

Instructions for the Preparation of an Informed Consent Document

An essential condition of any research study involving human subjects is the voluntary informed consent of every participant. Informed consent is defined as a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in a research activity. Informed consent reflects the basic principle of *respect for persons* and assures that prospective human subjects will understand the nature of the research study and can *knowledgeably and voluntarily* decide whether or not to participate. Voluntary informed consent protects the subject, whose *autonomy* is respected. No researcher may involve a human individual as a subject in any research activities unless the researcher has obtained the informed consent of the subject or the subject's legally authorized representative. Researchers must ensure that the human subjects, or their legally authorized representatives, are provided sufficient opportunity to consider whether or not to participate and must seek to minimize the possibility of coercion or undue influence. The information that is provided to the subject or representative shall be in language understandable to the subject or the representative. No informed consent, whether written or oral, may include any exculpatory language through which the subject or the legal representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the researcher, the funding source, the institution or its agents from liability for negligence (45 CFR 46.116). It is the responsibility of the IRB to evaluate the informed consent process.

The following instructions for preparation of a subject consent form may be used as a guideline for the submission of protocols for approval by the IRB. Because obtaining informed consent is an educational process, researchers should do what they can to enhance the prospective subject's comprehension of the information presented. The consent process should consider the nature of the proposed subject population, the type of information to be conveyed, the circumstances under which the consent process will take place (e.g., manner, timing, place, personnel involved, timing or location of first contact with potential subjects), how others will contact subjects during or following the study, and who has access to the data.

As outlined in 45 CFR 46.116(a), the following information is the basic elements of informed consent which shall be provided to each human subject when seeking informed consent:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

New basic elements

1. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens.
 - (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

***New additional elements of informed consent**

1. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
2. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
3. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

*New Mexico State University (NMSU) is currently not doing this type of research.

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

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new finds developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects participating in the study.

The information must be written in language that is understandable to the subjects or their legally authorized representative. It is vital that the consent is written at the appropriate reading level. The average person in the US reads at an eighth grade level, so the information must be written at an eighth grade reading level or less depending on the intended audience. The consent process may not involve the use of exculpatory language through which the subjects or their representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution, or agent from liability for negligence.

Researchers should always keep in mind the ability of certain populations (i.e., children or individuals with reduced mental capability or experiencing developmental disabilities) to understand the required information. In such cases, researchers must obtain the assent of the subject in addition to the consent of their legally authorized representative. Other populations (i.e., prisoners or institutionalized individuals) may be so situated that the voluntariness of their consent may be in doubt. Such subjects may need special protections, and researchers should show great concern to these individuals when obtaining their informed consent.

The following "boilerplate" statements are provided as a guideline for the submission of applications for approval by the IRB. Some of these "boilerplate" statements should be incorporated into each Informed Consent Form while some are dependent on the nature of the research activity to be conducted.

1. **DESCRIPTIVE TITLE FOR THE PROTOCOL** - The title should be descriptive of the research to be conducted and should not include any acronyms or abbreviations, if possible.
2. **DESCRIPTION OF STUDY** - This section should include a statement that the study involves research and a comprehensive description in lay terms of the study to be conducted. It should include information on who is conducting the study; an explanation of the purpose(s) of the study; why the subject is being asked to participate; a description of the procedures to be followed (e.g., "two blood samples not to exceed 150 ml each will be taken during a 4-week period" or "a 35-item survey questionnaire will be completed"); how long the subject will be expected to participate (e.g., "it will take approximately half an hour to complete the questionnaire"). The first-person pronoun "I" or "we" should be used to refer to the researcher(s) in this, as well as subsequent sections. The human subjects should be referred to as "you."
3. **EXCLUSION CRITERIA** - This section should address those preexisting conditions or other factors that would preclude the participation of an individual in the study. For example, if pregnancy would be a contraindication for participation, a statement such as "your participation in this study indicates that you are not pregnant and agree to practice an effective method of birth control for the duration of your participation in the study" would be appropriate.
4. **RISKS AND BENEFITS** - All potentially adverse effects of participation in the protocol must be clearly described. Any known risks associated with the study should also be stated. Examples would be "there is a chance of bruising and pain at the site of blood drawing," or "some of the

questions asked may be of a personal nature or may cause some emotional discomfort.” If there are no benefits to the subject, this should be clearly stated (e.g., “there are no specific benefits to you personally for participation in this study”).

