

Section 9: Informed Consent

9.1 General Requirements

9.2 Elements of Informed Consent/Assent Forms

9.3 Language

9.4 Technical Elements

9.5 Consent from Guardians

9.6 Non-English Speaking Subjects

9.7 Additional Consent Information for Different Types of Studies

9.8 Documentation of Informed Consent

9.9 New Findings

9.10 Distribution of Informed Consent Documents

9.11 Waiver of Written Informed Consent

9.12 Waiver of Informed Consent

9.13 Record Retention

9.14 FDA Inspection of Studies

9.15 Non-Compliance with IRB Requirements

SECTION 9.1 GENERAL REQUIREMENTS

Principal investigators are responsible for obtaining written informed consent in accordance with federal regulations and for ensuring human subjects will not be involved in research prior to obtaining consent. Each of the following points **MUST** be included in the consent document, except where the point is irrelevant to the research.

SECTION 9.2 ELEMENTS OF INFORMED CONSENT/ASSENT FORMS

1. A statement that the study involves research, an explanation of the purpose of the research and why the subject is asked to participate.
2. A description of the procedures and identification of any procedures which are experimental. For example, the description of procedures should include the length and frequency of hospitalizations; number, length and frequency of clinic visits; total amount of time a subject should expect to devote to the study; names and types of medication; types and number of tests; amount of blood to be drawn noted in tablespoons or teaspoons; use of questionnaires; special diets; withholding of standard treatment; follow-up studies; and randomization, use of placebo, double-blind, or cross-over methods. In the case of patient subjects, state clearly which procedures are experimental and which procedures would be performed for medical reasons if the patient were not a research subject.
3. A description of any reasonable risks or discomforts to the subject. These may include drug side effects, hazards of procedures, or withholding therapy of proven value. Describe what will be done to minimize the risks, counteract side effects, and which side effects might be irreversible.
4. A description of any benefits to the subject or to others which may reasonably be expected from the research.

5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. It is not necessary to provide a full account of the risks and benefits of standard alternative treatments in the consent form.
6. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. FDA and sponsor inspection of records in studies involving drugs and devices should be explained. The means of disclosure of information obtained during the study should be described, e.g., publication, entry in medical records, or transmission to another physician.
7. An explanation that only emergency medical treatment is available if a research-related injury occurs. If a company or agency sponsoring the research agrees to provide for additional treatment and/or monetary compensation for injuries and that agreement has been approved by the UNTHSC legal counsel, this should be included in the consent form.
8. A statement of additional costs to the subject for research procedures.
9. A statement of the amount of compensation for time and travel expenses associated with a subject's participation in the study. The compensation must not be contingent upon completion of the entire study. The amount of the compensation must not be coercive. The informed consent must indicate that compensation for subjects who withdraw early or are removed from the study by the investigator will be pro-rated accordingly. The UNTHSC legal counsel recommends that the following statement also be included: "As applicable, reimbursement to you may be withheld and credited to any outstanding debts you may have with the University of North Texas Health Science Center at Fort Worth or the State of Texas."
10. Identification (full name[s] and 24 hour phone numbers) of the investigator(s) the subject may contact for answers to questions about the research and the research subject's rights, and whom to contact in the event the subject believed that he or she has sustained a research-related injury. This should include the IRB Chairman.
11. A statement that participation is voluntary, and that the subject may refuse to participate or may withdraw from the research at any time without penalty or loss of benefits to which the subject is otherwise entitled. When appropriate, subjects should be assured that they would still receive standard treatment if they decide not to participate or to withdraw. They should also be assured that a decision not to participate would not adversely prejudice future interactions with the institution; this is particularly important when a dependent relationship exists between subject and investigator, such as physician-patient, employer-employee or faculty student. If withdrawal may be dangerous to a subject, the danger must be explained and the subject should be told not to withdraw without discussing it with the investigator.
12. Sample documents which contain all of the required elements are available from the IRB Coordinator.

SECTION 9.3 LANGUAGE:

The consent form should give a subject sufficient information about the study, its procedures, benefits, risks and alternatives to enable the subject to make an intelligent decision about participation. The form should be written in the second person with language and terminology the subject could be expected to understand (at approximately the 9th grade reading level). It should invite participation and not sound coercive.

SECTION 9.4 TECHNICAL ELEMENTS

At the top of the first page, the consent form should indicate the title of the study, name of the P.I. and the name of the institution. Date of consent must be documented. At the end of the consent form there should be statements that the subject will be given a copy of the form and that his/her signature means he or she has read the form and been given a chance to discuss it and ask questions. Spaces should be provided for (a) the signature of the person who consents to participate; and (b) the individual who witnesses the process of obtaining informed consent; and (c) the individual who obtains the consent of the subject.

SECTION 9.5 CONSENT FROM GUARDIANS

There may be rare occasions when the responsible family member or other legal guardian of a subject does not live in the same area as the subject. When it is physically impossible for the investigator to obtain consent in person, the consent may be obtained by mail. This must be pre-approved by the IRB.

