INFORMED CONSENT

Informed consent is an ongoing process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject without any form of direct or indirect coercion.

This policy refers to individuals who meet the criteria as adults. For information on consent-related procedures for children, please refer to those relevant sections on Protection of Children Involved in Research.

Three consent templates are available for research:

1. Informed Consent Template (this is to be used for research involving higher than minimal risk)

2. Informed Consent Abbreviated Signed for Minimal Risk (this is for protocols that need signed consents but are minimal risk)

3. Informed Consent for Anonymous Online (these are for online, anonymous surveys so that participants are aware they are being involved in a research study).

I. GENERAL REQUIREMENTS

1. Except as described in Section III below, PIs may not enroll human subjects in research unless they have obtained the legally effective, written, informed consent of the subject or the subject’s legally authorized representative prior to enrollment of the subject in the research.

2. PIs submitting protocols where health information of participants is involved must also refer to the HIPAA Policy in Research. PIs and anyone else involved with the study must be cognizant of the federal regulations regarding protection of health information for participants in research. Participants will need to sign a HIPAA Consent Form in addition to the written informed consent form.

3. PIs are responsible for insuring that subjects, or their representatives, are given sufficient opportunity to consider whether or not to participate and must seek to avoid coercion or undue influence.

4. Information given to potential subjects or their representatives must be in language that is understandable to the subject or representative.

5. A typical informed consent must be written at no higher than a 8th grade level of reading, and tailored to less than that as appropriate.
6. No process of obtaining consent may include exculpatory language through which the subject waives any of his/her legal rights, or releases or appears to release the PI, sponsor, or institution or its agents from liability for negligence.

7. The IRB must approve the consent form before it is used, and it must approve any changes made to a previously approved consent.

8. Subjects must be given a copy bearing the IRB approval stamp.

9. The IRB has the authority to observe the consent process and may do so without prior notification to the PI.

10. All potential subjects, especially those situations in which language and/or intellectual level of understanding may be an issue, must be able to verbalize to the PI or representative, that the project is research, general purpose of the research, risks, the voluntary nature of beginning and/or ending participation with no undue consequences, and who to contact if necessary for further information about the research.

II. ONGOING INFORMED CONSENT

Informed consent is communication process that continues during the entire study. Many of the elements of informed consent previously discussed apply throughout the study. The researcher and research team should:

- Feel confident that the participant maintains the ability to understand information, make an informed decision, and voluntarily continue to participate.
- Provide written and oral information about emerging study details in a manner understandable to the participant.
- Be satisfied that the participant understands the information provided, has had an opportunity to discuss the information and ask questions, and understands that he or she may withdraw from the study at any time.

When changes in the study occur, and/or significant new findings develop during the course of the study that may affect the participant and his or her willingness to continue participation, additional informed consent may be necessary. Continuation of the study may require having participants sign a new consent form (obtaining re-consent). All proposed changes in the protocol and the consent must be submitted to the IRB. Researchers should consult the IRB for the requirements for study changes and re-consent procedures.

1. The IRB has a sample consent form which contains all the required elements of consent and is written at the 7.9 grade level: http://uttyler.edu/research/compliance/irb/docs/irb-informed-consent-template-032612.doc
2. The UT Tyler IRB requires that all consent forms be written in the second
person, e.g., “you should understand that…”

3. The signature page may be written in the first person, e.g., “I understand that…”

III. BASIC ELEMENTS OF INFORMED CONSENT

The following are the required elements (extracted from 45 CFR Part 46.116 and 21 CFR 50.25):

a. A statement that the study involves research, an explanation of the purposes of the research, the duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

b. A description of any reasonably foreseeable risks or discomforts that the subjects may encounter, and, if appropriate, a statement that some risks are currently unforeseeable;

c. A description of possible benefits, if any, to the subject and others which may be reasonably expected. It should be stated that since it is an experimental treatment or procedure, no benefits can be guaranteed;

d. A discussion of possible alternative procedures or treatments, if any, that might be advantageous to the subject. One alternative might be to choose not to participate in the research;

e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA, the sponsor, the UT Tyler IRB, or others may inspect the records;

f. For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available if a research-related injury occurs and, if so, what they consist of, or where further information may be obtained;

g. An explanation of whom to contact for answers to pertinent questions about (i) the research (generally the PI or another staff member closely associated with the study), (ii) the rights of the research subject (usually the IRB chairperson), and (iii) any research-related injury to the subject (generally the PI or another staff member closely associated with the study). For item (iii), this should be a telephone number or numbers whereby the research subject can reach an appropriate person 24 hours a day, not just during normal working
hours; and

h. 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.

i. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is becomes pregnant), which are currently unforeseeable;

j. Anticipated circumstances under which the subject’s participation may be terminated by the PI without regard to the subject’s consent;

k. A description of any additional costs for which the subject will be responsible, that may result from participation in the research study;

l. The consequences of a subject’s decision to withdraw from the research and the procedures for orderly termination of participation by the subject;

m. A statement that significant new findings developed during the course of the research, which may relate to the subject’s willingness to continue participation, will be provided to the subject;

n. A description of any compensation or reimbursement for time, inconvenience, travel, and other similar costs to the subject; and

o. The anticipated number of subjects that will be involved with the study, both totally and at UT Tyler.

IV. WAIVER OF INFORMED CONSENT

The IRB may waive the requirements for obtaining 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:

1. The research involves no more than minimal risk to the subjects;

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

There are more stringent and specific requirements for the IRB waiver of informed consent in emergency situations in which the research involves more than minimal risk to the subjects. Information on the requirements and procedures may be obtained from the IRB Chair.

V. DOCUMENTATION OF INFORMED CONSENT

1. Informed consent must be documented by the use of a written consent form reviewed and approved by the IRB.

2. The informed consent should be signed and dated by the subject or subject’s legally authorized representative and a witness.

3. By signing the form, the witness is attesting to the fact that the subject, or the subject’s legally authorized representative, actually signed the form and volunteered to participate in the research.

4. A copy must be given to the subject or person signing the form.

5. For Texas Department of Criminal Justice (TDCJ) inmates, a copy of the signed consent form should also be placed in the subject’s medical record.

6. It is assumed that the consent form is only part of the total consent process in which the PI, perhaps using the written consent form as an outline, describes all facets of the study and answers the subject’s questions.

7. The PI 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.

VI. RECORD RETENTION REQUIREMENTS FOR SUBJECT CONSENT FORMS

1. The PI shall maintain, in a designated location, all executed subject consents.

2. These consent forms are to be available for inspection by authorized officials of the UT Tyler administration and IRB, as well as the FDA, DHHS, and other regulatory agencies and sponsors.

3. For FDA regulated test article studies, all signed subject consent forms
shall be retained by the PI for the appropriate period(s) specified below.

**Drugs:** Three (3) years following the date a marketing application is approved or the study is discontinued.

**Devices:** Three (3) years after a study is terminated or completed, or longer if the records are needed to support FDA approval.

4. Should a PI depart from UT Tyler prior to the completion of an activity, the PI is responsible for initiating mutually satisfactory arrangements with his or her department and the UT Tyler administration as to the disposition of executed subject consents.

**VII. INFORMED CONSENT OBTAINED BY TELEPHONE AND INTERNET**

The Office of Human Research Protections does not mandate a specific method of electronic signatures. They do permit IRBs to adopt such technologies for use as long as the IRB considers applicable issues, such as, how the electronic signature is being created, if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject ([http://answers.hhs.gov/ohrp/questions/7260](http://answers.hhs.gov/ohrp/questions/7260)).

- **Internet Consents**

  Of importance to note: regardless of the manner in which consent/assent is obtained, there must always be ample opportunity for the subject/participant to have any questions answered or concerns addressed prior to and after consenting/assenting to participating in any research. Documentation of the method for this must be integrated into the protocol.

1. Risks and complexities of the research must be taken into consideration when consent/assent are provided via the Internet. Three concerns are inherent to using the Internet for consent/assent; potential solutions for addressing these concerns can be found under Question 11 at: [http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf](http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf)

   a. verification of identification
   b. ensuring understanding per consent requirements
   c. obtaining appropriate documentation when needed

These concerns may be minimal, or substantial depending on the risks involved, and must be appropriately addressed in the IRB application and protocol.
b. Waiving or altering the required consent elements requires adherence to 46.116 (c) and (d) which state that:

The research presents no more than minimal risk; the waiver will not adversely affect subjects' rights and welfare; the research could not practicably be carried out without waiver; and, when appropriate, subjects will be provided with additional pertinent information after participation.

c. Children under the age of 13: If identifiable information may be collected about children under the age of 13, the COPPA requirement for parental consent will apply (there is no waiver provision).

