

01-101

ADMINISTRATION OF GOVERNMENT: VIRGINIA FREEDOM OF INFORMATION ACT.

HEALTH: HUMAN RESEARCH.

EDUCATIONAL INSTITUTIONS: GENERAL PROVISIONS.

Institutional Review Board is not ‘public body’ subject to the Act’s disclosure requirements. Records generated by such board are not ‘public records’ prepared, owned or possessed by public body; are not required to be open for public inspection. Act’s open meeting requirement does not apply to meetings of Institutional Review Boards and human research review committees.

The Honorable Thomas C. Wright Jr.
Member, House of Delegates
October 22, 2001

You ask several questions concerning the application of The Virginia Freedom of Information Act to an Institutional Review Board¹ ("IRB") of a public institution of higher learning² in the Commonwealth engaged in human research projects.

You advise that the IRBs with which you are familiar are permanent boards within public institutions of higher learning that meet on a regularly scheduled basis. Such IRBs are composed of individuals from within the institutions and from the private sector. You state that the institution pays all expenses associated with IRBs, including staff support from the institution. You also relate that public institutions of higher learning within the Commonwealth engaged in research using human subjects are required by federal and state law to submit proposed human research projects to review by an IRB.³ You explain that approval by an IRB is required prior to performing federally regulated human research projects at such universities.

The primary purpose for review by an IRB of human research projects subject to federal regulation is to "assure the protection of the rights and welfare of the human subjects."⁴ Certain criteria must be satisfied before an IRB may approve such projects. First, risks to human subjects must be minimal and reasonable in relation to anticipated benefits.⁵ In addition, selection of subjects must be equitable, and informed consent must be sought from each prospective subject and appropriately documented.⁶

Finally, the research plan must make adequate provision for monitoring and maintaining the confidentiality of data collected on human subjects and for protecting the privacy of such subjects.⁷

Sections 32.1-162.16 through 32.1-162.20 comprise Virginia's laws applicable to human research that is not subject to federal regulation for the protection of human subjects.⁸ Section 32.1-162.19(A) provides that "[e]ach institution or agency which conducts or which proposes to conduct or authorize human research *shall* establish a human research review committee." (Emphasis added.) Section 32.1-162.16 defines the term "'institution' or 'agency'" as "any facility, program, or organization owned or operated by the Commonwealth." In addition, § 32.1-162.19(A) requires anyone conducting, or proposing to conduct, human research to affiliate with an institution or agency having a human research review committee. Furthermore, § 32.1-162.19(B) stipulates that the human research review committee must review and approve any proposed human research project. Finally, § 23-9.2:3.3 provides:

Each board of visitors or other governing body of any public or private institution of higher education in which human research, as defined in § 32.1-162.16, is conducted *shall* [emphasis added] promulgate regulations pursuant to the Administrative Process Act (§ 9-6.14:1 et seq.) to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research. The regulations shall require the human research committee to submit to the Governor, the General Assembly, and the president of the institution or his designee at least annually a report on the human research projects reviewed and approved by the committee and shall require the committee to report any significant deviations from approved proposals.

The use of the word "shall" in a statute generally implies that the General Assembly intends its terms to be mandatory, rather than permissive or directive.⁹ Therefore, the human research review committee performs the same functions as an IRB and, in all respects, is similar to an IRB.

You first inquire whether an IRB is a "public body" as that term is defined in The Virginia Freedom of Information Act¹⁰ (the "Act").

Section 2.2-3701 of the Act defines the term "public body" as

any authority, board, bureau, commission, district or agency of the Commonwealth ..., boards of visitors of public institutions of higher education; and other organizations, corporations or agencies in the Commonwealth supported wholly or principally by public funds. It shall include any committee [or] subcommittee ... however designated, of the public body created to perform delegated functions of the public body or to advise the public body. It shall not exclude any such committee [or] subcommittee ... because it has private sector or citizen members.

The only category under the definition of "public body" within which an IRB or a human research review committee could fall is that of "other organizations ... supported wholly or principally by public funds."¹¹ The primary goal of statutory interpretation is to ascertain and give effect to the intent of the legislature.¹² The purpose underlying a statute's enactment is particularly significant in construing it.¹³ Moreover, statutes should not be interpreted in ways that produce absurd or irrational consequences.¹⁴ Instead, they should be harmonized with other existing statutes where possible to produce a consistently logical result that gives effect to the legislative intent.¹⁵

Section 2.2-3700(B) states that the primary purpose of the Act is to

ensure[] the people of the Commonwealth ready access to records in the custody of *public officials* and free entry to meetings of *public bodies* wherein the business of the people is being conducted. [Emphasis added.] The affairs of government are not intended to be conducted in an atmosphere of secrecy since at all times the public is to be the beneficiary of any action taken at any level of government....

The provisions of [the Act] shall be liberally construed to promote an increased awareness by all persons of governmental activities and afford every opportunity to citizens to witness the operations of government.

