

<b>Policies of the University of North Texas Health Science Center</b>	<b>Chapter 14 – UNT Health</b>
<b>14.402</b> Informed Consent	

Policy Statement.

It is the policy of the University of Texas Health Science Center to obtain voluntary and informed consent from all patients or their legally authorized representative prior to the start of any care, treatment or service involving more than a slight risk of harm to the patient's physical and/or mental health. Informed consent allows the patient to fully participate in care, treatment or service decisions.

Application of Policy.

Faculty/Staff involved in patient care.

Definitions.

1. Informed consent: permission granted by a patient or patient’s legally authorized representative after being fully informed about the possible benefits, risks, alternative treatments, and probability of success of the treatment or procedure that could influence a reasonable person in deciding whether or not to consent.

Informed consent is a process and not simply a documentation form. It is an ongoing process when additional information becomes available to the provider and is shared with the physician.

2. Voluntary: Being freely chosen or undertaken of one’s own free will.
3. More than slight risk of harm: when disclosure would be material to a reasonable patient's decision of whether to accept or reject treatment.

Procedures and Responsibilities.

<u>Procedure / Duty</u>	<u>Responsible Party</u>
<ol style="list-style-type: none"> <li>1. For all treatment involving more than a slight risk of harm to the patient’s physical or mental health, the process of informed consent with the patient or legally authorized representative (e.g. a parent for a minor patient) will be conducted that includes a detailed explanation of the procedure, including: <ul style="list-style-type: none"> <li>▪ The nature, expected duration, and purpose (reason for procedure)</li> <li>▪ The preparation required and period of time before normal activities can be resumed.</li> </ul> </li> </ol>	Healthcare Provider

- The potential benefits the patient may expect to receive from the procedure.
  - Risks and complications: Possible harmful effects that a reasonable person would find important in determining his or her course of action, as well as possible side effects.
  - The potential necessity for related or additional procedures associated with the procedure.
  - The risks of anesthesia or sedation analgesia if applicable.
  - Alternative management, including the consequences of not proceeding with the procedure/treatment.
  - Authorization of the use of additional personnel to participate in the diagnosis and treatment of this condition.
  - Following the discussion, the patient is allowed to ask questions and once satisfied, the patient makes a choice.
2. The duty of securing informed consent rests with the provider. (The nursing staff may deliver the consent form to the patient for his or her signature, but the nursing staff is not authorized to explain the procedure or treatment in lieu of the provider. To do so would be beyond the scope of nursing practice).
- Healthcare  
Provider/  
Nursing Staff
3. If the patient tells the nursing staff that he or she does not understand the nature of the impending procedure, has additional questions regarding the procedure or treatment, or has had second thoughts about consenting to the procedures, the nursing staff must stop the informed consent process and notify the provider that the patient needs additional information or further explanation about the proposed procedure or treatment before asking the patient to sign.
- Nursing Staff
4. With respect to the disclosure of the risk of a proposed treatment, the rule of thumb is that patients need sufficient information necessary to enable them to make an “intelligent” and “rational” decision as to whether to submit to a proposed treatment.
- Physician Standard: requires a practitioner to disclose information to patients to the extent that other practitioners, practicing in the same specialty, in the same or similar community, and in the same or similar circumstances, would disclose.
- Healthcare Provider

- Patient-based Standard: (“Need to know”). A practitioner must disclose those facts that a reasonable patient would consider “material” in deciding whether to submit to a procedure or treatment.

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| 5. | The provider should make a timed and dated notation in the patient’s medical record documenting the occurrence of the discussion and summarizing its contents.  | Healthcare Provider                   |
| 6. | The consent form is the final step in the process - memorializing in writing that the disclosures process has taken place to the satisfaction of the patient and that the patient authorized the providers to perform the discussed procedure or treatment.   | Healthcare Provider                   |
| 7. | In obtaining the patient’s signature, the nursing staff is witnessing only that the signature is the patient’s, not that the patient has been fully informed and understand the impending procedure or treatment.   | Nursing Staff                         |
| 8. | <p>Procedures Requiring Specific Consent:<br/>           The Texas Legislature through the Texas Medical Disclosure Panel has determined the requirement for disclosure by the physician on a medical or surgical consent form. The requirements are a minimum standard. Depending on the procedure or treatment, there may be specific risks that must be disclosed.</p> | Healthcare Provider/<br>Nursing Staff |

The specific risks that must be listed on the consent form are outlined in the Texas medical Disclosure Panel-List A. Procedures or treatments not requiring that specific risks be listed on the consent form are can be found on The Texas Medical Disclosure Panel-List B.

For List B procedures and procedures not found on either list, the physician must disclose the possible risks that a “reasonable patient” would want to know before giving consent.

Any doubts about the necessity of obtaining a special consent form the patient should be resolved in favor of processing the consent.

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| 9. | <p>Scope of Consent:</p> <ul style="list-style-type: none"> <li>▪ The authorization is limited to the named procedure or treatment.</li> </ul> | Healthcare Provider |
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- Authorization should be extended to other procedures when there is a clear indication to the practitioner that it is of benefit to the patient.
  - Express limitation on authorization by the patient and consent that is conditioned on the occurrence of a particular event must also be heeded.
  - The patient has the right to decide who will perform the procedures or treatment; thus a substitute practitioner may not be used unless approved by the patient.
10. Refusal of Treatment: If a patient rejects the recommended procedure of treatment, he or she should sign a written statement acknowledging that they have been informed of the risks of not agreeing to the recommended procedure and/or treatment, referred to as “informed refusal”.
- Healthcare  
Provider/  
Nursing Staff
11. Exceptions to Informed Consent:
- Emergency exception: a situation in which immediate treatment is needed to save the patient’s life or health, but in which, for some reason, consent cannot be obtained.
  - Therapeutic Privilege: If explaining the risk of the procedure would affect the patients ability to make a rational decision or cause harm to the patient that would likely exceed the risk itself.
- Healthcare  
Provider/  
Nursing Staff
12. If a patient requests to waive his right to informed consent (i.e., the patient does not want to receive any information about the treatment), the provider/staff must contact and consult with the Department of Healthcare Quality and Risk Management before initiating any type of treatment or procedures.
13. Documentation shall be completed in the medical record. A copy of the informed consent shall be placed in the medical record.
- Healthcare  
Provider/Nursing  
Staff

References and Cross-references.

General Consent to Treat Policy

Minor Consent to Treat Policy

Minors in Special Circumstances-Emancipated Minor Consent Guidelines (Available through the Department of Healthcare Quality & Risk Mgmt.)

Texas Medical Disclosure Panel List A and B [www.dshs.state.tx.us/HFP/tmdp.shtml](http://www.dshs.state.tx.us/HFP/tmdp.shtml)

Forms and Tools.  
Informed Consent Form

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