SECTION 9.6 NON-ENGLISH SPEAKING SUBJECTS

Federal regulations require that informed consent information be presented in “language understandable to the subject”. Informed consent must be obtained in the native language if English is not readily understood by a subject. Written translation of the consent form should be available at the outset of a study if it is anticipated that non-English speaking subjects will be enrolled. Non-English speaking subjects may not be excluded from therapeutic studies, i.e., from studies from which they might be expected to benefit, on the basis of language alone.

SECTION 9.7 ADDITIONAL CONSENT INFORMATION FOR DIFFERENT TYPES OF STUDIES

Studies involving blood samples. Blood samples will be obtained by venipuncture. This method involves inserting a needle into a vein in the arm and withdrawing a sample of blood. It is routinely used to obtain blood for physical examinations. Venipuncture is accompanied by minor discomfort at the site of the needle entry and may result in slight bruising and a feeling of faintness. In this study a trained technician will obtain a 30 ml (about 2 tablespoonfuls) sample of your blood that will be analyzed for...

Studies that involve students or employees, the Institutional Review Board considers UNTHSC employees and students to be special classes of subjects. Their participation must be completely

voluntary and must not include incentives such as compensatory time off. If extra course credit is offered, students must also have an alternative, which takes equal, or less effort to complete than would be required for the research study.

All informed consent documents must address the possible recruitment of students and/or employees. The informed consent should indicate that their participation (or non-participation) would in no way affect their academic standing or employment status. Direct or indirect coercion of students and employees to participate may be construed as academic misconduct.

Studies that involve physical risk. The Health Science Center has no facilities or insurance to cover research related injuries. If the study involves physical risk, assess the risk and add the statement “Neither the investigator conducting this study nor the University of North Texas Health Science Center at Fort Worth are able to offer financial compensation nor to absorb the cost of medical treatment should you be injured as a result of your participation in this research. If required, medical care will be made available to you in the case of such an injury, but you (or your private insurer, Medicare, Medicaid or other governmental healthcare program) will be responsible for the expense of any medical care, including hospitalization, that is needed.”

To avoid the appearance of coercion, the following statement should be included in all consent documents that involve risk to the subject: “You should know that by signing this form you are neither waiving any of your legal rights nor releasing the principal investigator, the University of North Texas Health Science Center at Fort Worth or any of their respective agents from liability for negligence with respect to the conduct of this study. If you are injured and feel that your injury justifies pursuing a legal remedy, you have the right to do so.”

If there is a risk to a fetus, the female participant must be informed of the risk and the methods to be used (such as a pregnancy test) to minimize the risk.

If the study involves drugs, the participants must be given a statement of known side effects, warned about possible drug interactions (including interactions with alcohol), and warned about activities that may be dangerous (such as driving with a drug that has a sedative effect).

Studies that involve psychological risk. The principles that apply to studies that involve psychological risk or mental stress are similar to those that involve physical risk. Participants should be informed of the risk and told that treatment will not be provided. They should be given the names and telephone numbers of agencies that may alleviate their mental concerns, such as a crisis hot line. If the principal investigator or the faculty sponsor of a student investigator is qualified to treat mental health problems, that person may be listed as a resource.

Studies on sensitive topics. Participants should be told that some of the questions are of a personal or sensitive nature and should be given examples of the topics or questions. They should also be told that they may skip a question if they do not wish to answer it. If questionnaires or interviews may generate reports of child physical or sexual abuse, the participant must be informed that the researcher is legally required to report this information to Child Protective Services. (See the information under item 6 of the synopsis and the Use and Disclosure of PHI for which an Authorization is not required. If the questionnaire or

interview may generate reports that the participant plans to harm him or herself or others, the participant must be told that the investigator is ethically required to report that information to the local police department. This information about the legal obligations to report abuse and threats of harm to oneself or others may be omitted if the responses are anonymous.

In the event that the Privacy rule is more restrictive than the procedures described in the consent requirements, the more restrictive rule must be followed.

Studies using deception. Deception should be employed only when there are no viable alternative procedures. Where deception is a necessary part of an experiment, the IRB will generally require that a preliminary consent be obtained, in which the investigator informs the subject that the experiment cannot be described fully in advance. After the experiment, the subject should be informed of the deception and its purpose. We recognize that there are rare instances in which no consent can be obtained or debriefing done. Deception requires that a PI get formal approval of a waiver of informed consent, due to the initial consent being used.