Prior opinions of the Attorney General conclude that a variety of organizations that are not governmental agencies in the traditional sense, but which receive primary support for their activities from public funds, fall within the Act's definition of "public body."¹⁶ Both the IRB and the human research review committee are appointed by the public institution of higher learning pursuant to a statutory mandate for the purposes set forth in § 32.1-162.19 and applicable federal regulations.¹⁷ The necessary expenses incurred by the human research review committee and IRB in performing the required statutory functions are paid out of public funds from the budgets of public institutions of higher learning.

The Circuit Court of the City of Richmond construed the meaning of the term "organization" as used in the Act in a petition filed under the Act. Petitioners requested the circuit court to "order that meetings of the Animal Research Committee of the University of Virginia be treated as public meetings under the Act."¹⁸ "The Animal Research Committee ... is an arm of the University assigned to the task of establishing standards concerning the care and use of animals at the University."¹⁹ The court concluded that the term "organization," as used in the phrase "other organizations, corporations or agencies in the Commonwealth, supported wholly or principally by public funds"²⁰ means

an organization having an independent status which is charged by law with the governance of, or responsibility for, some discrete public agency. It does not include subordinate, dependent groupings of individuals who are charged with carrying out a part of the mission of a parent body.^[21]

The court reasoned that the term "organization" referred to an organization similar to those specifically enumerated in § 2.2-3701, such as legislative bodies, authorities, boards, bureaus, and commissions.²² Under the doctrine of *noscitur a sociis*,²³ the court was required to construe the term "organization" "with reference to the words it is used with" in the Act.²⁴

Under the facts you provide, IRBs and human research review committees are supported wholly by public funds, but do not perform delegated functions of institutions of higher learning. I cannot conclude that an IRB or a human research review committee is an independent entity charged by law with the governance of, or responsibility for, some discrete public agency. It is clear that such boards and committees are subordinate, dependent groupings of individuals charged with effecting a mission of public institutions of higher learning. Therefore, I must conclude that an IRB is not a "public body" as that term is defined in the Act.

You next ask whether the records generated by an IRB are "public records" as that term is defined by the Act.

Section 2.2-3701 broadly defines the term "public records" to mean

all writings and recordings that consist of letters, words or numbers, or their equivalent, set down by handwriting, typewriting, printing, photostating, photography, magnetic impulse, optical or magneto-optical form, mechanical or electronic recording or other form of data compilation, however stored, and regardless of physical form or characteristics, prepared or owned by, or in the possession of a public body or its officers, employees or agents in the transaction of public business.

"Where a statute is unambiguous, the plain meaning is to be accepted without resort to the rules of statutory interpretation."²⁵ All public records are open for inspection and copying during regular office hours, unless otherwise specifically provided by law.²⁶ The definition of "public records" in the Act includes "all writings ... that consist of letters, words or numbers, or their equivalent, set down ... regardless of physical form or characteristics, prepared or owned by, or in the possession of a public body."²⁷ The IRB and the human research review committees are not public bodies,²⁸ subject to the Act's disclosure requirements. The Act requires that "[a]ny exemption from public access to records ... shall be narrowly construed."²⁹ Since I conclude that an IRB is not a "public body" as defined in the Act, I must also conclude that records generated by an IRB are not "public records" prepared or owned by, or in the possession of, a public body.

You next ask whether the open meeting requirements set forth in § 2.2-3707 of the Act apply to the meetings of IRBs.

"The provisions of [the Act] shall be liberally construed to promote an increased awareness by all persons of governmental activities and afford every opportunity to citizens to witness the operations of government."³⁰ Since I am of the opinion that IRBs and human research review committees do not fall within the Act's definition of "public body," I must also conclude that they would not be subject to the Act's open meeting requirement. Accordingly, I am of the opinion that the Act does not require that the meetings of these boards and committees be open to the public.

Your final inquiry is whether IRB records are "public records" open to inspection under § 2.2-3704 of the Act.

Section 2.2-3704(A) provides that, "[e]xcept as otherwise specifically provided by law, all public records shall be open to inspection and copying by any citizens of this Commonwealth during the regular office hours of the custodian of such records." Section 2.2-3705 contains 77 exceptions to the mandatory disclosure provisions of § 2.2-3704. Section 2.2-3705(A)(20) clearly excludes

[d]ata, records or information of a proprietary nature produced or collected by or for faculty or staff of public institutions of higher education ... in the conduct of or as a result of study or research on medical, scientific, technical or scholarly issues, whether sponsored by the institution alone or in conjunction with a governmental body or a private concern, where such data, records or information has not been publicly released, published, copyrighted or patented.

IRBs and human research review committees are not, in my opinion, public bodies. As a result, these boards and committees are not subject to the provisions of the Act. The records of an IRB, therefore, are not subject to inspection and copying by any citizen. Consequently, I must conclude that the Act does not require that the records of an IRB be open for public inspection.

¹An Institutional Review Board is "any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research [regulated by the Food and Drug Administration] involving human subjects." 21 C.F.R. § 56.102(g) (2001).

