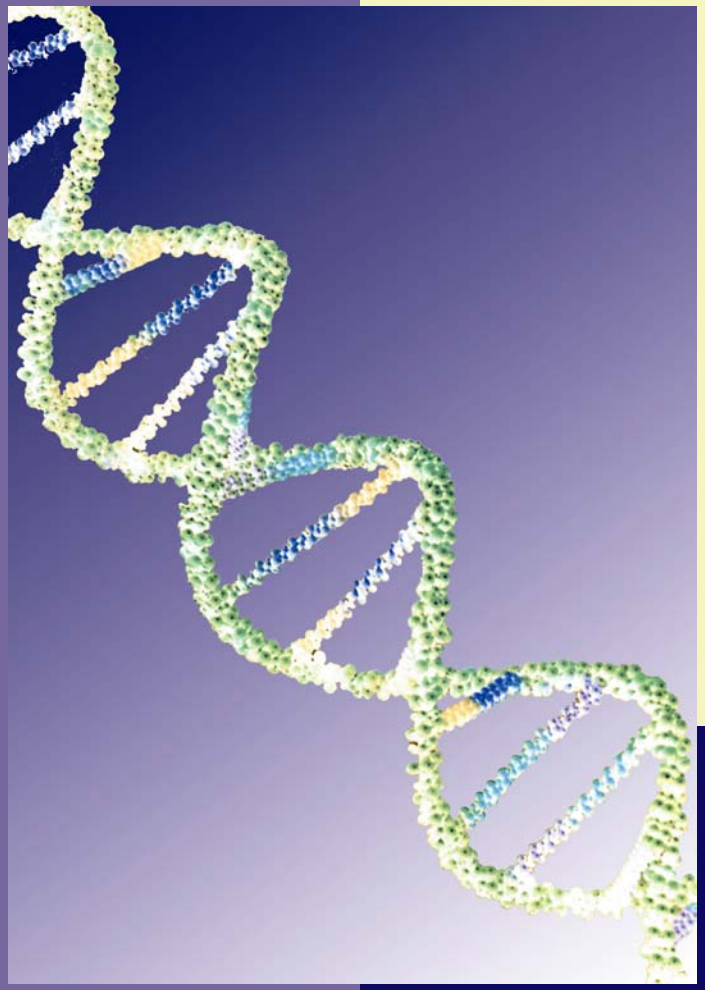

New Resources from the NIH Office of Biotechnology Activities

Medical Research Summit
Washington, D.C.

April 22, 2004

New Resources from the NIH Office of Biotechnology Activities

- Genetic Modification Clinical Research Information System (GeMCRIS)
  - A public database of human gene transfer trials registered with the National Institutes of Health
- Informed Consent Guidance
  - A new resource for investigators, IRBs, IBCs, potential research participants, and others concerned with informed consent in gene transfer trials

New Resources from the NIH Office of Biotechnology Activities

Genetic Modification Clinical Research Information System (GeMCRIS)

GEMCRIS - Home - Netscape

File Edit View Go Bookmarks Tools Window Help

GeMCRIS

Genetic Modification Clinical Research Information System
Version 1.8

Home | Search | User Help

Support

- **Feedback**
- **Frequently Asked Questions**
- **Contact Us**
- **Browser Requirements**

Welcome to the NIH Genetic Modification Clinical Research Information System (GeMCRIS). GeMCRIS is a comprehensive information resource and analytical tool for scientists, research participants, institutional oversight committees, sponsors, federal officials, and others with an interest in human gene transfer research. GeMCRIS allows users to access an array of information about human gene transfer trials registered with the NIH, including medical conditions under study, institutions where trials are being conducted, investigators carrying out these trials, gene products being used, route of gene product delivery, and summaries of study protocols.

To facilitate access to this information, GeMCRIS offers a number of preformatted reports. You can also create your own query tailored to your particular information needs. To get started, use the "Search" menu item above, or click the "Frequently Asked Questions" link on the left to learn more about using the system.

