

Service providers shall select an existing program or develop an appropriate program that is culturally relevant or Navajo-specific, respectful of the Navajo culture, and reflects current knowledge and clinical guidelines about medical care and treatment is appropriate, respectful, and reflects current knowledge and clinical guidelines about HIV/AIDS related illnesses. Patients and their families shall have input into these processes.

B. Use of traditional Navajo treatment. Traditional Navajo healing methods may evolve as a primary means of treatment for persons already suffering from HIV/AIDS. As appropriate, the Navajo Division of Health shall include and assist such organizations as the Diné Spiritual and Cultural Society, Inc., in their efforts to develop treatment methodologies.

#### **History**

CO-100-94, October 21, 1994.

#### **§ 3206. Amendments**

Upon the recommendation of the Health and Social Services Committee of the Navajo Nation Council, the Navajo Nation Council may amend the Navajo Nation HIV/AIDS Code by majority vote of the members present.

#### **History**

CO-100-94, October 21, 1994.

### **Chapter 25. Navajo Nation Human Research Code**

#### **§ 3251. Title**

This Code shall be known as the Navajo Nation Human Research Code.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

#### **§ 3252. Purpose**

The purpose of this Code shall be to set forth the conditions under which investigators, physicians, researchers and others may perform research activities on living human subjects within the territorial jurisdiction of the Navajo Nation.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

#### **§ 3253. Policy**

A. All persons within the territorial jurisdiction of the Navajo Nation are free from unreasonable harmful, intrusive, ill-conceived or otherwise offensive research and investigation procedures.

B. Research conducted is beneficial, community-based, and consistent with Navajo Nation priority and concerns.

C. Research information and data generated by and about Navajo individuals, communities, culture represent inalienable intellectual properties of the Navajo people and over which the Navajo Nation will provide oversight.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

#### **§ 3254. Rules and regulations**

The Health and Social Services Committee is authorized to promulgate rules and regulations consistent with and necessary to implement this Code.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

#### **§ 3255. Definitions**

As used in this Code, the following definitions apply:

A. Subjects. As used in this Code, "Subjects" means a living individual about whom a researcher (whether professional or student) conducting research obtains private information or data through intervention or interaction with the individual, involving physical procedures by which data are gathered (for example, venipuncture) and/or manipulations of the subject or the subject's environment.

B. Navajo Nation Human Research Review Board. This is the Board created in Section 3256 of this Code

C. Research. As used in this Code, "research" is the use of systematic methods (including but not limited to note taking, interviewing, video and audio taping) to gather and analyze information for the purpose of proving or disproving a hypothesis, concepts or practices, or otherwise adding to knowledge and insight in a particular medical or psychological discipline. Generally, proposed studies are defined as "research" if their goal is to produce generalizable descriptive knowledge through the use of human subjects or volunteers whose protection must be assured in accordance with the ethical principles of respect for persons; the duty to help others or beneficence; and justice or fairness. This may include, at the discretion of the Navajo Nation Human Research Review Board, quality assurance activities, chart reviews

and program evaluations. All data and research subject to this Code are the property of the Navajo Nation, although a researcher may be given a permit.

D. Publication. As used in this Code, the term "Publication" includes all proposed professional and program papers and reports concerning Navajo individuals. Also requiring advance approval are papers based on research conducted within the territorial jurisdiction of the Navajo Nation, prepared for presentation at national or international professional society meetings by researchers. Papers or reports for technical and lay audiences prepared and approved by Indian Health Service or the Navajo Nation for compliance with contract or grant requirements are specifically excluded from this definition.

E. Researcher. As used in this Code, the term "researcher" means any person, organization, business or other entity which conducts research within the territorial jurisdiction of the Navajo Nation.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

#### **§ 3256. Creation of the Navajo Nation Human Research Review Board**

There is hereby created the Navajo Nation Human Research Review Board, whose purpose is to review all proposals (notwithstanding other IRB approvals) for human research which will occur within the territorial jurisdiction of the Navajo Nation or which otherwise concerns Navajo individuals as an identifiable group, issue permits for those projects which are consistent with the terms and intent of this Code, and, as appropriate, review and approve the results of such studies before publication. However, this Board is to coordinate with the Historic Preservation Department to avoid jurisdiction conflicts. The Navajo Nation Human Research Review Board is administratively assigned to the Navajo Nation Division of Health for support services.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

#### **§ 3257. Composition and term of the Navajo Nation Human Research Review Board**

A. The Navajo Nation Human Research Review Board shall be composed of 15 individuals, selected as follows: three persons appointed by the Navajo Area Health Board; three persons appointed by the Office of the President of the Navajo Nation; three persons appointed by the Health and Social Services Committee of the Navajo Nation Council; three persons appointed by the Navajo Area Indian Health Service Area Director; and three persons appointed by the Education Committee. At least two persons serving on the Navajo Nation Human Research Review Board shall be licensed physicians and at least one of the appointees must be a community representative.

