



Title:	Genetic & Stem Cell Research		
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1 Genetic Studies

Genetic research studies may create special risks to human subjects and their relatives. These involve medical, psychosocial, legal and economic risks, such as the possible loss of privacy, insurability, and employability, change in immigration status and limits on education options, and may create a social stigma. Knowledge of one's genetic make-up may also affect one's knowledge of the disease risk status of family members.

In studies involving genetic testing, several questions need to be addressed, including:

1. Will test results be given?
2. Will disease risk be quantified, including the limits on certainty of the testing?
3. Will a change in a family relationship be disclosed, such as mistaken paternity?
4. Does the subject or family member have the option not to know the results? How will this decision be recorded?
5. Could other clinically relevant information be uncovered by the study? How will disclosure of this added information occur?
6. Do any practical limitations exist on the subject's right to withdraw from the research, withdraw data, and/or withdraw DNA?
7. Is the subject permitted to participate in the study while refusing to have genetic testing (such as in a treatment study with a genetic testing component)?

For DNA banking studies, several questions need to be addressed, including:

1. Will DNA be stored or shared? If shared, will the subject's identity be known by the new recipient investigator?
2. Will the subject be contacted in the future by the investigator to obtain updated clinical information?
3. How can the subject opt out of any distribution or subsequent use of his/her genetic material?

2 Gene manipulation in human subjects research

All research involving gene transfer into human subjects or any form of recombinant DNA research must be reviewed by the University's Institutional Biosafety Committee in addition to

IRB review. All recombinant DNA research must be reviewed and approved by the NIH's Recombinant DNA Advisory Committee (RAC). The results of these additional reviews should be submitted to the IRB.

NIH guidelines on recombinant DNA and gene transfer research are available online at: <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

3 Human embryonic stem cell research

Federal regulation of human embryonic stem cell research is both complex and evolving. Research proposals that involve human embryonic stem cells must be submitted to the Embryonic Stem Cell Research and Oversight (ESCRO) committee. Not all such studies (e.g., in vitro studies or animal experimentation) constitute human subjects research requiring IRB review. Studies that do involve human subjects research as defined in the regulations should be submitted to the IRB for review, in addition to the ESCRO committee.

4 Human fetal tissue transplantation research

It is unlawful for any person to knowingly acquire, receive or transfer any human fetal tissue for valuable consideration. It is unlawful for any person to solicit or knowingly acquire, receive or accept a donation of human fetal tissue for transplantation if the tissue is obtained pursuant to an induced abortion and the donation is made pursuant to a promise that it will be transplanted to any specified individual, to a relative of the donating individual, or in valuable consideration for the costs associated with the abortion. Additionally, all other ethical and regulatory requirements for the welfare and protection of human research subjects apply to both the donors and the recipients of human tissue used in transplantation research.

Human fetal tissue may be used only if it has been obtained in accord with the following requirements: (1) the woman providing the tissue must declare in a signed written statement that she is donating the tissue without any restrictions regarding the identity of the transplant recipients and without being informed of the identity of the recipients; (2) the attending physician must declare in a signed written statement that the tissue was donated by the woman and with full disclosure with regard to the physician's interest in the research and any known medical or privacy risks associated with the research. If the tissue is obtained pursuant to an induced abortion, the attending physician must also declare in her or his signed written statement that the consent of the women for the abortion was obtained prior to requesting or obtaining consent for the donation of the tissue, no alteration of the timing, method or procedures used to terminate the pregnancy was made solely for the purpose of obtaining the tissue; and the abortion was performed in accordance with applicable state law; and (3) the PI for the research must declare in a signed written statement that: the tissue is human fetal tissue; the tissue may have been obtained pursuant to a spontaneous or induced abortion or stillbirth; the tissue was donated for research; the investigator had provided this information to other individuals involved in the research and received written acknowledgement of the receipt of this information; and the investigator has had no influences on the decision to terminate the pregnancy.

(For more information see OHRP Guidance on “Fetal Tissue Transplantation” dated February 7, 2003.

5. Research use of cord blood from births at UNC Hospitals

According to UNC Hospitals policy (February 15, 2000), any collection for research use of placental tissue, umbilical cord tissue or cord blood from births at UNC Hospitals will require written consent of the mother. Investigators seeking to acquire such specimens for research use should prepare an IRB application including a consent form. They must also notify the Department of OB/GYN, since protocols involving obstetrical patients also require review by the OB/GYN Department Research Committee and requests for cord blood may need to be prioritized. Investigators will be responsible for making arrangements for obtaining consent and collecting the specimens.

This policy is based on the following considerations:

1. Cord blood and placental tissue are a unique source of stem cells and other biologic materials, with great therapeutic potential. Consequently there is increasing demand.
2. Certain research uses of these tissues already require informed consent. In particular, the recent designation of UNC Hospitals as a collection site for an NHLBI-sponsored Cord Blood Bank for stem cell research will result in approaching most if not all mothers for permission to collect cord blood for this purpose.
3. Certain ethnic groups do not view the placenta and placental blood as waste, but as sacred objects. Using tissues from such persons without their consent would constitute a serious violation of their rights.

FDA regulations do not apply to biological specimens unless they are gathered as part of a clinical investigation involving human subjects or being used to test a medical device. HIPAA does not cover biological specimens but does cover protected health information (PHI) linked to the specimens.

Registries are sometimes created by a public authority (e.g., the North Carolina Central Cancer Registry was created by the North Carolina Legislature, see [North Carolina General Statute Chapter 130A - Article 7](#)) If the research meets the definition of human subjects research, then all of the requirements of this document apply.