

Office for
Protection from
Research
Risks

National Institutes of Health
Suite 3B01
6100 Executive Boulevard
Rockville, MD 20892-7507

Date: FEB 10 1995

To: KAREN GUSS

FAX: 202-456-7431
Phone: _____

From: Gary B. Ellis

FAX: 301-402-2071
Phone: 301-496-7005

Comments:

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PROTECTION OF HUMAN SUBJECTS

**TITLE 45
CODE OF FEDERAL REGULATIONS
PART 46**

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THE PUBLIC HEALTH SERVICE ACT
AS AMENDED BY THE HEALTH RESEARCH EXTENSION ACT OF 1985
PUBLIC LAW 99-158
NOVEMBER 20, 1985

"INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

"SEC. 491. (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

"(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

"(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.

"FETAL RESEARCH

"SEC. 498. (a) The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

"(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

"(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

"(b) In administering the regulations for the protection of human research subjects which—

"(1) apply to research conducted or supported by the Secretary;

"(2) involve living human fetuses in utero; and

"(3) are published in Section 46.208 of Part 46 of Title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in Section 46.102(g) of such Part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

NOTE: Section 46.102(g) becomes Section 46.102(i) in Title 45 CFR Part 46 as revised on June 18, 1991.

THE CODE OF FEDERAL REGULATIONS,
TITLE 45 CFR PART 46,
IMPLEMENTS THESE AMENDMENTS
TO THE PUBLIC HEALTH SERVICE ACT

CODE OF FEDERAL REGULATIONS

TITLE 45

PUBLIC WELFARE

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE FOR PROTECTION FROM RESEARCH RISKS**



PART 46—PROTECTION OF HUMAN SUBJECTS

Revised June 18, 1991

(Effective August 19, 1991)

PART 46—PROTECTION OF HUMAN SUBJECTS

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Authority: 5 U.S.C. 301; Sec. 474(a), 88 Stat. 352 (42 U.S.C. 2891–3(a)).

Note: As revised, Subpart A of the DHHS regulations incorporates the Common Rule (Federal Policy) for the Protection of Human Subjects (56 FR 28003). Subpart D of the HHS regulations has been amended at Section 46.401(b) to reference the revised Subpart A.

The Common Rule (Federal Policy) is also codified at

7 CFR Part 1c Department of Agriculture

10 CFR Part 745 Department of Energy

14 CFR Part 1230 National Aeronautics and Space Administration

15 CFR Part 27 Department of Commerce

16 CFR Part 1028 Consumer Product Safety Commission

22 CFR Part 225 International Development Cooperation Agency, Agency for International Development

24 CFR Part 60 Department of Housing and Urban Development

28 CFR Part 46 Department of Justice

32 CFR Part 219 Department of Defense

34 CFR Part 97 Department of Education

38 CFR Part 16 Department of Veterans Affairs

40 CFR Part 26 Environmental Protection Agency

45 CFR Part 690 National Science Foundation

49 CFR Part 11 Department of Transportation

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)

Source: 56 FR 28003, June 18, 1991.

§ 46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each Department or Agency head may adopt such procedural modifications as may be appropriate from an administrative

standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

(1) Research that is conducted or supported by a Federal Department or Agency, whether or not it is regulated as defined in § 46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a Federal Department or Agency but is subject to regulation as defined in § 46.102(e) must be reviewed and approved, in compliance with § 46.101, § 46.102, and § 46.107 through § 46.117 of this policy, by an Institutional Review Board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception

that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or Agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or Agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Department or Agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a Department or Agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the Department or Agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the Department or Agency head, notices of these actions as they occur will be published in the **Federal Register** or will be otherwise published as provided in Department or Agency procedures.

(i) Unless otherwise required by law, Department or Agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the Department or Agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services (DHHS), and shall also publish them in the **Federal Register** or in such other manner as provided in Department or Agency procedures.¹

¹ Institutions with DHHS-approved assurances on file will abide by provisions

§ 46.102 Definitions.

(a) *Department or Agency head* means the head of any Federal Department or Agency and any other officer or employee of any Department or Agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or Agency (including Federal, State, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a Federal Department or Agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a Federal Department or Agency solely as part of the Department's or Agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for

example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or

(2) identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). *Private information* must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an Institutional Review Board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting Department or Agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an

IRB in accordance with an approved assurance.

