**Instructions for Informed Consent – revised 01-08-19**

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](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) 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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116), 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.

1. 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)].