

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2005

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HOUSE BILL 1709

Short Title: Voluntary DNA Database. (Public)

Sponsors: Representatives Miller, Walend (Primary Sponsors); and Faison.

Referred to: Judiciary I, if favorable, Appropriations.

May 12, 2005

1 A BILL TO BE ENTITLED  
2 AN ACT TO ESTABLISH A DNA DATABANK FOR THE VOLUNTARY  
3 SUBMISSION BY INDIVIDUALS OF DNA SAMPLES LINKED WITH THE  
4 INDIVIDUAL'S MEDICAL RECORD.

5 The General Assembly of North Carolina enacts:

6 **SECTION 1.** Chapter 116 of the General Statutes is amended by adding the  
7 following new Article to read:

"Article 33.

"Voluntary DNA/Medical Records Database.

10 **"§ 116-265. Voluntary DNA Database established; purpose.**

11 (a) There is established at North Carolina Central University the Voluntary DNA  
12 Database for the recording of DNA data and related medical records submitted  
13 voluntarily by individuals for the purposes authorized in this Article. DNA data and  
14 related medical records stored in the Database shall be stripped of all information that  
15 would personally identify the individual submitting the data. The Director of the  
16 Voluntary DNA Database shall oversee the development, implementation, and  
17 maintenance of the Database at a suitable location at NCCU and shall be responsible for  
18 marketing the Database to potential donors and companies that may wish to access the  
19 Database.

20 (b) The Database must be capable of classifying, matching, and storing the  
21 results of analyses of DNA and other biological molecules.

22 (c) The Database may contain DNA records and related medical records of  
23 individuals who have volunteered to provide the DNA sample and medical records. The  
24 Director may receive, analyze, store, and destroy a record, blood sample, or other  
25 specimen for the purposes described in subsection (d) of this section.

26 (d) The principal purpose of the Database is to advance scientific study of the  
27 links between genetics and common diseases in order to improve diagnosis and  
28 treatment of the diseases, provided that DNA samples and related medical records may  
29 only be stored in the Database if all personal identifying information is removed. The

1 information contained in the Database may not be collected, analyzed, or stored to  
2 obtain information about human physical traits or predisposition for disease unless the  
3 purpose for obtaining the information is authorized by this subsection.

4 (e) The Director may publish educational materials about the Database for  
5 dissemination to the general public. The materials shall describe the purposes for which  
6 data in the Database will be used, who will have access to the Database, the confidential  
7 nature of samples in the Database, and other information.

8 **"§ 116-266. Collection of DNA samples.**

9 (a) The Director shall adopt procedures in accordance with this Article for the  
10 collection, preservation, analysis, and use of blood samples or other specimens in a  
11 manner that permits the exchange of DNA samples between DNA laboratories and the  
12 use of the data for the purposes authorized under this section.

13 (b) The Director may contract with a laboratory, other State agency, private  
14 entity, or institution of higher education for services to perform DNA analyses.

15 (c) The Database may not accept a voluntarily submitted blood sample from a  
16 person unless the sample is collected in a medically approved manner by a physician or  
17 registered nurse or other person who is trained to properly collect samples or other  
18 specimens and supervised by a licensed physician. A person collecting a blood sample  
19 or other sample or specimen under this section shall not be liable in any civil action if  
20 the person collects the sample or other specimen in a reasonable manner according to  
21 generally accepted medical or other professional practices. A person voluntarily  
22 submitting hair or saliva samples or specimens, or other samples or specimens except  
23 for blood, may send the hair, saliva, or sample or specimen other than blood directly to  
24 the research institution.

25 (d) The Director shall provide at no cost to the individual the specimen vials,  
26 mailing tubes and labels, report forms, and other instructions for collection of blood  
27 samples or other specimens from individuals voluntarily submitting DNA to the  
28 Database.

29 (e) A person who collects a blood sample or other specimen under this section  
30 shall send the sample or specimen to the Database in accordance with instructions  
31 provided by the Director.

32 (f) A DNA laboratory may analyze a blood sample collected under this section  
33 or other DNA specimen only for the purposes authorized under this section.

34 **"§ 116-267. Data collection.**

35 (a) The Director shall make available on the Internet or by mail a medical history  
36 questionnaire that shall be required as part of every voluntary submission to the  
37 Database. Upon receipt of the completed questionnaire from the donor, the Director  
38 shall provide for a donor test kit to be mailed to the donor. The test kit, returned  
39 samples or specimens, and the completed questionnaire will be linked and uniquely  
40 identified by a bar code or other unique number in order to preserve the donor's  
41 anonymity. When a sample is mailed to the lab site for housing, the sample will be  
42 transferred to a stain card for storage before any analysis of the sample is undertaken.  
43 The transfer to a stain card shall be in a manner and time period that preserves the  
44 integrity of the sample for future testing. The medical history questionnaire shall be

1 developed by the Director, in consultation with the following persons, or their  
2 designees:

- 3 (1) The Director of the Genomic Science Program, North Carolina State  
4 University.
- 5 (2) The Chair of the Department of Genetics, University of North Carolina  
6 School of Medicine.
- 7 (3) The Director of the Biomedical/Biotechnology Research Institute,  
8 North Carolina Central University.
- 9 (4) The Chair of the Department of Pediatrics/Genetics, East Carolina  
10 University School of Medicine.
- 11 (5) The Director of the Genomic Science Program, Western Carolina  
12 University.

