

## Informed Consent

Informed consent is one of the primary ethical requirements underlying all research with human subjects; its purpose addresses the basic principle of respect for persons (Belmont Report). Informed consent ensures that subjects understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. Informed consent must be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 or 21 CFR 50.27. ([www.hhs.gov/ohrp/humansubjects/guidance](http://www.hhs.gov/ohrp/humansubjects/guidance)).

The outline provided below incorporates those basic components in the referenced federal regulations

### Informed Consent Outline

**The proposed consent/assent/permission form or statement must include or address the following elements:**

1. Title of study, identification of investigator(s), and (if applicable) sponsor(s) of the research.
2. A.) a statement of **research**, B.) **purposes** of the research C.) expected **duration** of the subject's participation, D.) **procedures** to be followed, E.) identification of any experimental procedures
3. a description of any reasonably foreseeable **risks** or discomforts, **benefits** to the subject or to others which may reasonably be expected from the research;
4. a description to which **confidentiality** of records identifying the subject must be maintained;
5. a statement that addresses that A.) participation is **voluntary**, B.) refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and C.) that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
6. **those procedures used for orderly termination** of participation by the subject and explanation of any **compensation** for participation
7. Other areas as deemed appropriate