Studies with audio or video recordings. Participants must be told: (a) that the interviews or sessions will be audio or videotaped; (b) that the cassettes will be coded so that no personally identifying information is visible on them; (c) that they will be kept in a secure place (e.g., a locked file cabinet in the investigator's office); (d) that they will be heard or viewed only for research purposes by the investigator and his or her associates; and (e) that they will be erased after they are transcribed or coded. If you wish to keep the recordings because of the requirements of your professional organization with respect to data or because you may wish to review them for additional analyses at a later time, the statement about erasing them should be omitted and you should state that they will be retained for possible future analysis. If you wish to present the recordings at a convention or to use them for other educational purposes, you should get special permission to do so by adding, after the signature lines on the consent form, the following statement, "We may wish to present some of the tapes from this study at scientific conventions or as demonstrations in classrooms. Please sign below if you are willing to allow us to do so with the tape of your performance." And add another signature line prefaced by, "I hereby give permission for the video (audio) tape made for this research study to be also used for educational purposes." This procedure makes it possible for a participant to agree to being taped for research purposes and to maintain the confidentiality of the information on that tape.

Studies with monetary or other compensation. The amount and type of the stipends or other compensations and the requirements to earn them must be clearly specified. Write this part of the consent form as if it were a contract.

SECTION 9.8 DOCUMENTATION OF INFORMED CONSENT

Informed consent must be documented by the use of a written consent form reviewed and approved by the IRB and signed by the subject or subject's legally authorized representative. A copy must be given to the subject or person signing the form. It is assumed that the consent form is only part of the total consent process in which the investigator, perhaps using the written consent form as an outline, describes all facets of the study and answers the subject's questions. The investigator is responsible for insuring that research subjects understand the research

procedures and risks. Failure of the subjects to ask questions should not be construed as understanding on the part of the subject.

SECTION 9.9 NEW FINDINGS

It is the Principal Investigator's responsibility to report new findings to the IRB **immediately**. If the information may affect a subject's willingness to begin or continue participation in a research study, the informed consent must be modified accordingly. New findings includes information reported by the sponsor of the research, periodic reports by a data and safety monitoring board, announcement by the Food and Drug Administration and publications in medical and other scientific journals.

SECTION 9.10 DISTRIBUTION OF INFORMED CONSENT FORMS

A signed copy of the consent form must be given to the subject. The original copy must be retained in the investigator's file. If the subject is a patient, a copy of the signed consent form must be placed in the subject's hospital or clinic record.

SECTION 9.11 WAIVER OF WRITTEN INFORMED CONSENT

Principal Investigators may request that the use of consent form be **waived** if:

1. The only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality;
2. The research presents no more than minimal risk of harm to subjects;
3. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
4. The research could not practicably be carried out without the waiver;
5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation;
6. The research is to be conducted for the purpose of demonstrating or evaluating:
 - a. Federal, state or local benefit or service programs which are not themselves research programs;
 - b. Procedures for obtaining benefits or services under these programs; or
 - c. Possible changes in or alternatives to these programs or procedures.

Reasons for request that a written consent be waived should be explicitly stated in a cover memo accompanying the research proposal and protocol. When the documentation requirement is waived or altered, the IRB may still require the research investigator to provide subjects with a written statement regarding the research. Any other consent waiver than those mentioned here may be given only upon recommendation of the IRB and approval by the President of the Health Science Center.

SECTION 9.12 WAIVER OF INFORMED CONSENT

The IRB may waive the requirements for obtaining written informed consent or approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent listed above, provided that all of the following four conditions are met:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or amendment will not adversely effect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or amendment; and

Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

SECTION 9.13 RECORDS RETENTION REQUIREMENTS FOR SUBJECT CONSENT FORMS/PHI AUTHORIZATION FORMS

FDA regulations require investigators to retain records for a specified time period. For investigational new drug (IND) studies (and medical food and food additive studies), records are to be maintained for two years following the date of marketing application approval for the drug for the indication for which it was being investigated. If no application is filed, or if the application is not approved for the indication, the records are to be retained for two years after the investigation (i.e., the IND) is discontinued, and FDA is notified of that fact. For device studies, records are to be maintained for two years after the later of the following dates: the date on which the investigation is terminated or completed, or; the date that the records are no longer required to support a pre-market approval application or a notice of completion of a product development protocol.

To comply with FDA record retention requirements, clinical investigators should arrange with study sponsors to be kept informed of the status of the application for their respective studies.

For non-FDA studies, all records must be maintained for a *minimum of 5 years* after completion of the study.

SECTION 9.14 FDA INSPECTION OF STUDIES

The Principal Investigator is responsible for sending the IRB copies of all correspondence pertaining to FDA inspection of studies. This includes Form FDA 483 (Inspectional Observations), and all other related follow-up correspondence, both to and from the FDA. This correspondence must be sent to the IRB within five working days of receipt/transmittal.

SECTION 9.15 NON-COMPLIANCE WITH IRB REQUIREMENTS

Federal regulations require that all documentation for projects involving human subjects be completed accurately and submitted in a timely manner. Failure to comply with this request will result in suspension or termination of IRB approval. If IRB approval is suspended or terminated, the IRB Chair will notify the study sponsor and the FDA or OHRP, as applicable, in writing within five working days.