§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a Federal Department or Agency shall provide written assurance satisfactory to the Department or Agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual Department or Agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, National Institutes Health, DHHS, and approved for Federalwide use by that office. When the existence of an DHHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to Department and Agency heads shall also be made to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Department or Agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to Department- or Agency-supported or regulated research and need not be

of Title 45 CFR Part 46 Subparts A–D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

applicable to any research exempted or waived under § 46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Department or Agency head, unless in accord with § 46.103(a) of this policy, the existence of a DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any

suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the Department or Agency head prescribes.

(d) The Department or Agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the Department or Agency and such experts or consultants engaged for this purpose as the Department or Agency head determines to be appropriate. The Department or Agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Department or Agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Department or Agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a Federal Department or Agency and not otherwise exempted or waived under § 46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by § 46.103 of this policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the Department or Agency to which the application or proposal is submitted. Under no condition shall research covered by § 46.103 of the policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a

request for such a certification from the Department or Agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§§ 46.104—46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one

member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in § 46.103(b)(4) and to the extent required by § 46.103(b)(5).

(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the *Federal Register*, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the *Federal Register*. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, DHHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of

the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Department or Agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§ 46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or

economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one

institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the Department or Agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ 46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in § 46.103(b)(4) and § 46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department or Agency at reasonable times and in a reasonable manner.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risks or discomforts to the subject;

(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of

records identifying the subject will be maintained;

(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) any additional costs to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to

obtain informed consent provided the IRB finds and documents that:

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) the research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

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§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the

IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 46.101 (b) or (j), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Department or Agency.

§ 46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the Department or Agency, and final approval given to the proposed change by the Department or Agency.

§ 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The Department or Agency head will evaluate all applications and proposals involving human subjects submitted to the Department or

Agency through such officers and employees of the Department or Agency and such experts and consultants as the Department or Agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the Department or Agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 46.121 [Reserved]

§ 46.122 Use of Federal funds.

Federal funds administered by a Department or Agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The Department or Agency head may require that Department or Agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Department or Agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the Department or Agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Department or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the Department or Agency head may impose additional conditions prior to or at the time of approval when in the judgment of the Department or Agency head additional conditions are necessary for the protection of human subjects.

Subpart B—Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Source: 40 FR 33528, Aug. 8, 1975, 43 FR 1758, January 11, 1978; 43 FR 51559, November 3, 1978.

§ 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health and Human Services grants and contracts supporting research, development, and related activities involving: (1) the fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§ 46.203 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services (DHHS) to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of

implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the *Federal Register* guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

§ 46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these Board(s) shall be so selected that the Board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No Board member may be a regular, full-time employee of the Department of Health and Human Services.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the

policies and requirements of this part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.
Nullified June 10, 1993 (Public Law 103-43)

§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human *in vitro* fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

- (1) determine that all aspects of the activity meet the requirements of this subpart;
- (2) determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) overseeing the actual process by which individual consents required by this subpart are secured either by

approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.120 of Subpart A of this part.

(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

§ 46.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) appropriate studies on animals and nonpregnant individuals have been completed;

(2) except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity;

(3) individuals engaged in the activity will have no part in: (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) no procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

Source: 40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975.

§ 46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) the purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

§ 46.208 Activities directed toward fetuses in utero as subjects.

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus *ex utero* is

viable, a fetus *ex utero* may not be involved as a subject in an activity covered by this subpart unless:

(1) there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

(1) vital functions of the fetus will not be artificially maintained,

(2) experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§ 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart,

with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the Federal Register.

Subpart C—Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Source: 43 FR 53655, Nov. 16, 1978.

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and

any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "DHHS" means the Department of Health and Human Services.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in § 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) the research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) the information is presented in language which is understandable to the subject population;

(6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) the institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) in the judgment of the Secretary the proposed research involves solely the following:

(A) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the *Federal Register*, of his intent to approve such research; or

(D) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the *Federal Register*, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or

supported by DHHS shall not involve prisoners as subjects.

Subpart D—Additional DHHS Protections for Children Involved as Subjects in Research.

Source: 48 FR 9818, March 8, 1983; 56 FR 28032, June 18, 1991.

§ 46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of § 46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at § 46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at § 46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at § 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of § 46.101 of Subpart A are applicable to this subpart.

§ 46.402 Definitions.