We are seeking comments on GeMCRIS's utility and ease of use. Please take a moment to respond to the questions on the form provided through the "Feedback" link on this page. Your input is critical to ensuring that the system meets the needs of all its diverse users.

Related Information

- **About The RAC**
- **NIH Guidelines**
- **Documents (With Quarterly Reports)**

Key Features of GeMCRIS:

- On-line adverse event reporting to NIH
  - One format for NIH and FDA
- Security measures to protect trade secret and patient confidential information
- On-line search capability
- Implementation of controlled medical vocabularies
- Controlled scientific vocabulary developed specifically for gene transfer research

GeMCRIS: Key Information

- Protocol title
- Study phase
- Clinical indication(s)
- Investigator(s)
- Clinical trial site(s)
- Scientific abstract
- Non-technical abstract
- Investigational strategy
- Vector
- Transgene
- Route of administration

Accessing GeMCRIS:

Connect to:

http://www.gemcris.od.nih.gov/

New Resources from the NIH Office of Biotechnology Activities

NIH Guidance for Informed Consent for Gene Transfer Research

Informed Consent Guidance for Gene Transfer Research

Impetus

- RAC review of informed consent documents revealed that investigators were having difficulty conveying important concepts pertinent to gene transfer research and to human subjects research more generally
  - inappropriately positive description of benefits
  - therapeutic misconception
  - presumptive use of the first person pronoun ("I understand that...)

Informed Consent Guidance for Gene Transfer Research

Intent

- Assist gene transfer investigators with the development of forms and with the communication process
- Educate other users (IRBs, IBCs, potential participants) about important issues related to informed consent
- Serve as a model resource for the research and IRB community more generally
- Not new policy or an amendment to Appendix M

RAC Informed Consent Working Group

Roster

Baruch Brody (co-chair)
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Nancy King (co-chair)
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James Childress
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National Institutes of Health
Office of Biotechnology Activities

NIH Guidance on Informed Consent For Gene Transfer Research

Search Site

Print | Tools & Materials

Appendix M-III-A

Communication about the Study to Potential Participants

MAIN POINTS

- Informed consent is a communication process, not a form.
- Various methods and tools exist to improve comprehension of information.

DISCUSSION

Informed Consent - A Process, Not a Form:
Informed consent is much more than a document or obtaining a participant's signature on a consent form. Informed consent is a process of communication between an investigator and a potential research participant.

The purpose of the consent process is to:

- Ensure that potential participants understand that they are being asked to participate in research, and that they appreciate the differences between research and treatment
- Foster potential research participants' understanding of what to expect from participation in a study
- Encourage and respond to questions about study participation
- Facilitate discussion, reflection, and free and informed decision making

National Institutes of Health
Office of Biotechnology Activities

NIH Guidance on Informed Consent For Gene Transfer Research

Appendix M-III-A-2
Comprehensibility

NIH GUIDELINES: "How will the major points covered in Appendix M-II, Description of Proposal, be disclosed to potential participants and/or their parents or guardians in a language that is understandable to them?"

DISCUSSION

Gene transfer research concepts are often difficult for potential participants to understand. Thus, particular care should be given to convey these concepts in the consent form in a readable and understandable manner. Readability and understandability are not synonymous; it is possible to make use of computerized readability scales and still have a consent form that is difficult to understand. Sometimes, reducing reading level without providing additional

TOOLS & BACKGROUND MATERIALS

- Simplification Guide to Medical Terms
- Dartmouth Informed Consent Evaluation Tool
- Written Assessment Tool
- Telephone Evaluation Plan
- FDA Guidance on Non-English Speaking Subjects

MAIN POINTS

- Investigators should be attentive to using language easily read and understood by potential participants.
- Various methods and tools exist to improve and assess comprehension of information.
- All verbal and written

Accessing this Resource

Connect to:

http://www4.od.nih.gov/oba/rac/ic/

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