B. The term of an appointment to the Navajo Nation Human Research Review

Board shall be three years from appointment.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

#### **§ 3258. Meetings, quorum**

The Navajo Nation Human Research Review Board shall meet at least quarterly, but as often as necessary. Five members, one of whom must be a licensed physician and one of whom must be a community representative, of the Navajo Nation Human Research Review Board shall constitute a quorum.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

#### **§ 3259. Purposes of the Navajo Nation Human Research Review Board**

The purposes of the Navajo Nation Human Research Review Board are to assure that research and publication activities:

A. Are consistent with the health and education goals and objectives of the Navajo Nation.

B. Do not detract from, nor interfere with, the provision of human services to the Navajo people.

C. Do not endanger the well-being of individuals or communities.

D. Require informed consent of all affected individuals or their legal representatives.

E. Are culturally relevant to the extent possible and are appropriate clinically, technically, epidemiologically and statistically.

F. Present only reasonable risks to subjects in relation to anticipated benefits, if any, to those subjects, and the importance of knowledge that reasonably may be expected to result.

G. Select subjects equitably. In making this assessment the Navajo Nation Human Research Review Board shall take into account the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

### **§ 3260. Powers of the Navajo Nation Human Research Review Board**

Consistent with the requirements of this Code, the powers of the Navajo Nation Human Research Review Board shall include:

- A. The review and approval or disapproval of research proposals.
- B. The review and approval or presentation materials and manuscripts, including thesis, dissertations and abstracts, prior to publication.
- C. The negotiation of additional and/or revised procedures, methodologies, and approaches to research and publication with researchers.
- D. The Board may request assistance from other persons with specialized knowledge in the review of any application, proposal or manuscript. When research is reviewed involving a category of vulnerable subjects (e.g., prisoners, children, and individuals who are mentally disabled), the Navajo Nation Human Research Review Board shall include in its reviewing body one or more individuals who have a particular concern for the welfare of these subjects.
- E. Subject to the approval of the Health and Social Services Committee, and Education Committee and the requirements of this Code, the Navajo Nation Human Research Review Board shall adopt appropriate rules and procedures regarding: confidentiality of subjects; storage of specimens and other research materials; monitoring of research activities; amendments to any research proposals; financial disclosure regarding the research; volunteer payments and fees; adverse reactions of any volunteers; applications and their contents; fees for permits and other services; and other procedures to implement this Code.
- F. The Board will coordinate with other appropriate boards and committees including but not limited to, other Institutional Review Boards, and the Historic Preservation Department for activities which may also be subject to the Cultural Resources Preservation Act (CMY-19-88).

### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

### **§ 3261. Record retention**

The Navajo Nation Human Research Review Board shall develop and maintain an up-to-date file on all research projects, past and ongoing, approved and disapproved. Records of research projects will be maintained at least 10 years after the Navajo Nation Human Research Review Board receives the proposal or five years after publication of a paper derived from the research activity, whichever is longer. The Navajo Nation Human Research Review Board shall maintain a file of reprints of publications resulting from all research projects conducted within the territorial jurisdiction of the Navajo Nation.

### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

### **§ 3262. Research permit required**

Prior to undertaking any human research within the territorial jurisdiction of the Navajo Nation, a researcher must apply for and receive from the Navajo Nation Human Research Review Board a Research Permit as provided for in Section 3264 or within the Cultural Preservation Act.

### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

### **§ 3263. Administrative fees**

The Navajo Nation Human Research Review Board may assess reasonable costs associated with the review of proposals and other materials; any monies generated are for the exclusive use of the administration of this Code.

### **History**

CAP-16-02, April 16, 2002.

### **§ 3264. Research application**

The Research Application shall be in a form developed by the Navajo Nation Human Research Review Board in accordance with Section 3259, but such application, at a minimum shall include research goals, methodology, and anticipated results. The application shall also include a separate section addressing specific anticipated benefit to the study's subjects, Navajo individuals or groups of tribal members, the Navajo Nation and all other readily identifiable potential beneficiaries. The Research Application must be signed by the Researcher and include a provision that the Researcher agrees to the civil jurisdiction of the Navajo Nation with respect to the research to be undertaken and any publications arising from such research.

### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

### **§ 3265. Confidentiality and security**

There must be adequate assurance, as determined by the Navajo Nation Human Research Review Board, that the data and information generated during the conduct of research is protected from unauthorized access and misuse consistent with informed consent provisions, the Navajo Nation Privacy Act, and other

Navajo Nation information technology requirements.

#### **History**

CAP-16-02, April 16, 2002.

#### **§ 3266. Informed consent**

Before any research may be conducted on any subject, the researcher must obtain the active informed consent of that prospective subject, or their parent, legal custodian or guardian, as appropriate. At a minimum, this informed consent must be in writing, acknowledged by the subject, which informs the subject of the purpose of the research, any potential risks, and alternative treatments or procedures. The Informed Consent may not include any exculpatory language or disclaimer of liabilities.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

#### **§ 3267. Progress reports on research**

A. Researchers shall report to the Navajo Nation Human Research Review Board the progress of their research as often and in the manner prescribed by the Navajo Nation Human Research Review Board in the research permit.

B. Researchers shall promptly report any injuries or adverse impacts (including violations of an individual's privacy) to human subjects to the Navajo Nation Human Research Review Board.

C. Researchers shall promptly report any unanticipated problems which involve risks to the human research subjects or others to the Navajo Nation Human Research Review Board.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

#### **§ 3268. Continuing review of research activities**

The Navajo Nation Human Research Review Board shall regularly review all research activities conducted within the territorial jurisdiction of the Navajo Nation. If, during the course of a research activity, the research conditions change, the Navajo Nation Human Research Review Board may require the researcher to amend their application consistent with the changed conditions. If the Navajo Nation Human Research Review Board determines that a research project is no longer viable because of changes in the scope or effect of the research, it may rescind any research permit or otherwise limit the scope of research activities which may be conducted under the permit.

### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

### **§ 3269. Publication review procedures**

A. All individuals proposing publishing covered by this Code are required to submit a manuscript to the Navajo Nation Human Research Review Board for approval, in advance of publication.

B. The manuscript will be reviewed for technical content and validity, organization of content, readability, as well as assurance that they are consistent with the goals, intent and policies of this Code.

### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

### **§ 3270. Permit appeal procedures**

A. Researchers who are denied a research permit may request reconsideration of their application upon a showing of good cause. A request for reconsideration shall be deemed to have shown good cause if it:

1. Presents significant relevant information not previously considered by the Navajo Nation Human Research Review Board;

2. Demonstrates that significant changes have occurred in the factors or circumstances considered by the Navajo Nation Human Research Review Board in reaching its decision; or

3. Demonstrates that the Navajo Nation Human Research Review Board failed to follow its adopted procedures in reaching its decision.

B. A request for reconsideration must be received within 30 days after the researcher is notified of a decision.

C. If deemed in good cause, reconsideration shall be conducted within 30 days after receipt of the appeal request.

### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

### **§ 3271. Enforcement**

Whenever it appears that a researcher or other person or entity has violated the provisions of this Code, the Navajo Nation Human Research Review



Board on its own initiative may petition the Courts of the Navajo Nation for injunction or other appropriate relief. If the Court, after a hearing, finds that this Code has been violated, it may assess civil penalties of up to five thousand dollars (\$5,000), in addition to any other damages resulting from an unpermitted research activity.

#### **History**

CAP-16-02, April 16, 2002.

CO-106-95, October 25, 1995.

### **Chapter 31. Community Works Program**

#### **§ 3301. Purpose**

The purpose of this Chapter is to set guidelines for the Administration and expenditures of the Community Works Program funds of the Navajo Nation.

#### **History**

ACJY-83-78, July 18, 1978.

ACAP-77-76, April 1, 1976.

ACAU-189-75, August 28, 1975.

ACJY-79-74, July 3, 1974.

ACAU-114-74, August 15, 1974.

ACMA-83-75, March 21, 1975.

ACAP-108-75, April 9, 1975.

ACAU-317-73, August 8, 1973.

ACJA-7-74, January 11, 1974.

ACJY-222-72, July 13, 1972.

ACAU-302-72, August 25, 1972.

ACS-368-72, September 28, 1972.

ACD-401-72, December 6, 1972.

ACJY-198-71, July 1, 1971.

ACJY-244-71, July 14, 1971.

ACF-30-72, February 10, 1972.