

Informed Consent – The Process

Ethical Considerations

[The Belmont Report](#) (1979) – Respect for Persons principle

The Informed Consent process:

- Is **more** than a signed document
- Provides for an **ongoing educational exchange of information**, (before, during and after enrollment), between the investigator, study staff, prospective subject, family, etc.
- Enables **voluntarily decision** (whether or not to participate)
- Provides **documentation of consent** from research participant prior to any research activities (unless the IRB approves a waiver or alteration)

Applicable Code of Federal Regulations

Citation	Title
21 CFR 50	FDA – Protection of Human Subjects, Informed Consent
21 CFR 56	FDA – Institutional Review Boards
45 CFR 46 , Subpart A	DHHS – Basic Policy for Protection of Research Subjects (Common Rule)
45 CFR 46 , Subpart B	DHHS – Research Involving Fetuses, Pregnant Women, and Human In-Vitro Fertilization
45 CFR 46 , Subpart C	DHHS – Additional Protection for Children Involved as Subjects in Research
45 CFR 46 , Subpart D	DHHS – Additional Protections Pertaining to Research Involving Prisoners as Subjects
DHHS – Department of Health and Human Services; FDA – Food and Drug Administration	

Basic Elements of Informed Consent – must be included (per Federal Regulations)

1. Research Statement
Involves research, purpose, duration, procedures
2. Risks and Discomforts
Reasonably foreseeable and realistic risks/discomforts
3. Benefits
Presumed positive outcome of trial is not a benefit
4. Alternatives
Disclosure of subjects' alternatives to research participation, including possibly advantageous alternative procedures
5. Confidentiality
Extent of confidentiality of identifiable records
For FDA regulated research, a statement disclosing that the FDA may inspect records
6. Compensation
7. Contact Person
8. Voluntary Participation and Right to Withdraw
Completely voluntary
Refusal or discontinuation to participate will not result in any penalty or loss of benefits to which is otherwise entitled

Additional Required Elements of Informed Consent (Required, when appropriate, for studies involving drugs, devices or biologics)

1. Unknown risks to participants
2. Termination of participation (by someone other than participant)
3. Costs
4. Consequences of withdrawal
5. Notification that new findings will be given to participants
6. Number of participants

Children and Informed Consent

- Parental permission (consent) must be obtained before speaking with minors about participating in research.
- Signatures of one of both parents may be required (as determined by the IRB) on the consent form.
- Minors must be in agreement on participating in research and their assent (agreement) must be obtained when required by the IRB.
- [UH IRB Policy: Assent from Children in Research Studies](#)

Age of Minor	Is Assent Form Required?	Comments
Infant – Age 6	No (Verbal or written assent is usually not required)	A brief verbal explanation of the research procedure should be provided to the child. If the investigator or IRB determines that the child is capable of understanding the research, an information sheet must be provided to the child.
Ages 7 -13	Yes	A separate assent form is required.
Ages 14-17	Maybe	A consent or assent form may be used. A separate assent form may also be provided to the child if the investigator believes it would better describe the information provided to the child about the nature of the study.

Documentation of the Process

The consent process must be documented in the participant's medical/research record by the person obtaining consent. Required documentation:

- How consent was obtained
- Participant's level of comprehension
 - o Did participant appear to understand
 - o Did participant ask questions
 - o Was participant able to reiterate purpose of study; procedures; risks; benefits; alternative treatments etc.
- Description of participant's decision making capacity at time
 - o Alert/oriented?
- Time given for consent decision-making, and whether others were involved in decision-making
- Who was present during the consent process
- That a copy of informed consent document was provided to participant

Click [here for Informed Consent Documentation Template](#)

Documentation Provided to Research Participants

Copy of informed consent

- best practice is to provide signed and dated copy to participant
- photocopy or have participant sign 2 originals

HIPAA Authorization

- MUST give participant signed copy of their HIPAA authorization
- photocopy or have participant sign 2 originals

Medical Records and Consent

UH requires a copy of the consent document must be placed in the medical record "for procedures and treatment for which consent is required." ([UH Policy GM-68](#), section 2.13)

Recommendations/Tips

- Before beginning the informed consent process, consider how you will:
 - Explain the study
 - Ensure process occurs without undue pressure
 - Promote and assess comprehension
- Read and know your protocol
- Use the **current IRB approved/stamped** consent form
- Ensure continued informed and voluntary decisions
- Give short oral quiz following consent document review to assess understanding
- Provide potential subject with list of common questions to ask after reviewing a consent form
- Send informed consent document to potential subjects several days in advance