

INFORMED CONSENT GUIDELINES

The regulations regarding informed consent are complex. Generally speaking, research subjects need to have sufficient information in the project in which they are being asked to become involved, and should voluntarily agree to participate. **The information given to the prospective subjects or the representatives needs to be in language they can understand.** For those less than 18 years of age, the researcher must obtain the informed consent of parents or legal guardians.

The informed consent must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.
2. Short description of methodology and duration of participant involvement.
3. Statement of risks/benefits to the participants.
4. Statement of data confidentiality.
5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.
6. An offer to answer any questions the participant may have.
7. Contact information of all Principal Investigators
8. Line for signature of participants and/or parents or legal guardian
9. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.