ONE HUNDRED NINTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

June 20, 2005

The Honorable Elias Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

The Committee on Energy and Commerce is investigating the adequacy of the National Institutes of Health (NIH) policies for maintaining research samples of human tissue.

Our interest in the NIH's maintaining of human tissue samples arises from concerns raised by a scientist at NIH ("NIH scientist"). She contacted the Committee staff about the problems she encountered in locating spinal fluid samples she and her colleagues had collected from over 30 patients with Alzheimer's disease.

The NIH scientist had previously worked at the National Institute of Mental Health (NIMH) with the Geriatric Psychiatry Group. She left the NIMH in 1997, and returned to NIH at another institute/center in August 2001. Prior to leaving the NIMH in 1997, she was the principal investigator on drug studies in which she and other colleagues collected spinal fluid from over 30 Alzheimer's patients. Approximately 20 ccs of spinal fluid were collected with each spinal tap. The NIH scientist left the NIMH before conducting these studies and did not use the spinal fluid samples. According to the NIH scientist, these spinal fluid samples were stored in appropriately backed-up freezers when she left NIMH in 1997.

Sometime in mid-2004, the NIH scientist, now at another NIH institute/center, asked her former supervisor at NIMH for these patient samples for a study she wanted to conduct. After several months, the former supervisor in January 2005 reported to the NIH scientist that his group would be able to produce 10 subjects total (before and after taps) with only 0.5 cc

available for most of the subjects. The former supervisor and the NIMH have been unable to account for what happened to the rest of the spinal fluid samples.

The Committee staff has learned from NIH officials that the NIH has no uniform, centralized, and mandatory authority regulating the handling of human tissue samples. Some NIH laboratories keep a written record on the maintenance of these samples, but other NIH laboratories do not. Although there are explicit regulations defined in 42 C.F.R. 72.6 detailing the handling for hazardous biological materials and select agents, there is no explicit policy for the handling and accounting of human tissue samples. In addition, there is no formal inventory control or tracking system at NIH. If a freezer or other storage facility malfunctions and the human tissue samples become unusable, NIH laboratories are not required to account for the disposition of these samples. There is reason to believe that there are cases where NIH loses human tissue samples but has no record of what has been lost. Moreover, the lack of accountability leaves NIH wholly vulnerable to theft and diversion of valuable human tissue samples.

We are extremely concerned over what was described to Committee staff by NIH officials of a fairly loose, ad-hoc approach to controlling human tissue samples. These samples were collected under informed consent from human subjects who agreed to provide their tissue because they were told that the sample would be used for a particular purpose in the study, perhaps even used to look at the effects from a particular drug. Some of these samples are extraordinarily precious from a research standpoint because some patients who donated samples had a rare disease. For example, we note that the National Institute of Allergy and Infectious Diseases obtained blood samples from SARS patients as part of its immunological research of SARS and coronaviruses. In addition, NIH intramural researchers sometimes rely on obtaining human tissue samples from sources outside NIH for their laboratory work, or even in their work for Cooperative Research and Development Agreements with third parties.

NIH has an obligation to the human subjects and the outside scientific community to require an appropriate tracking system or protocol for all laboratories involved with collection and maintenance of human tissue samples. NIH officials acknowledged to Committee staff the importance of maintaining human research samples because for all published work, scientists are expected to provide access to other researchers to the human tissue samples for the purpose of reproducing the results reached in the scientist's reported study.

In light of the concerns about the current handling by NIH of human tissue samples, pursuant to Rules X and XI of the U.S. House of Representatives, please provide the following by no later than Tuesday, July 5, 2005:

1. The current total number of human tissue samples maintained at NIH, with a breakdown for each Institute or Center. The current total number of laboratories at NIH that maintain human tissue samples and the current total number of laboratories that have a tracking system accounting in place for the human tissue samples.

2. All records dated on or since January 1, 2002, in possession of NIH, including communications within each Institute/Center and each laboratory, relating to any distinct direction, instruction, or policy relating to the handling of human tissue samples.

3. All records dated on or since January 1, 2002, in possession of the NIH Office of Intramural Research or the NIH Office of Management Assessment relating to any closed investigation of an allegation relating to the handling or accounting of human tissue samples. Please also state whether there are any open investigations and, if so, which institutes or centers are under investigation.

4. The current total amount of expenditures for FY2005 by NIH for maintaining and repairing freezers or other storage facilities containing human tissue samples.

5. An estimate of the total number of human tissue samples lost each year at NIH laboratories, and an estimate of the number of human tissue samples lost each year at NIH laboratories because of freezer or storage facility malfunctions.

6. A description of any measures NIH is taking to reduce the number of research freezer or other storage facility malfunctions or breakdowns.

7. List the names of the ten rarest diseases for which NIH has human tissue samples, the name of the Institute and laboratory that has possession of these samples, and the specific measures currently being taken to track these samples.

8. All records relating to the CSF samples collected by the NIH scientist and others in a NIMH study on lithium in early Alzheimer's disease patients. Patient identifiers may be redacted.

Additionally, please provide the following:

9. Since January 1, 1995, has any official at NIH authorized the use of human tissue samples in possession of NIH to be used by any NIH employee in support of an outside activity?

10. Since January 1, 1995, has any official at NIH ever used human tissue samples that were in possession of NIH in connection with any of his or her outside activities?

Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. In addition, we are requesting that following production of the records to the Committee, you make available NIH employees for Committee staff interviews as requested by Committee staff.

If you have any questions, please contact Alan Slobodin of the Majority Committee staff at (202) 225-2927 and David Nelson of the Minority Committee staff at (202) 226-3400.

Sincerely,

Joe Barton
Chairman

John D. Dingell
Ranking Member

Ed Whitfield
Chairman
Subcommittee on Oversight
and Investigations

Bart Stupak
Ranking Member
Subcommittee on Oversight
and Investigations

Attachment

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.