COPPA information and guidelines are at:
http://www.coppa.org/comply.htm

o Electronic Signatures

1. Considerations to Address

   a. First, the investigator and the IRB need to be aware of relevant laws pertaining to electronic signatures in the jurisdiction where the research is going to be conducted.

   b. Unless the IRB waives the requirement for the investigator to obtain a signed consent or permission form based on the HHS regulations at 45 CFR 46.117(c), a written consent or permission form, which may be an electronic version, must be given to and signed by the subjects or the subjects' legally authorized representatives or the parents of subjects who are children.

   c. Some form of the consent document must be made available to the subjects or the parents of subjects who are children in a format they can retain. OHRP would allow electronic signature of the document if such signatures are legally valid within the jurisdiction where the research is to be conducted.

   d. If at all possible, use a system for electronic or digital signature that provides an encrypted identifiable “signature.”

o Telephone Consents
1. The informed consent process should be an active process of sharing information between the investigator and the prospective subject.

2. An oral approval does not satisfy the 21CFR56.109(c) requirement for a signed consent document, as outlined in 21CFR50.27(a).

3. However, it is acceptable to send the informed consent document to the subject by facsimile, standard mail, or electronically, and conduct the consent interview by telephone when the subject can read and return the consent as it is discussed. If the subject agrees, he/she can sign the consent and return the signed document by facsimile, electronically, or standard mail.

4. When the subject makes the first study visit, informed consent must be obtained again. This is to ensure that the patient understands the study and in fact still wants to participate. Both informed consents should be kept on file.

5. Any questions regarding this process should be directed to the IRB Chair.

° Telephone Surveys

1. In some cases, the informed consent process may be altered from the written standard where a telephone survey methodology is used.

2. Where research is considered to be minimal risk, often consent may be obtained via telephone. The following items minimally must be included in the consent script:

   i. the purpose of the research, the researcher’s name and his or her association with UT Tyler IRB
   ii. how confidentiality of their responses will be maintained, and
   iii. a statement that participation is voluntary, the participant can refuse to answer any questions or terminate his or her participation at any time.
   iv. Additional items may be required based on the subject matter and risks to subjects.
   v. Determinations regarding what information must be included and if the research qualifies for a waiver of signed consent will be made by the UT Tyler IRB.

• Family of Origin Research and Third Party Consent Issues

When an investigator conducting research obtains identifiable private information about that living individual, that individual becomes a research subject. For example, when asking for family medical history, if the subject is asked to identify if his/her mother or father has a condition or ailment and the
original subject is identifiable, the parent then becomes a research subject. This parent would be referred to as a “third party subject” or “secondary subject” and would need to be consented regarding the information being obtained.

An agreement to participate in research constitutes valid consent only if voluntarily given by the individual whose identifiable private information is obtained by the researcher. Thus the regulations require consideration of all living individuals about whom a researcher obtains identifiable private information, be they family members, or not.

**Incentives**

Federal regulations governing research with human subjects contain little specific guidance for IRB review of payment practices. However, the UT Tyler IRB will make sure that prospective subjects realize that their participation is voluntary, and that choosing not to participate will not adversely affect their relationship with the institution or its staff in any way.

To make this determination, the UT Tyler IRB will know who the subjects will be, what incentives are being offered, and the conditions under which the offer will be made. Informed consent documents must contain a detailed account of the terms of payment, including a description of the conditions under which a subject would receive partial or no payment.

Determining the appropriateness of the incentive is another matter. For research that requires subjects to undergo only minor inconvenience or discomfort, a modest payment will usually be adequate. Reimbursement for travel, babysitting, and so forth may also be provided. In more complex research projects, IRBs tend to base their assessment on the prevailing payment practices within their institution or general locale. Volunteers are often compensated for their participation according to an established fee schedule, based upon the complexity of the study, the type and number of procedures to be performed, the time involved, and the anticipated discomfort or inconvenience. Extra payments are usually provided for a variety of additional inconveniences (e.g., the imposition of dietary restrictions). Payments may vary according to a number of factors, and therefore, the UT Tyler IRB will be familiar with accepted standards within the community as well as the anticipated discomforts and inconveniences involved in a particular study to judge the appropriateness of payments.

