49-7-120. Confidentiality of research records and materials.

(a) As used in this section, unless the context otherwise requires:

(1) "Patentable materials" means inventions, processes, discoveries or other subject matter that the public higher education institution or the sponsor reasonably believes to be patentable under 35 U.S.C.;

(2) "Proprietary information" means:

(A) Any information used directly or indirectly in the business of any person or entity that gives the person or entity an advantage or an opportunity to obtain an advantage over competitors who do not know or use the information and that is disclosed by the person or entity to the public higher education institution; or

(B) Any information received, developed, generated, ascertained or discovered by the public higher education institution under terms of a contract for the development thereof that recognizes the proprietary interest of the person or entity in the information;

(3) "Sponsored research or service" means any research, analysis, or service conducted pursuant to grants or contracts between the public higher education institution and a person or entity. "Sponsored research or service" does not include research, analysis or service conducted under an agreement with other agencies of the state, unless the research, analysis or service is a subcontract to a sponsored research or service contract with a person or entity; and

(4) "Trade secrets" means any information, knowledge, items or processes used directly or indirectly in the business of a person or entity that give the person or entity an advantage or an opportunity to obtain an advantage over competitors who do not know or use them.

(b) The following records or materials, regardless of physical form or characteristics, received, developed, generated, ascertained or discovered during the course of sponsored research or service conducted by a public higher education institution, or in the course of fulfilling a grant agreement between a public higher education institution and the Tennessee department of economic and community development, shall not be open for public inspection:

(1) Patentable material or potentially patentable material;

(2) Proprietary information;

(3) Trade secrets or potential trade secrets, including, but not limited to, manufacturing and production methods, processes, materials and associated costs;

(4) Business transactions, commercial or financial information about or belonging to research subjects or

sponsors;

(5) Summaries or descriptions of sponsored research or service, unless released by the sponsor;

(6) Personally identifiable information; and

(7) Any other information that reasonably could affect the conduct or outcome of the sponsored research or service, the ability to patent or copyright the sponsored research or any other proprietary rights any person or entity might have in the research or the results of the research, including, but not limited to, protocols, notes, data, results or other unpublished writing about the research or service.

(c) Nothing in this section shall prohibit voluntary disclosure of the records or materials by the sponsor or by the public higher education institution with the consent of the sponsor.

(d) The public higher education institution shall make available, upon request by a citizen of this state, the titles of sponsored research or service projects, names of the researchers and the amounts and sources of funding for the projects.

(e) All records or materials, regardless of physical form or characteristics, received, developed, generated, ascertained or discovered during the course of research or service that is not sponsored research or service, as defined in subdivision (a)(3), shall not be open for public inspection if the disclosure of the information reasonably could affect the conduct or outcome of the research or service, the ability of the public higher education institution to patent or copyright the research or any other proprietary rights any person or entity might have in the research or the results of the research, including, but not limited to, proprietary information and trade secrets received from a person or entity cooperating in the research, protocols, notes, data, results or other unpublished writing about the research or service.

(f) Upon agreement of a subject and the clinical study physician assigned to the human subject and upon the withdrawal, termination or conclusion of the research project, the assigned clinical study physician shall, upon notification and request of the human subject, disclose all pertinent medical information in that human subject's research records. Disclosure shall take place as soon as reasonably practical, not to exceed three (3) business days.

HISTORY: Acts 1991, ch. 135, § 1; 1997, ch. 352, § 1; 1999, ch. 349, § 1; 2000, ch. 783, §§ 1-9, 11, 12; 2010, ch. 1135, § 2; 2011, ch. 297, § 6.