The definitions in § 46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) the risk is justified by the anticipated benefit to the subjects;

(b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that

presented by available alternative approaches; and

(c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) the risk represents a minor increase over minimal risk;

(b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

DHHS will conduct or fund research that the IRB does not believe meets the requirements of § 46.404, § 46.405, or § 46.406 only if:

(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) the Secretary, after consultation with a panel of experts in pertinent

disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of § 46.404, § 46.405, or § 46.406, as applicable, or (2) the following:

(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) the research will be conducted in accordance with sound ethical principles;

(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the

health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 46.404 or § 46.405. Where research is covered by § 46.406 and § 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with

Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

(a) Children who are wards of the State or any other agency, institution, or entity can be included in research approved under § 46.406 or § 46.407 only if such research is:

(1) related to their status as wards; or

(2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

RESEARCH ACTIVITIES WHICH MAY BE REVIEWED THROUGH EXPEDITED REVIEW PROCEDURES

Research activities involving no more than minimal risk *and* in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board through the expedited review procedure authorized in § 46.110 of 45 CFR Part 46.

(1) Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity,

electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

Source: 46 FR 8392; January 26, 1981.

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*** THIS SECTION IS CURRENT THROUGH THE 1994 SUPPLEMENT ***
*** (1994 SESSION OF THE GENERAL ASSEMBLY) ***

TITLE 37. JUVENILES
CHAPTER 10. MISCELLANEOUS PROVISIONS
PART 3. PARENTAL CONSENT FOR ABORTIONS BY MINORS

Tenn. Code Ann. @ 37-10-301 (1994)

37-10-301. Legislative intent and findings

(a) It is the intent of the general assembly in enacting this parental consent provision to further the important and compelling state interests of:

- (1) Protecting minors against their own immaturity;
- (2) Fostering the family structure and preserving it as a viable social unit; and
- (3) Protecting the rights of parents to rear children who are members of their household.

(b) The general assembly finds as fact that:

- (1) Immature minors often lack the ability to make fully informed choices that take into account of both immediate and long-range consequences;
- (2) The medical, emotional, and psychological consequences of abortion are serious and can be lasting, particularly when the patient is immature;
- (3) The capacity to become pregnant and the capacity for mature judgment concerning the wisdom of an abortion are not necessarily related;
- (4) Parents ordinarily possess information essential to a physician's exercise of his best medical judgment concerning the child; and
- (5) Parents who are aware that their minor daughter has had an abortion may better ensure that she receives adequate medical attention after her abortion.

(c) The general assembly further finds that parental consultation is usually desirable and in the best interests of the minor.

HISTORY: Acts 1988, ch. 929, @ 1.

NOTES:

CROSS-REFERENCES. Abortion, title 39, ch. 15, part 2.

Ambulatory surgical care centers terminating pregnancies, licensing, @ 68-11-223.

Public school nurse program, title 68, ch. 1, part 12.

CITED: Planned Parenthood Ass'n of Nashville, Inc. v. McWherter, 923 F.2d 474 (6th Cir. 1991).

NOTES TO DECISIONS

1. CONSTITUTIONALITY.

Due to the vagueness problem for physicians and the possible chilling effect on minors' constitutional rights, the Parental Consent for Abortions by Minors Act is unconstitutional on its face. Planned Parenthood Ass'n v. McWherter, 716 F. Supp. 1064 (M.D. Tenn. 1989), vacated, 945 F.2d 405 (6th Cir. 1991).

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*** THIS SECTION IS CURRENT THROUGH THE 1994 SUPPLEMENT ***
*** (1994 SESSION OF THE GENERAL ASSEMBLY) ***

TITLE 39. CRIMINAL OFFENSES
CHAPTER 15. OFFENSES AGAINST THE FAMILY
PART 2. ABORTION

Tenn. Code Ann. @ 39-15-202 (1994)

39-15-202. Consent of pregnant woman required prior to abortion -- Information provided by doctor -- Waiting period -- Penalty for violation -- Notice to parents or guardians -- Requirements inapplicable in certain cases

(a) An abortion otherwise permitted by law shall be performed or induced only with the informed written consent of the pregnant woman, given freely and without coercion. Such consent shall be treated as confidential.