5. **ALTERNATIVE TREATMENT** - If relevant, the subject should be made aware of any alternative treatment or participation that might be available, including no treatment or participation at all.
6. **COSTS AND PAYMENTS** - If it can be reasonably expected that participation in the protocol will result in additional expenses to the subject, these additional costs must be clearly identified. This must include a statement about additional professional fees, hospital costs, laboratory fees, and device fees (for example, if as a result of participating in the study, the subject is referred to a facility for further treatment which will not be paid for by the research protocol). If the human subject is to be compensated, the amount of compensation, the schedule of payment, and how the payment would be prorated should the subject withdraw or be withdrawn from the study should also be described. If a subject is to receive course-credit for participation, this should also be described.
7. **NEW INFORMATION** - If relevant, the following or comparable statement should be included: “Any new information obtained during the course of the research that may affect your willingness to continue participation in the study will be provided to you.”
8. **CONFIDENTIALITY** - Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust, with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission. This includes obtaining information about the subject that would, if disclosed by the researcher, jeopardize their job or lead to prosecution for criminal behavior, or provide cause for legal action against a researcher or the institution. Under less serious circumstance, a breach of confidentiality can be considered a moral wrong.

The following are examples of statements which may be included in an informed consent form:

“Any information obtained about you from this research including answers to questionnaires, history, laboratory data findings, or physical examination will be kept strictly confidential” (choose appropriate items);

“The information you give us will not be shared with anyone outside the research team with your name attached”;

“We will protect your confidentiality by coding your information with a number so that no one can trace your answers to your name, properly disposing of computer sheets and other papers, limiting access to identifiable information, telling the research staff the importance of confidentiality, and storing research records in locked cabinets”; or

“The data derived from this study could be used in reports, presentations, and publications but you will not be individually identified.”

The informed consent form should describe who has access to the confidential information and the way in which the information will be recorded. If appropriate, the consent form should

identify any limitations that may impact whether confidentiality can be assured, e.g., identification of criminal wrongdoing, evidence of child abuse, or issues affecting the subject's psychological well-being or mental health, i.e., a subject who threatens violence to self or others.

Researchers should carefully consider the following issues related to confidentiality:

1. Whether the researchers will record subject identifiers at all (including consent forms);
2. Whether identifiers are to be collected and whether they will be retained after data are coded;
3. How will identifiers be maintained if they are not destroyed upon completion of the research study; and
4. What information will be provided to subjects regarding confidentiality matters as part of the informed consent process?

Various methods are available for protecting confidentiality in different situations, including situations in which there is a possibility that deductive identification of otherwise anonymous subjects could occur on the basis of separate elements of data (e.g., birth date, occupation, and zip code). Among the available methods for assuring confidentiality are statistical techniques and physical or computerized methods for maintaining the security of stored data. The more sensitive the data being collected, the more important it is for the researcher to be familiar with the state of the art in protecting confidentiality.

Under the Public Health Service Act, researchers engaged in biomedical, behavioral, clinical, or other research (including research on mental health or research on the use and effect of alcohol and other psychoactive drugs) may be authorized to protect the privacy of their subjects by withholding from all persons not connected with the research the subjects' names or other identifying characteristics. Researchers so authorized to protect the subjects' privacy may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such subjects.

The privacy of such research subjects is protected through the issuance of Certificates of Confidentiality, which provide protection against compelled disclosure of identifying information about those subjects enrolled in sensitive biomedical, behavioral, clinical, or other research. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help to minimize risks to subjects by adding an additional level of protection for maintaining confidentiality of private information.

Certificates of Confidentiality do not prevent other types of intentional or unintentional breaches of confidentiality. Therefore, researchers must ensure that other appropriate mechanisms and procedures are in place to protect the confidentiality of any identifiable private information obtained in the research study.

This protection is not limited to federally supported research. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) and other HHS agencies.

For more information on Certificates of Confidentiality and their limitations, see <http://grants.nih.gov/grants/policy/coc/index.htm>.

For Certificate of Confidentiality contacts at the National Institutes of Health, see <http://grants.nih.gov/grants/policy/coc/contacts.htm>.

