**Guidelines for Informed Consent (Assent) for Minors and Low Reading Comprehension Adults Participating in Human Subjects Research**

For minors:

1. Parent or guardian informed consent form is to be submitted for all subjects less than 18 years of age.
2. Minor subject's assent form must be written on the comprehension level of the minors who are subjects. Assent will generally be required of children of six years or older.
3. Infants, toddlers, or other minors whose oral comprehension level is too low to understand the form do not sign a consent form. The parent or guardian signed consent form is sufficient.
4. The assent form should record the age of the child and the date of the signatures.
5. For prolonged studies (i.e. more than one year) it may be appropriate to request the subject to reaffirm their assent at regular intervals.

Informed consent form for low-reading or non-reading comprehension subjects should follow this procedure:

1. Submit the consent form that will be read verbatim to subjects.
2. The scripted consent form must be comprehensible to subjects who hear it and include:
3. A statement of the purpose of the research.
4. An explanation of all aspects of the research that might reasonably be expected to influence subject's willingness to participate including any possible negative consequences of participation.
5. An explanation of all other aspects of the research addressed on the standard informed consent form for the project.
6. An explanation of all other aspects of the research about which the subject may inquire.
7. A statement that the subject may withdraw from the research at any time without penalty.
8. The Principal Investigator’s name and contact phone number and, if a student researcher, the name and phone number of the instructor supervising the research. A place for subject’s signature and, if subject uses a mark, a place for the signatures of two witnesses not affiliated with the research.