(b) In order to ensure that a consent for an abortion is truly informed consent, an abortion shall be performed or induced upon a pregnant woman only after she has been orally informed by her attending physician of the following facts and has signed a consent form acknowledging that she has been informed as follows:

(1) That according to the best judgment of her attending physician she is pregnant;

(2) The number of weeks elapsed from the probable time of the conception of her unborn child, based upon the information provided by her as to the time of her last menstrual period or after a history, physical examination, and appropriate laboratory tests;

(3) That if more than twenty-four (24) weeks have elapsed from the time of conception, her child may be viable, that is, capable of surviving outside of the womb, and that if such child is prematurely born alive in the course of an abortion her attending physician has a legal obligation to take steps to preserve the life and health of the child;

(4) That abortion in a considerable number of cases constitutes a major surgical procedure;

(5) That numerous public and private agencies and services are available to assist her during her pregnancy and after the birth of her child, if she chooses not to have the abortion, whether she wishes to keep her child or place him for adoption, and that her physician will provide her with a list of such agencies and the services available if she so requests; or

(6) Numerous benefits and risks are attendant either to continued pregnancy and childbirth or to abortion depending upon the circumstances in which the patient might find herself. The physician shall explain these benefits and risks to the best of his ability and knowledge of the circumstances involved.

(c) At the same time the attending physician provides the information required by subsection (b), he shall inform the pregnant woman of the particular risks associated with her pregnancy and childbirth and the abortion or child delivery technique to be employed, including providing her with at least a general description of the medical instructions to be followed subsequent to the abortion or childbirth in order to ensure her safe recovery.

(d) (1) There shall be a two (2) day waiting period after the physician provides the required information, excluding the day on which such information was given. On the third day following the day such information was given, the patient may return to the physician and sign a consent form.

(2) A violation of this subsection by a physician is a Class E felony.

(3) This subsection shall not apply when the attending physician, utilizing his experience, judgment, or professional competence, determines that a two (2) day waiting period or any waiting period would endanger the life of the pregnant woman. Such determination made by the attending physician shall be in writing and shall state his medical reasons upon which he bases his opinion that the waiting period would endanger the life of the pregnant woman. This provision shall not relieve the attending physician of his duty to the pregnant woman to inform her of the facts under subsection (b).

(e) The attending physician performing or inducing the abortion shall provide the pregnant woman with a duplicate copy of the consent form signed by her.

(f) (1) The attending physician or agency performing an abortion upon a minor of less than eighteen (18) years of age shall inform the parents or legal guardians of such minor, or if the whereabouts of the parents cannot be determined and there is no other legal guardian, then the agency or other individual to whom the minor's custody has been transferred, two (2) days prior to the operation that an abortion is to be performed upon such minor; provided, however, that the provisions of this section shall in no way be construed to mean, provide for, or authorize parental objection to, in any way, prevent or alter the decision of the minor to proceed with the abortion.

(2) Notice shall not be required if:

(A) The minor is emancipated by marriage; or

(B) The attending physician determines that, in his best medical judgment, the abortion is necessary to preserve the life or health of the pregnant woman and must be performed prior to the expiration of the two (2) day notice period.

(g) "The physician" or "the attending physician," as used in this section, means any licensed physician on the service treating the pregnant woman.

(h) The provisions of this section shall not apply in those situations where an abortion is certified by a licensed physician as necessary to preserve the life of the pregnant woman.

HISTORY: Acts 1989, ch. 591, @ 1.

NOTES:

SENTENCING COMMISSION COMMENTS. Chapter 15, part 2 of this title is identical to prior code ch. 4, part 2 of this title. No substantive changes were made in these sections.

CROSS-REFERENCES. Infants prematurely born alive during abortion, @@ 39-15-206, 39-15-207.

Parental consent for abortion by minor, title 37, ch. 10, part 3.

Penalty for Class E felony, @ 40-35-111.

TEXTBOOKS. Tennessee Criminal Practice and Procedure (Raybin), @ 28.92.

LAW REVIEWS. Right to Privacy -- Parental Notice Requirements in Abortion Statutes, 48 Tenn. L. Rev. 974.

CITED: Planned Parenthood Ass'n of Nashville, Inc. v. McWherter, 923 F.2d 474 (6th Cir. 1991).

NOTES TO DECISIONS

1. SECTION 37-10-303 REPEALED BY IMPLICATION.

This section has had the effect of repealing @ 37-10-303 by implication, and unless and until subsection (f) is successfully challenged in court on constitutional grounds, it represents the current state of the law in Tennessee with regard to abortions performed on minors. Planned Parenthood Ass'n v. McWherter, 817 S.W.2d 13 (Tenn. 1991).

USER NOTE: For more generally applicable notes, see notes under the first section of this subpart, part, chapter, or title.

