- Consent in the content of medical profession implies to permission by the patient to perform an act on his body either for diagnosis or therapeutic procedure.
- It is a process of information exchange that may include reading and signing the informed consent document.
- Institutional Review Boards (IRB), clinical investigators and research sponsors all share responsibility for ensuring that the informed consent process is adequate.
- The clinical investigator is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study.
- FDA does not require the investigator to personally conduct the consent interview.
- In addition to signing the consent, the subject/representative should enter the date of signature on the consent document, to permit verification that consent was actually obtained before the subject began participation in the study

- A copy of the consent document must be provided to the subject and the original signed consent document should be retained in the study records.
- The IRB should be aware of who will conduct the consent interview.

Goals:

The goal of the informed consent process is to provide people with sufficient information so they can make informed choices about whether to begin or continue participation in clinical research.

Types of ICF:

There are three principal forms of (informed) consent:

i- Presumed consent: in which participants are presumed to have consented to participation in the research unless they indicate otherwise.

ii- Verbal consent: in which the researcher verbally informs participants and receives oral confirmation of consent.

- Written consent: in which the researcher provides written information regarding the research project to participants and retains a signed copy of this consent form.

Components of ICF:

- Informed consent should involve the provision (تقدیم، تدارک) or collection of information on:
  - Name and contact details of researcher
  - Name and contact details of participant
  - Aims and objectives of the research project
  - Role of the participant in the research project
  - Treatment of material/information collected
  - Potential risks to the participant
  - Sources of advice/help/support/treatment
  - Voluntary participation and freedom to withdraw
  - Signature and date of researcher and participant

Basic Elements of ICF: 5M

- The following elements are required in all consent

forms as per FDA:

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed and identification of those being done for research purposes
- Identification of any experimental procedures
- A description of any reasonably risks or discomforts to the subject.
- A description of any benefits to the subject or to others.
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained
- A statement that the FDA may inspect the records.
- For research involving more than minimal risk, an explanation as to whether any compensation exists if injury occurs.

- For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist.
- An explanation of whom to contact for answers to pertinent questions about research and research subject's rights. At least one contact's name and phone number must be other than the investigator's or study personnel.
- A statement that participation is voluntary.
- A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- Eligibility for medical care is based upon the usual eligibility policy and is not guaranteed by participation in a research study.
- A copy of this consent form will be placed in your medical record.

- Your records may be reviewed by quality assurance and federal regulatory authorities as well as the Institutional Review Board.

- General Requirement:

- No investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

- The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

- No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's rights.

- The IRB should ensure that technical and scientific terms are adequately explained or that common terms are substituted.

- The IRB should ensure that the informed consent document properly translates complex scientific concepts into simple concepts that the typical subject can read.

Example: Format of informed consent form subjects participating in clinical trial:

Study title: ..... Study number: .....

Subject's initial: ..... Subject's name: .....

Date of birth/age: ..

1- I confirm that I have read and understand the information sheet dated ..... for the above study and have had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose.

4. I agree to take apart in the above study:---

Signature of the Subject: Date:

Signature of investigator: Date:

Study investigator's name: Date:

Signature of witness:

Name of witness: شاهد