9. **WITHDRAWAL PRIVILEGE** - The informed consent document must state that (a) the subject may withdraw from the study at any time; (b) their participation is entirely voluntary; (c) if the subjects decide not to participate, there will be no penalty or loss of benefits to which they are otherwise entitled; and (d) if the subjects decide to participate, they may discontinue at any time without penalty or loss of benefits to which they are otherwise entitled.
10. **COMPENSATION FOR ILLNESS OR INJURY** - If relevant, the informed consent document should clearly state whether the subject will be compensated for any emergency medical treatment which may be necessary in the event of a physical injury or physical illness resulting from their participation in the research study.

If the human subject is to be compensated, a description of how much such compensation will be provided or if there will be any limitations included on the consent form. The following are examples of such statements:

- (a) “If as a result of participating in the study the subject is referred to a facility for further treatment, such treatment will not be paid for by the research protocol”;
- (b) “In the unlikely event of a physical injury or physical illness resulting from the research protocol, no monetary compensation will be made, but any emergency medical treatment which may be necessary will be made available to you without charge by the investigators”;
- (c) “If any injury should result from your participation in this research project, New Mexico State University, (NMSU) provides no insurance coverage, compensation plan, or free medical care plan to compensate you for such injuries”; or
- (d) “If you agree to participate in the study, then your consent does not waive any of your legal rights. However, no funds have been set aside to compensate you in the event of injury.”

The informed consent document may not contain any exculpatory language. Subjects may not be asked to waive any of their legal rights, nor may they be asked to release the investigator, sponsor, or institution (or its agent) from liability for negligence.

11. **AIDS TESTING** - To maintain conformity with guidelines issued by the Public Health Service, the following “boilerplate” statement should be included in the informed consent document for every research study that involves the testing of a subject’s tissue sample for the presence of the HIV virus, whether it is discarded tissue or not, if applicable. “The [tissue sample] will be tested for the HIV antibody (AIDS). If the result of a positive test is confirmed by a second test (Western Blot), you will be notified in writing of the positive result. At that time, the Principal

Investigator will provide you with the name of a qualified individual whom you may contact for counseling as to the proper interpretation of the positive result, and for advice on how you may obtain further counseling if needed. The test result will be maintained in strictest confidence consistent with current state and federal laws unless otherwise specified in the experimental protocol for which you are consenting.”

12. **VOLUNTARY CONSENT** - The following or a comparable statement should be included in all informed consent documents:

“Your signature below means that you have freely agreed to participate in this research study. You should consent only if you have read this form or it has been read to you and you fully understand its contents. If you have any questions pertaining to the research, you may contact (Principal Investigator) whose phone number is (575) 646-xxxx or at (e-mail address). If you have any questions about your rights as a research subject, please contact the Institutional Review Board (IRB) Chair, through the Office of Research Compliance at New Mexico State University at (575) 646-7177 or at ovpr@nmsu.edu.”

13. **Signature and Date Block** - If applicable, a signature and date block should be included on the informed consent document.

If the subject is a minor, the signature of a guardian or a legally authorized representative is required in addition to the subject’s signature. The following statement or a comparable one should be included: “Your signature certifies that you are the lawful guardian of _____ and that you have the legal authority to consent to his/her participation in this study. You hereby grant consent for him/her to participate in this study.”

When the elements of informed consent are presented **orally** to the subject or the subject’s legally authorized representative, there must be a witness to the oral presentation. The witness may be the researcher or his/her designee who must be a competent adult over the age of 18. The witness must sign the informed consent document or a written summary, approved by the IRB, of what is to be orally presented to the subject or the legally authorized representative. The witness and the person actually obtaining consent must sign a copy of the summary. A copy of the informed consent document or summary shall be given to the subject or legally authorized representative.

If the subject’s consent is witnessed, the following statement (or a similar variation) may be used:

“I certify that I have explained to the above individual(s) the nature and purposes of the research and the potential benefits and possible risks associated with participation in this study to the individual identified above. I have explained the above information, answered any questions that have been raised, and have witnessed the individual’s signature on the date indicated on this form.”

A signature and date block must be provided for the witness.

***Examples of Informed Consent documents will soon be available.