DATE: FEBRUARY 9, 1995

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39-4-202

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1ST CASE of Level 1 printed in FULL format.

PLANNED PARENTHOOD ASSOCIATION OF NASHVILLE, INC., MEMPHIS
PLANNED PARENTHOOD, INC., and PETER CARTWRIGHT, M.D.,
Plaintiffs-Appellees, v. NED R. NCWHERTER, GOVERNOR, and
CHARLES W. BURSON, ATTORNEY GENERAL, STATE OF TENNESSEE,
Defendants-Appellants

PLANNED PARENTHOOD ASSN. OF NASHVILLE, INC. v. NCWHERTER

No. 01-S-01-9101-01-0004

Supreme Court of Tennessee, at Nashville

817 S.W.2d 13; 1991 Tenn. LEXIS 347

September 9, 1991, Filed

SUBSEQUENT HISTORY: Rehearing Denied October 14, 1991, Reported at 1991 Tenn. LEXIS 428.

PRIOR HISTORY: Certified Question from the United States Court of Appeals for the Sixth Circuit.

COUNSEL: [**1]

For the Appellees: BARBARA E. OTTEN, ROGER K. EVANS, DARA KLASSEL, New York City, New York, LARRY WOODS, IRWIN VENICK, Nashville, Tennessee.

For the Appellants: CHARLES W. BURSON, Attorney General & Reporter, JOHN KNOX WALKUP, Solicitor General, ANDY D. BENNETT, MICHAEL W. CATALANO, Deputy Attorneys General, Nashville, Tennessee.

Of Counsel: EDWARD KAPLAN, TERESA J. SIGMON, Memphis, Tennessee, BARRY FRIEDMAN, Nashville, Tennessee.

JUDGES: Martha Craig Daughtrey, J. Ried, C.J., Drowota, O'Brien, Anderson, JJ., concur.

OPINIONBY: DAUGHTREY

OPINION: [*13] OPINION

This matter is before us on a certified question of law referred from the United States Court of Appeals for the Sixth Circuit. That court has asked us to render an opinion on the relative validity of two conflicting Tennessee statutes, T.C.A. @@ 37-10-301 through 370, requiring "parental consent for abortions by minors," and T.C.A. @ 39-15-202(f), requiring "notice to parents or guardians" or minors seeking an abortion. The two statutes were enacted by the Tennessee General Assembly in 1988 and 1989, respectively. We conclude that the more recent statute has had the effect of repealing the prior statute by implication and, further, that unless [**2] and until T.C.A. @ 39-15-202(f) is successfully challenged in court on constitutional grounds, it represents the current state of the law in Tennessee with regard to abortions performed on minors.

BACKGROUND

Pursuant to the provisions of Chapter 334 of the Public Acts of 1979, the Tennessee General Assembly enacted the following requirement regarding parental notification of intent to perform an abortion on an unemancipated minor:

The attending physician or agency performing an abortion upon a minor of less than eighteen (18) years of age shall [*14] inform the parents or legal guardians of such minor, or if the whereabouts of the parents cannot be determined and there is no other legal guardian then the agency or other individual to whom the child's custody has been transferred, two (2) days prior to the operation that an abortion is to be performed upon such minor. Provided, however, the provisions of this Act shall in no way be construed to mean, provide for, or authorize parental objection to, in any way, prevent or alter the decision of the minor to proceed with the abortion.

This act became effective on July 1, 1979. On October 24, 1979, however, the Davidson County [*3] Chancery Court granted summary judgment in favor of plaintiffs seeking to have the notification provisions declared unconstitutional. Planned Parenthood of Nashville v. Lamar Alexander, Davidson Chancery No. 79-843-II. That order was never appealed, however, and the statute was codified and subsequently carried on the books as T.C.A. @ 39-4-202(f). n1

- - - - -Footnotes- - - - -

n1 In a memorandum dated October 24, 1979, the chancellor indicated that he was granting the plaintiffs' motion for summary judgment because the state had "advised the Court of its intent not to defend the constitutionality of [the notification statute] . . . based upon a series of United States Supreme [Court] decisions, including the recent holding in Bellotti v. Baird, 47 U.S.L.W. 4969 (July 2, 1979)." As it turns out, the Bellotti opinion, later reported at 443 U.S. 622 (1979), concerned the constitutionality of a parental consent statute, not a notification statute, and mustered only a plurality of four justices on the United States Supreme Court. The ruling of the chancellor on the motion for summary judgment was not appealed. As a result, the parental notification act was still on the books at the time it was repealed by implication in 1988.