13 (b) The completed medical questionnaire shall be maintained in the Database.  
14 After not fewer than 1,000 samples have been collected, a medical marker DNA test  
15 shall be performed, computerized, and attached to the original completed medical  
16 questionnaire. Information from the completed medical questionnaire and the medical  
17 marker test shall be linked using the unique bar code or identifying number assigned.  
18 The Director may make available the information from each linked marker and  
19 questionnaire to North Carolina-based biotechnology companies and research  
20 institutions.

21 **"§ 116-268. Access to Voluntary DNA Database information.**

22 (a) The Director shall adopt policies and procedures:

- 23 (1) To prevent unauthorized access to the DNA Database.
- 24 (2) To release DNA records, specimens, or analyses from the DNA  
25 Database for authorized purposes.
- 26 (3) Relating to the internal disclosure, access, or use of a sample,  
27 specimen, or DNA record in the DNA laboratory.

28 (b) A DNA sample, analysis, or record may be released only if personally  
29 identifiable information is removed, for:

- 30 (1) A population statistics database.
- 31 (2) Identification research and protocol development.
- 32 (3) Quality control.

33 (c) The Director may release a record of the number of requests made for a DNA  
34 record and the name of the requesting person. The Director shall maintain a record of  
35 requests made under this section.

36 **"§ 116-269. Confidentiality of DNA records.**

37 (a) A DNA record stored in the Database is confidential and is not subject to  
38 disclosure except for the purposes authorized in this Article.

39 (b) A person who knowingly discloses information in a DNA record or  
40 information related to a DNA analysis of a blood specimen except as authorized by this  
41 Article is guilty of a Class 1 misdemeanor.

42 (c) A violation of this section constitutes official misconduct.

43 **"§ 116-270. Segregation of records.**

1        The Associate Provost shall adopt policies and procedures providing for the  
2 segregation of DNA records created under this Article from records created under  
3 Article 13 of Chapter 15A of the General Statutes.

4 **"§ 116-271. Fees; other funds.**

5        The Director shall charge to participating North Carolina-based biotechnology  
6 corporations and research institutions an equal portion of the cost to store and retrieve  
7 information in the Database. The annual fee for each biotechnology corporation or  
8 research institution shall be twenty-five thousand dollars (\$25,000) for the first year of  
9 operating the Database. After the first year, the fee shall be adjusted based on the actual  
10 cost of maintaining the system. NCCU, on behalf of the Database, may accept grants,  
11 contributions, devises, bequests, and gifts, which shall be kept in a separate fund, which  
12 shall be nonreverting, and shall be used to fund the implementation and continuing  
13 operation of the Database. NCCU may also accept donations of equipment and storage  
14 facilities from a State, private, or public research institution to be used for the purposes  
15 of the Database.

16 **"§ 116-272. Definitions.**

17        As used in this Article, unless the context clearly requires otherwise:

- 18        (1) 'Database' means the Voluntary DNA Database established under this  
19 Article for the recording of DNA samples and related medical records  
20 voluntarily submitted by an individual.
- 21        (2) 'Director' means the Director of the Voluntary DNA Database  
22 established under this Article.
- 23        (3) 'DNA' means deoxyribonucleic acid.
- 24        (4) 'DNA record' means DNA identification information stored in the  
25 Voluntary DNA Database for the purposes stated in this Article.
- 26        (5) 'DNA sample' means a blood sample or other specimen voluntarily  
27 submitted to the Database by an individual.
- 28        (6) 'Medical record' means the questionnaire completed and submitted by  
29 the individual volunteering to participate in the Database.
- 30        (7) 'NCCU' means North Carolina Central University."

31        **SECTION 2.** There is appropriated from the General Fund to the Board of  
32 Governors of The University of North Carolina the sum of three hundred thousand  
33 dollars (\$300,000) for the 2005-2006 fiscal year. These funds shall be allocated to  
34 North Carolina Central University ("NCCU") to establish the Voluntary DNA Database  
35 in accordance with Section 1 of this act. NCCU shall establish a schedule of  
36 implementation that ensures that the most cost-effective plan is pursued. The following  
37 order of priorities shall serve as a guide for implementation of this act:

- 38        (1) Development and implementation of the medical history questionnaire,  
39 test kits for volunteer submissions to the Database, and collection and  
40 storage of DNA samples.
- 41        (2) Computerization of DNA data submissions.
- 42        (3) Availability of DNA Database for marketing to North Carolina  
43 research institutions and biotechnology companies.

1           **SECTION 3.** Section 2 of this act becomes effective July 1, 2005. The  
2 remainder of this act is effective when it becomes law.