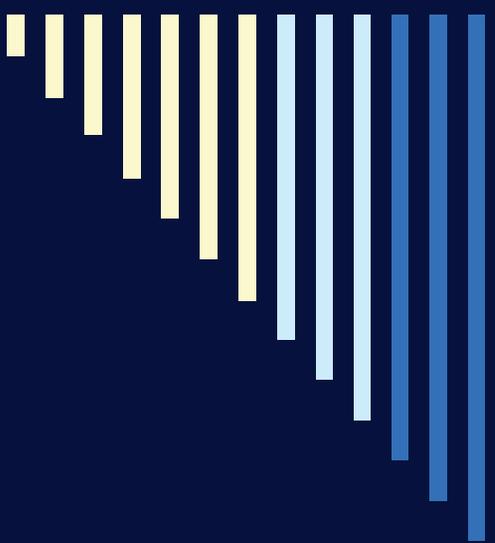


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# Subject Selection and Informed Consent

Recombinant DNA Advisory  
Committee Meeting  
September 17, 2007

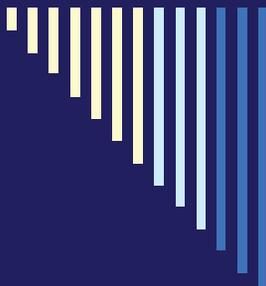


# RESEARCH ETHICS

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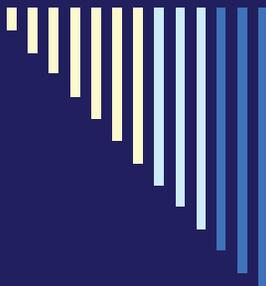
- 
- ❖ **RISK versus BENEFIT must be balanced**
  - ❖ **RISK, to the subject, means *Probability and Magnitude***
  - ❖ **BENEFIT to :**
    - **Subject**
    - **Society**
    - **Investigator/Sponsor**
-

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# Research Ethics

- ❖ **When is Gene Transfer appropriate therapy for non-life-threatening conditions**
    - **Quality of Life**
    - **Failure of Conventional Therapy**
-



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# The Informed Consent Document and the Consent Process

- ❖ How can the document clearly explain the theory behind the intervention without creating a therapeutic misconception?
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# The Informed Consent Document

- ❖ The **purpose of this study** is to find out if repeat injections of the investigational gene transfer agent tgAAC94 (study agent) to a single joint are **safe. An investigational agent is one which has not been approved by the US. Food and Drug Administration (FDA).** It is not known if gene transfer will work in people with inflammatory arthritis (page2).
  - ❖ By injecting tgAAC94 directly into an affected joint in your body (called the target joint), **we hope it will help the body make a protein that stops the inflammatory process and reduces the progressive joint destruction and resulting disabilities associated with inflammatory arthritis** (page 2).
  - ❖ **Potential Benefits: We do not expect you to receive any direct medical benefit from participation in this study** (page 10).
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# The Informed Consent Document and the Consent Process

- ❖ **How does one avoid therapeutic misconception if the trial design is such that interventions are based, in part, on clinical symptoms?**
    - **For example, in this trial, timing of administration of second injection of active agent is done in part on basis of clinical symptoms of target joint in contrast to some studies in which gene transfer is scheduled and not based on symptoms.**
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# Recruitment of Subjects

- ❖ **What steps can a physician/investigator take to avoid therapeutic misconception and insure that the informed consent process is not unduly influenced by the physician/patient (as opposed to the investigator/subject) relationship:**
  - ❖ **Discussion of Roles:**
    - 1. Clear Disclosure of Potential Conflict**
    - 2. Waiting Periods**
    - 3. Consent monitoring process**
-



**The guidance provided here is intended to serve as a resource and learning tool for individuals involved in gene transfer studies and others with an interest in this field.**

**Investigators when providing information to potential participants about, and preparing informed consent forms for, gene transfer studies**

**Sponsors of gene transfer research when drafting model consent forms and advising investigators on the consent form and process**

**Institutional review boards (IRBs) and institutional biosafety committees (IBCs) when reviewing gene transfer protocols and consent forms**

**Potential participants when making a decision about whether to participate in a gene transfer study**

**The general public seeking to learn more about the issues involved in gene transfer research**

**<http://www4.od.nih.gov/oba/rac/ic/>**

- ❖ **Your physician 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.**



## NIH Guidance on Informed Consent For Gene Transfer Research

- ❖ **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 a family member, friend or another health provider.**

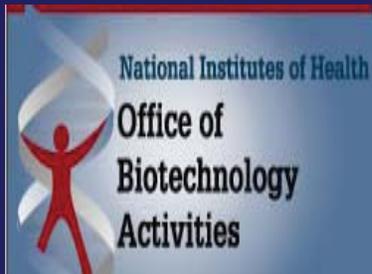


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# Recruitment of Subjects

- ❖ **What steps can a physician/investigator take to avoid therapeutic misconception and insure that the informed consent process is not unduly influenced by the physician/patient relationship:**
    1. **Clear Disclosure of Potential Conflict**
    2. **Waiting Periods**
    3. **Consent monitoring process**
-

- ❖ **Participants in gene transfer studies may desire or require very different amounts of time to decide whether to participate in the study.**
- ❖ **Some participants may have made up their mind to participate before they even review the informed consent.**



## NIH Guidance on Informed Consent For Gene Transfer Research

### ❖ **Sample Language:**

**You may have already thought a lot about participating in this study. You may even have already made a decision about whether to be in the study. Even if this is true for you, it is important that we provide you with this information and talk about it before we start you in the study. Some information may be new or different. Some could even change your mind. It is always okay to change your mind about being in the study. And even if you don't change your mind, the information can help you understand the study better.**



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# Recruitment of Subjects

- ❖ **What steps can a physician/investigator take to avoid therapeutic misconception and insure that the informed consent process is not unduly influenced by the physician/patient relationship:**
    - 1. Clear Disclosure of Potential Conflict**
    - 2. Waiting Periods**
    - 3. Consent monitoring process**
-

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# Bioethics Presenters

- ❖ **Eric D. Kodish, M.D.**
  - ❖ **Robyn Shapiro, J.D.**
  - ❖ **Jeffrey Kahn, Ph.D., M.P.H.**
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