- - - - -End Footnotes- - - - -

[**4]

In its 1988 session, the legislature amended Tennessee's juvenile law statutes by enacting T.C.A. @@ 37-10-301 et seq. Pursuant to this legislation, written consent from both parents was required before an abortion could be performed on a minor. The minor, however, could seek to "bypass" the parental consensual requirement by petitioning the juvenile court for a waiver of the statutory duty. T.C.A. @ 37-10-303(c).

Under the terms of Chapter 929 of the Public Acts of 1988, this parental consent statute took effect on July 1, 1989. However, a few weeks later it was declared unconstitutional in federal district court in Nashville, on the ground that language relieving the physician of the obligation to notify a parent who was "not available to the person performing the abortion . . . in a reasonable time or manner" was too vague to comport with due process. Planned Parenthood Association of Nashville et al. v. Ned McWherter et al., United States

District Court for the Middle District of Tennessee, No. 3-89-0520, 716 F. Supp. 1064 July 20, 1989 (emphasis added). That ruling was appealed to the Sixth Circuit Court of Appeals and forms the basis for the current certification request to [**5] this Court.

The specific question before us arose because of legislative action which intervened between the time the 1988 statute was declared invalid by the federal district court and the time the appeal was heard by the Sixth Circuit Court of Appeals.

That intervening action occurred on May 24, 1989, when the legislature enacted Chapter 591 of the Public Acts of 1989, which revised Tennessee's criminal laws and sentencing procedures. As part of this massive revision, the General Assembly passed what has since been codified as T.C.A. @ 39-15-202(f). That statute is, in all pertinent respects, identical to the provisions of T.C.A. @ 39-1-202(f), quoted above, which was first enacted ten years earlier. The parental notification requirements of T.C.A. @ 39-15-202(f) became effective on November 1, 1989.

THE CERTIFIED QUESTION

Faced with what appeared to be conflicting statutes on the same subject, the Sixth Circuit Court of Appeals thereafter referred the following question of state law to this Court:

Before ruling on the constitutionality of the [1988] consent statute, this Court needs to know the effect, if any, of the later [1989] notification statute, Tenn. [*15] Code [**6] Ann. @ 39-15-202(f), on the earlier [1988] consent statute, Tenn. Code Ann. @@ 37-10-301 through 307. Which of the provisions of the two statutes respecting parental notification and consent, if any, is in effect under Tennessee statutory and constitutional principles of interpretation?

ANALYSIS

An examination of the Tennessee statutory scheme regarding abortions performed on unemancipated minors reveals that the provisions of Tennessee's 1988 parental consent statute, T.C.A. @ 39-10-303, are in direct conflict with the provisions of Tennessee's 1989 parental notification statute. T.C.A. @ 39-15-202(f). T.C.A. @ 39-10-303(a) provides explicitly that no abortion shall be performed on an unemancipated minor (except when the judicial bypass procedures are invoked) unless "the written consent of both parents or the legal guardian of the minor" is obtained. In contrast, T.C.A. @ 39-15-202(f)(1), while requiring notification to the parents or legal guardian of an unemancipated minor two days prior to an abortion, clearly forbids that the requirement "be construed to mean, provide for or authorize parental objection to, in any way, prevent or alter the decision of the minor [**7] to proceed with the abortion." In other words, while the 1988 consent statute requires parental consent before the performing of an abortion on an unemancipated minor not invoking the judicial bypass provisions, the 1989 notification statute forbids the withholding of an abortion based on lack of such parental consent.

The principle of statutory construction is well-established in Tennessee that the courts should construe statutes so as to avoid placing one statute in conflict with another. Parkridge Hospital, Inc., v. Woods, 561 S.W.2d 754,

755 (Tenn. 1978). However, it is equally well-settled that in the event of an irreconcilable conflict, or "[where] two statutes cover the same subject matter, the last enactment repeals the former by implication." *Steinhouse v. Neal*, 723 S.W.2d 625, 627 (Tenn. 1987). Such repeals are commonly said to be "disfavored" by the law and are recognized only to the extent of actual conflict. See, e.g., *Reams v. Trostel Mechanical Industries*, 522 S.W.2d 170, 173 (Tenn. 1975). However, statutory repeal by implication is recognized as a "matter of necessity," *English v. Farrar*, 206 Tenn. 188, 332 S.W.2d 215, 219 (1960), [**8] and sometimes even as a matter of legislative intent. *Hart v. Pierce*, 169 Tenn. 411, 88 S.W.2d 798, 800 (1935).

