N.D.A.G. Letter to Bushfield (April 6, 1990)

April 6, 1990

Martee Bushfield, Ph.D.
Director of Research, Curriculum
and Development
Department of Family Medicine
501 North Columbia Road
Grand Forks, ND 58201

Dear Dr. Bushfield:

Thank you for your March 19, 1990, letter requesting my opinion on participation in a blinded seroprevalence study of the human immunodeficiency syndrome (HIV).

Your first question is whether or not any North Dakota statutes limit the Family Practice Residency Training Program's participation in the proposed study. The study is defined by you as a process which would use excess blood which was taken from a patient as a "blinded" sample. This excess blood would be tested for HIV. The information and test results would not be returned to the Family Practice Center and the Center for Disease Control would use the information to determine the prevalence, by region, of HIV in populations which are not at risk. The proposed study contemplates testing of blood specimens without informed consent of the patient.

N.D.C.C. § 23-07.5-02(1) provides:

> Except when testing and disclosure is otherwise provided for by law, a health care provider, blood bank, blood center, or plasma center may not subject a person to a test for the presence of an antibody to the human immunodeficiency virus unless the subject of the test first provides informed consent for testing or disclosure as provided under subsection 2.

N.D.C.C. § 23-07.5-02(1). The only testing and disclosure for HIV "otherwise provided for by law" is in the following cases:

1. Persons convicted of a crime who are imprisoned for a period of more than 15 days;

2. Persons who have been convicted of certain sexual offenses;

3. Persons convicted of using a controlled substance which involves use of paraphernalia "that creates an epidemiologically demonstrated risk of transmission of" HIV:

4. Persons who are infected with a sexually transmitted disease;

5. Persons who die before being able to give informed consent when there has been a significant exposure; and

6. Blood and tissue donors.

N.D.C.C. §§ 23-06.2-11.1, 23-07-07, 23-07.3-02, and 23-07-07.5. Copies of these statutes are included for your information.

Unless the study you propose involves only persons within these categories, North Dakota law would prohibit the blind HIV seroprevalence study described because it does not contemplate an informed consent of the "participating" patients.

A member of my staff spoke with you regarding your second question. As she explained, whether the UND Institutional Review Board (IRB) must provide consent for the protocol if it has already passed the IRBs of the United States Department of Health and Human Services and the Center for Disease Control depends upon the rules governing the UND IRB. This office does not have ready access to those rules. Approval by the UND IRB of this protocol will not solve the protocol's legal deficiency with regard to informed consent, however. Thus, it is not necessary to review the IRB rules at this time.

I trust this gives you the guidance you seek. If you have other questions, please contact my office again.

Sincerely,

Nicholas J. Spaeth

jfl
Enclosures