²Public institutions of higher learning in the Commonwealth include "The College of William and Mary in Virginia, at Williamsburg; the rector and visitors of Christopher Newport University, at Newport News; Longwood College, at Farmville; the Mary Washington College, at Fredericksburg; George Mason University, at Fairfax; the James Madison University, at Harrisonburg; Old Dominion University, at Norfolk; the State Board for Community Colleges, at Richmond; the Virginia Commonwealth University, at Richmond; the Radford University, at Radford; the Roanoke Higher Education Authority and Center; the rector and visitors of the University of Virginia, at Charlottesville; the University of Virginia's College at Wise; the Virginia Military Institute, at Lexington; the Virginia Polytechnic Institute and State University, at Blacksburg; the Virginia Schools for the Deaf and the Blind; the Virginia State University, at Petersburg; Norfolk State University, at Norfolk; the Woodrow Wilson Rehabilitation Center, at Fishersville; the Medical College of Hampton Roads; and the Southwest Virginia Higher Education Center." Va. Code Ann. § 23-14 (Michie Supp. 2001).

³See 45 C.F.R. pt. 46 (2000) (regulations of Department of Health and Human Services applicable to "Protection of Human Subjects"); 21 C.F.R. pt. 56 (2001) (regulations of Food and Drug Administration applicable to "Institutional Review Boards"); Va. Code Ann. tit. 32.1, ch. 5.1, §§ 32.1-162.16 to 32.1-162.20 (Michie Repl. Vol. 2001) (statutes governing human research conducted by institution or agency of Commonwealth).

⁴See 21 C.F.R. § 56.102(g).

⁵See 45 C.F.R. § 46.111(a)(1)-(2).

⁶See *id.* § 46.111(a)(3)-(5).

⁷See *id.* § 46.111(a)(6)-(7).

⁸See § 32.1-162.20.

⁹See *Andrews v. Shepherd*, 201 Va. 412, 414-15, 111 S.E.2d 279, 281-82 (1959); see also *Schmidt v. City of Richmond*, 206 Va. 211, 218, 142 S.E.2d 573, 578 (1965); *Op. Va. Att'y Gen.*: 1998 at 56, 58; 1996 at 178, 178; 1991 at 238, 240; 1989 at 250, 251-52; 1985-1986 at 133, 134.

¹⁰Va. Code Ann. §§ 2.2-3700 to 2.2-3714 (Matthew Bender Repl. Vol. 2001).

¹¹Section 2.2-3701.

¹²See *Turner v. Commonwealth*, 226 Va. 456, 459, 309 S.E.2d 337, 338 (1983).

¹³*VEPCO v. Prince William Co.*, 226 Va. 382, 388, 309 S.E.2d 308, 311 (1983).

¹⁴*McFadden v. McNorton*, 193 Va. 455, 461, 69 S.E.2d 445, 449 (1952); see *Op. Va. Att'y Gen.*: 1993 at 192, 196; 1991 at 5, 7; 1986-1987 at 307, 308.

¹⁵2A Norman J. Singer, *Sutherland Statutory Construction* § 46.05 (5th ed. 1992 & Supp. 1999); 1993 *Op. Va. Att'y Gen.*, *supra*.

¹⁶See, e.g., *Op. Va. Att'y Gen.*: 1984-1985 at 431 (Student Senate of Old Dominion University); 1983-1984 at 447, 448 (Governor's Advisory Board of Economists and Governor's Advisory Board on Revenue Estimates); 1982-1983 at 719 (Fairfax Hospital Association); *id.* at 726 (volunteer fire department); 1977-1978 at 482 (university honor committee); 1975-1976 at 406, 407; 1974-1975 at 584, 584 (General Professional Advisory Committee, composed of university presidents, established by State Council of Higher Education to serve Council in advisory capacity). *But see Op. Va. Att'y Gen.*: 1978-1979 at 316 (city mayor's citizen advisory committee is not subject to Act; is not created by public body, performs no delegated functions of public body, does not advise public body, and receives no public funding); 1974-1975, *supra*, at 584-85 (voluntary association of college presidents, with no official status as creature of State Council of Higher Education and receiving no public funds, is excluded from Act).

¹⁷See 45 C.F.R. § 46.111(a); 21 C.F.R. § 56.102(g).

¹⁸*Students for Animals v. University of Virginia*, 12 Va. Cir. 247, 247 (1988).

¹⁹*Id.*

²⁰Section 2.2-3701 (defining "public body").

²¹*Students for Animals*, 12 Va. Cir. at 249.

²²*Id.*

²³"The meaning of a word ... takes color and expression from the purport of the entire phrase of which it is a part, and it must be construed so as to harmonize with the context as a whole." *Kohlberg v. Va. Real Estate Comm.*, 212 Va. 237, 239, 183 S.E.2d 170, 172 (1971). "[I]t is known by its associates." *Black's Law Dictionary* 1084 (7th ed. 1999) (noting Latin derivation of *noscitur a sociis*).

²⁴*Students for Animals*, 12 Va. Cir. at 249.

²⁵*Last v. Virginia State Bd. of Medicine*, 14 Va. App. 906, 910, 421 S.E.2d 201, 205 (1992).

²⁶Section 2.2-3704(A).

²⁷*Id.*

²⁸Section 2.2-3701 (defining "public body").

²⁹Section 2.2-3700(B).

³⁰*Id.*

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