Despite the absence of an explicit repealer bill, there can be little question about legislative intent with regard to the two conflicting statutes involved here. During the floor debate on the 1989 notification bill, the Senate discussed and adopted an amendment, part of which eventually became T.C.A. @ 39-15-202(f). The following exchange occurred during that discussion:

SENATOR HENRY: Mr. Speaker, one item I forgot to ask Senator Haynes. [The amendment] replaces both the law of abortion and the law of parental consent, is that correct, Senator Haynes?

SENATOR HAYNES: That is correct, Senator Henry.

Senate Session, May 10, 1989 (Tape S-91) (emphasis added).

Despite the fact that the legislature has clearly manifested its intent that the parental notification provisions of the 1989 statute "replace" the 1988 parental consent requirement, the Attorney General argues that this Court may not give effect to those 1989 provisions. According to the Attorney General's argument, the parental notification requirement is identical [**9] to the former notification provisions of T.C.A. @ 39-4-202(f) that were held to be unconstitutional by the Davidson County Chancery Court back in 1979. As a result, the Attorney General argues, the 1989 statute is also unconstitutional on its face, is void ab initio, and cannot replace the 1988 parental consent requirements.

In support of his position, the Attorney General cites the cases of *Franks v. State*, 772 S.W.2d 428 (Tenn. 1989), *Leech v. American Booksellers Assn.*, 582 S.W.2d 738 (Tenn. 1979), and *McMinn County Board of Education v. Anderson*, 200 Tenn. 333, 292 S.W.2d 198 (1956). In *Franks*, we recognized that "an unconstitutional act is not a law . . . [but is] inoperative as though it had never been passed." 772 S.W.2d at 431. Likewise, in *Leech*, we concluded that "[an] unconstitutional act that purposes to supersede or repeal an existing law is ineffective to do so, since a void law has no force and effect." 582 S.W.2d at 740 (citing *State v. Dixon*, 530 S.W.2d 73, 74-75); accord *McMinn County Board of Education*, supra, 200 Tenn. at 336-37, 292 S.W.2d at 199. [**10] In each of those cases, however, the plaintiff actually brought suit challenging the constitutionality of the statute, so as to place the enactment before the courts for review.

By contrast, the constitutionality of the 1989 notification statute has not yet been challenged in this or any other court. Consequently, "[because] of the presumption in favor of the constitutionality of statutes, the public and individuals are bound to observe a statute though unconstitutional until it is

817 S.W.2d 13, *16; 1991 Tenn. LEXIS 347, **10

declared void by an authoritative tribunal." *Franks v. State*, supra, 772 S.W.2d at 431 (emphasis added; citing *O'Brien v. Rutherford County*, 199 Tenn. 642, 288 S.W.2d 708 (1956)). See also *Bayless v. Knox County*, 199 Tenn. 268, 279, 286 S.W.2d 579, 584 (1955).

The fact that a prior notification statute was determined to be unconstitutional by a trial-level court some 12 years ago does not overcome the presumption that the law reenacted in 1989 is constitutionally valid. Because of that presumption and because of potential changes in the interpretation of constitutional principles over the years, we conclude [**11] that a reenacted provision of a statute must be challenged in a lawsuit before being declared invalid by a court. We therefore reject the state's invitation to hold the 1989 notification statute unconstitutional, and we suggest instead that in the absence of a proper court challenge, the issue is currently nonjusticiable.

CONCLUSION

Our response to the question put to us by the Sixth Circuit Court of Appeals is as follows:

Because of an irreconcilable conflict between the provisions of the 1988 parental consent statute, T.C.A. @ 37-10-303, and those of the 1989 parental notification statute, T.C.A. @ 39-15-202(f), the latter statute has effectively repealed the former by implication. Under Tennessee principles of statutory construction and constitutional interpretation, the provisions of T.C.A. @ 39-15-202(f) must be considered valid, unless and until they are successfully challenged before a court having jurisdiction to rule on their validity. We decline to deliver an advisory opinion on the constitutionality of either statute.

The clerk is directed to submit this opinion under seal to the Chief Judge of the United States Court of Appeal for the Sixth Circuit, in conformity [**12] with Rule 23, Section 8 of the Rules of the Supreme Court. Any costs will be divided equally between the parties.

