**Consent form module: Human Gene Transfer (HGT) Trials**

***The National Institutes of Health (NIH) has published the*** [***Informed Consent Guidance for Human Gene Transfer Trials subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules***](http://osp.od.nih.gov/sites/default/files/resources/IC2013.pdf)***.***

***Sample consent form language from this guidance has been provided below and can be added to informed consent documents for HGT studies. The language below is provided as guidance to illustrate how various issues could be conveyed.***

**B1. WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?**

Request for autopsy sample language: (use 1 of 3)

1. When you die, no matter what the cause, the <researcher/ research doctor/ research director> will ask your family if they can do an autopsy. An autopsy will help the study team learn more about the safety and efficacy of gene transfer. Please advise you family about your wishes regarding autopsy.
2. Because you are a study participant, the <researcher/ research doctor/ research director> will ask your family for permission to do an autopsy when you die, even though this may be years after the study. This may help the study team learn about the effects of gene transfer. By signing this consent form, you are not forcing your family to agree to this. You should talk about this request with your family and advise them of your wishes.
3. Your <researcher/ research doctor/ research director> will ask your family for permission to perform an autopsy when you die, no matter what the cause. The evaluation of your organs after your death is a very valuable method to learn more about the good and bad effects of gene transfer. A “partial autopsy,” in which needles are used to take samples of specific organs, may also be helpful. This type of autopsy does not require surgical incisions. You should talk about the possibility of autopsy with your family and health providers, and advise them of your wishers. The <researcher/ research doctor/ research director> may be able to tell you or your family what kind of autopsy information will be most helpful for this study. The study sponsor will pay all costs of the autopsy.

Long term follow-up sample language: (use 1 of 2)

1. Long-term follow-up in gene transfer research allows for the collection of important information on the long-term safety and effects of the gene transfer intervention used in this study. The long-term follow-up planned for this study will occur [frequency] for [length of time]. It includes [study specific information, as available, e.g., drawing a small amount of blood once a year; completing a health history questionnaire every year; having a biopsy of the injection site every five years; etc.]. The <researcher/ research doctor/ research director> will try to make it easier for you to participate in long-term follow-up by [study specific information as available, e.g., using mail and telephone to collect some information; arranging with your local doctor to collect blood or biopsy specimens and send them to investigators; etc.].
2. At the end of the experimental phase of the study you will be asked to participate in the long-term follow-up phase for the rest of your life. Once a year you will be asked to have your blood drawn (~[amount]) and answer questions about your general health and medical condition. The <researcher/ research doctor/ research director> may ask you to report any recent hospitalizations, new medications, or the development of conditions or illness that were not present when you enrolled in the study and may request that physical exams and/or laboratory tests be performed if necessary. We will also ask you to participate in the long-term follow-up phase if you leave the study early.

**C4. REPRODUCTIVE RISKS**

If applicable, add: (use 1 of 2)

1. Risks of harm from this study include the possibility that the genes in some of your sperm (men) or eggs (women) may be permanently changed. Some of these changes could lead to miscarriage or birth defects in your future children. Other changes may have no apparent effects but could still be passed on to future generations. The likelihood of such outcomes is currently unknown.
2. It is not known if DNA injected into your muscles can become part of the DNA of your reproductive cells (eggs or sperm). If this happens, it may cause fetal death or birth defects in future pregnancies of participants and their partners. It is also unknown whether or not the gene transfer vector will be present in body fluids (semen, vaginal secretions) and, if so, whether it will be transmitted to a sexual partner.

**E2. Who will see the health information collected for this study?**

Interest of the Media sample language:

1. The media may be interested in this study. You can talk to reporters about being in the study if you want to. The <researcher/ research doctor/ research director> will not talk about the results of the study until study information has been published in a scientific journal. The <researcher/ research doctor/ research director> will not give away your identity to news reporters at any time.