participant 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.

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 participants 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:

the research involves no more than minimal risk to the participants;

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

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;

the waiver or alteration will not adversely affect the rights and welfare of the participants;

whenever appropriate, the participants will be provided with additional pertinent information after participation.

In cases where documentation is waived, the IRB may require the investigator to provide participants 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 participants without the informed consent of the prospective participant or participant's legally authorized representative, if either of the following conditions are met:

The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative, or

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 participants 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 participant.

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)].