DEPARTMENT OF HEALTH AND HUMAN SERVICES

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ATTACHMENT 5-4 NIH POLICY ON REPORTING RESULTS TO SUBJECTS

Date: March 16, 1999

From: Deputy Director for Intramural Research,
NIH Director,
Clinical Center and NIH Associate Director For Clinical Research

Subject: NIH Policy on Reporting Clinical Research Results to Subjects

To: IC Scientific Directors
IC Clinical Directors
IRB Chairs
Laboratory, Branch and Section Chiefs
Clinical Investigators

In general, one of the expectations human subjects have when they participate in research is that they learn something from their involvement. Principal Investigators (PIs) usually share appropriate research information with the subjects of their studies, either during the course of participation or after the study has been completed. However, the sharing of information with research subjects is not always explicitly addressed in informed consent documents.

In some cases, PIs and IRBs agree that, for various reasons, certain research information, particularly genetic research information, ought not to be shared with research subjects, and occasionally, NIH informed consent documents contain IRB-approved language which states that certain information will not be provided to research subjects. However, the Federal Privacy Act applies to the records of research conducted at the NIH when such records are retrievable by an individual identifier (see attached Summary of the Privacy Act). This means that any language in a consent form that waives an individual's right to obtain access to his/her records is inconsistent with the Privacy Act as well as with the Federal Regulations for the Protection of Human Subjects (45 CFR 46). These regulations prohibit the use of language in informed consent documents that would waive or appear to waive the rights of the subject (45 CFR 46.116).

In order to ensure compliance with the Privacy Act and the Federal regulations, effective immediately, for new protocols where the IRB and the PI agree that it is in research subjects' best interests not to have research information provided to the subjects, informed consent documents must explain the reason for this limitation and not remain silent about it. Also, the consent documents must state explicitly that subjects do not waive any rights they may have regarding access to research information. Current consent documents that restrict subjects' access to research information should be carefully checked by the IRB and PI at the time of continuing review and revised appropriately.

A subcommittee of the Human Subjects Research Advisory Committee (HSRAC), which included the NIH Legal Advisor, has developed the following suggested informed consent language for use in such cases. The first paragraph offers various options (italicized in brackets) for informing subjects that their access to information may be limited. This paragraph may be altered or expanded by the PI and the IRB as necessary to fit the protocol, but the language of the second paragraph **must not be changed**, although where it is placed in the informed consent document should be as judged appropriate by the PI and the IRB. Furthermore, it is only necessary to include these two paragraphs in consents where subjects' access to research information is to be limited; they are not required if PIs plan to allow subjects unlimited access to information."

> ***" The investigators conducting this study do not plan to provide you with the results of any medical tests or evaluations or other information pertaining to you, or other research data or results because [the results will be preliminary] [the results will require further analysis] [the results may reveal unwanted information about family relationships] [further research may be necessary before these results are meaningful]. [If meaningful information is developed from this study that may be important for your health, you will be informed when it becomes available.]***
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> ***" By agreeing to participate in this study, you do not waive any rights that you may have regarding access to and disclosure of your records. For further information on those rights, please contact Dr. _____(PI)."***

It is important for PIs to know that if a subject requests medical/research information about himself or herself, the Federal Privacy Act requires the PI to give that information either to the subject or to a third party designated by the subject (such as a family physician) whether or not the subject has signed a consent form that contains language similar to that above. The Privacy Act regulations' special access provision applies to medical records, and although there is no definition of "medical," the NIH Legal Advisor considers the term broad enough to encompass records of experimental tests and treatment provided in clinical research. PIs are strongly urged to familiarize themselves with the provisions of the Privacy Act in order to make sure they understand how this act applies to their research.

If you have any questions about the use of the suggested informed consent document language, please contact Dr. Alan Sandler, Director, Office of Human Subjects Research, at 2-3444.

Michael M. Gottesman, M.D. John I. Gallin, M.D.

Attachment

cc: Mr. Lanman
Dr. Sandler