It should be noted that providing subjects with monetary awards through UT Tyler IRB can create a problem of maintaining strict confidentiality. If the award is made through funding from a contract or grant, usually subjects receive a check for the predetermined (and approved) amount. UT Tyler IRB must have the subject’s Social Security number in order to issue the check. Such payroll records are not available to the public, but do constitute a link between the
subject and the research.

X. PRIVACY AND CONFIDENTIALITY AND FERPA

In reviewing some protocols, the UT Tyler IRB may have to consider whether an invasion of privacy is involved. The IRB will base decisions on its sense of propriety and the particular circumstances of the study. Among the several relevant factors are:

- the private nature of the information sought,
- the likelihood that the subjects would regard the release of information as an invasion of privacy, the importance of the research, and
- the availability of alternative ways to do the study.

Investigators sometimes want access to existing records to identify people suitable for inclusion in a study. The UT Tyler IRB will always need to know if the subjects' names will be recorded by the investigator for follow-up (either for further record review or for personal contact).

This is because the level of review may be affected, and the UT Tyler IRB will need to determine whether the consent of subjects should be sought (e.g., by the institution holding the records) before the researcher gains access to the records.

Factors used in deciding if consent must be sought include the sensitivity of the information reviewed, the vulnerability of the subject population, and the purpose for which the investigator wants access to the information.

The Buckley Amendment [the General Education Provisions Act (20 USC 1232)], also known as FERPA, requires parental consent for release of records or identifiable information about children in public schools; instructional materials to be used in connection with any research or experimental program must be open to inspection by the parents or guardians of the children to be involved.

In most research, ensuring confidentiality is only a matter of following some routine practices:

- substituting codes for identifiers,
- removing face sheets (containing such items as names and addresses) from survey instruments containing data,
- properly disposing of computer sheets and other papers,
- limiting access to identified data,
- impressing on the research staff the importance of confidentiality, and
- storing records in locked cabinets.

Most researchers are familiar with the routine precautions that should be taken to maintain the confidentiality of data. More elaborate procedures may be needed in some
studies, either to give subjects the confidence they need to participate and answer questions honestly, or to enable researchers to offer strong, truthful assurances of confidentiality.

Such elaborate procedures may be particularly necessary for studies in which data are collected on sensitive matters such as sexual behavior or criminal activities. When information linked to individuals will be recorded as part of the research design, the UT Tyler IRB will make sure that adequate protections will be taken to safeguard the confidentiality of the information.

Sensitive information is sometimes obtained in the course of behavioral studies, research with the cognitively impaired, AIDS research, and research dealing with drug and alcohol abuse. There is a regulatory provision for waiving documentation of consent when a signed consent form would itself constitute a risk to the subjects [45 CFR §46.117(c)(1)].

Researchers must be aware that promising subject anonymity is misleading. Neither the researcher or the institution can promise anonymity, except when a Certificate of Confidentiality has been obtained from a federal agency. Otherwise, research records can be subpoenaed. For details about obtaining and using a Certificate of Confidentiality, see http://grants1.nih.gov/grants/policy/coc/faqs.htm#187

XI. MANAGEMENT OF DATA FOR ENSURING SUBJECT SAFETY AND PRIVACY

One of the areas to be reviewed in proposed research is the researcher's plan for collection, storage, and analysis of data. Monitoring of the research by the researcher is important because preliminary data may signal the need to change the research design, change the information presented to subjects, or even to terminate the project before the scheduled ending date.

Both the timing and adequacy of the plan for analysis are important. If the data are not analyzed until the project is terminated, the chance for making mid-course corrections is lost. If the data are not properly analyzed, the research itself is not valid, and correct conclusions may not result.

For the UT Tyler IRB to approve proposed research, the protocol must, when appropriate, include plans for monitoring the data collected to ensure the safety of subjects (45 CFR §46.11(a)(6)]. Investigators sometimes misinterpret this requirement as calling for annual reports so the UT Tyler IRB can monitor the project. However, it does in fact require, when appropriate, that researchers provide the IRB with a description of their plans for analyzing the data during the collection process.

Concurrent collection and analysis enable the researcher to identify flaws in the study design early in the project. At this point, researchers are able to reevaluate the risks to human subjects to assure they are no greater than initially predicted. Like other
considerations, the level of monitoring in the research plan should be related to the degree of risk posed by the research.