# Elements of Informed Consent

HENRY FORD COLLEGE
FUTURE DRIVEN

## Institutional Review Board

Researchers must obtain the informed consent of all study participants. For those less than 18 years of age, the researcher must obtain the informed consent of parents or a legal guardian and all reasonable attempts must be made to obtain each minor participant's assent, which is defined as the participant's agreement to participate in the study.

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, and for HFC’s Institutional Review Board chair.
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.

In situations where participants will be deceived, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, after the study is complete, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" to guarantee informed consent.