



Biological Testing Release August 6 and 7, 2010 Indianapolis, Indiana

Presented by the Indiana Historical Society

Additional Requirements for Exhibitors Engaged in Biological Testing or Sampling:

1. Collection of human blood or other human tissue samples obtained through cutting, piercing, or other procedures generally considered invasive is not permitted.

2. An exhibitor offering testing services to members of the public shall provide each client with a written statement of its privacy policy, which shall describe the extent to which the client may control future use of the sample or data derived from it, whether or not it is associated with a means of identifying the donor. The exhibitor shall also provide evidence of its technical qualification through at least one of the following:
 - a. Certification by the U.S. Department of Health and Human Services for performing tests of major complexity under the Clinical Laboratories Improvement Act and Title 42, Code of Federal Regulations, Part 493, or
 - b. Accreditation for DNA testing by the American Society of Crime Laboratory Directors (ASCLD) Laboratory Accreditation Board, or
 - c. Accreditation by the American Association of Blood Banks (AABB) Parentage Testing Committee, or
 - d. Recent periodic external proficiency testing for agreement with National Institute of Standards and Technology (NIST) DNA Profiling Standard SRM 2391, for polymerase chain-reaction (PCR) tests, and SRM 2392, for mitochondrial DNA tests.

3. An exhibitor proposing to use samples for research purposes, either exclusively or in conjunction with services provided to individuals, shall present evidence of registration and filing of assurances with the U.S. Department of Health and Human Services (DHSS) under its rules for protection of human subjects, Title 45, Code of Federal Regulations, Part 46, and shall provide to prospective subjects sufficient disclosure regarding safety, privacy, and future use of samples and data so that the subject will have a reasonable basis for informed consent.

4. The exhibitor shall identify any applicable regulations promulgated by OSHA, the FDA, or other cognizant Federal agencies and certify its compliance with them.

Company Representative Signature

Date

Name of Company

Company Mailing Address

City, State, and Zip