**Guidance on Informed Consent**

The goal of the informed consent (IC) process is to provide individuals with sufficient information for making an informed decision before participating in a research study. By providing a summary of the research procedures, risk and benefits and describing the individual's rights as a research participant the IC document serves as a starting point for the necessary exchange of information between the investigator and research subjects. It is important to note that the IC document is only one part of the entire **process** of informed consent.

Templates for creating an informed consent document that meets the requirements of Federal Regulations at 45 CFR §46.116 and §46.117to facilitate consistency and accuracy of informed consent language in human subject research protocols may be found in the Investigator’s Toolbox. The template language included is intended to serve as a guide and/or example of appropriate text. You may modify the italicized text as you see fit; **however, all of the bold and capitalized headings must be included.** These headings are all of the elements required by the federal regulations and institutional policy.

Informed consent documents should be constructed in such a way that it is scored at or above 70on the Flesch Reading Ease test and score of approximately 7.0 to 8.0 on the Flesch-Kincaid Grade Level test. To access these tests, click here.

If you would like to omit any of the required elements you will need to complete a waiver form which is also located in the Investigator’s Toolbox.

**Guidance for Conflicts Disclosure in Informed Consent**

Conflicts of Interest Disclosures. To facilitate appropriate disclosure of potential conflicts of interest in the informed consent document, the following suggested language is provided. It is not required to use these specific provisions. Language should be modified to fit the specific facts and circumstances.

Sample 1 - Non-financial Conflict of Interest

Your clinician is a researcher in this study. As a researcher in this study, he/she is interested not only in your health and well-being, but also in the results of this study. It is possible that sometimes these two goals may conflict with one another. Researchers protect the rights and interests of participants by carefully following the rules of the study.

You do not have to be in any research study offered to you by your health provider. When you are deciding if you should join the study, you may want to talk with someone not part of the study about your questions and feelings about joining. This could be s a family member, friend, or another health provider.

Sample 2 - Financial Conflict of Interest (adapt for specific circumstances)

The investigator of this study, [name], is an officer in the company that makes the gene transfer agent you will get if you join the study. The investigator also holds stock and options in the company. This means the investigator may make more money if the study shows that the gene transfer agent is helpful. Although the investigator is not supposed to let his/her financial interests affect the study, this may not be always possible.

Sample 3 - Financial Conflict of Interest Disclaimer

This research is sponsored by [name of sponsoring company, agency, or group]. This means that [name of sponsoring company, agency, or group] is paying the research team for the costs of doing the study. The researchers do not have a financial stake in the results of the study.

If you have any questions about this template please contact the Research Compliance Coordinator at 617-557-2006