DATE: FEBRUARY 9, 1995

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TITLE 68. HEALTH, SAFETY AND ENVIRONMENTAL PROTECTION
HEALTH
CHAPTER 34. FAMILY PLANNING

Tenn. Code Ann. @ 68-34-103 (1994)

68-34-103. Declaration of policy

It is the legislative declaration of the general assembly that:

(1) Continuing population growth either causes or aggravates many social, economic and environmental problems, both in this state and in the nation;

(2) Contraceptive procedures, supplies, and information, and information as to and procedures for voluntary sterilization, are not sufficiently available as a practical matter to many persons in this state;

(3) It is desirable that inhibitions and restrictions be eliminated so that all persons desiring and needing contraceptive procedures, supplies, and information shall have ready and practicable access thereto; and

(4) Section 68-34-104 sets forth the policy and authority of this state, its political subdivisions, and all agencies and institutions thereof, including prohibitions against restrictions, with respect to contraceptive procedures, supplies and information.

HISTORY: Acts 1971, ch. 400, @ 1; T.C.A., @ 53-4603.

USER NOTE: For more generally applicable notes, see notes under the first section of this subpart, part, chapter, or title.

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TITLE 68. HEALTH, SAFETY AND ENVIRONMENTAL PROTECTION
HEALTH
CHAPTER 34. FAMILY PLANNING

Tenn. Code Ann. @ 68-34-104 (1994)

68-34-104. Contraceptives -- Availability -- Information -- Religious belief

It is the policy and authority of this state that:

- (1) All medically acceptable contraceptive procedures, supplies, and information shall be readily and practicably available to each and every person desirous of the same regardless of sex, race, age, income, number of children, marital status, citizenship or motive;
- (2) Contraceptive procedures, including medical procedures for permanent sterilization, when performed by a physician on a requesting and consenting patient, are consistent with public policy;
- (3) Nothing herein shall inhibit a physician from refusing to furnish any contraceptive procedures, supplies or information where such refusal is for medical reasons;
- (4) Dissemination of medically acceptable contraceptive information by duly authorized persons in state and county health and welfare departments, in medical facilities at institutions of higher learning, and at other agencies and instrumentalities of this state is consistent with public policy;
- (5) No private institution or physician, nor any agent or employee of such institution or physician, shall be prohibited from refusing to provide contraceptive procedures, supplies, and information when such refusal is based upon religious or conscientious objection, and no such institution, employee, agent, or physician shall be held liable for such refusal; and
- (6) To the extent that family planning funds are available, each public health agency of this state and each of its political subdivisions shall provide contraceptive procedures, supplies, and information, including voluntary sterilization procedures for male or female persons eligible for free medical service as determined by rules and regulations promulgated by the commissioner. The same service shall be available to all others who are unable to obtain the service privately, at a cost to be determined by rules and regulations promulgated by the commissioner.

HISTORY: Acts 1971, ch. 400, @ 1; T.C.A., @ 53-4604.

NOTES:

SECTION TO SECTION REFERENCES. This section is referred to in @ 68-34-103.

Tenn. Code Ann. @ 68-34-104 (1994)

CITED: Cardwell v. Bechtol, 724 S.W.2d 739 (Tenn. 1987).

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724 S.W.2d 739 printed in FULL format.

WILMA CARDWELL and ROBERT CARDWELL, Individually and as
Mother and Father and Next Friend of SANDRA K. CARDWELL, and
SANDRA K. CARDWELL, Individually, Plaintiffs-Appellees, v.
Dr. E. L. BECHTOL, Defendant-Appellant

CARDWELL v. BECHTOL

No. 36

Supreme Court of Tennessee

724 S.W.2d 739; 67 A.L.R.4th 479

February 9, 1987, Filed

PRIOR HISTORY:

ANDERSON LAW

Hon. James B. Scott, Jr., Judge.

DISPOSITION: COURT OF APPEALS REVERSED IN PART AND AFFIRMED IN PART; JUDGMENT OF
THE TRIAL COURT REINSTATED; DISMISSED.

COUNSEL: John H. Hogin, Margaret G. Klein, for Appellant.

Kenneth E. Hall, T. Harold Pinkley, for Appellee.

JUDGES: Drowota, J., Brock, C.J., Fones, Harbison and Cooper, JJ., Concur.

OPINIONBY: DROWOTA

OPINION: [*741] OPINION

DROWOTA, J.

An issue of first impression in Tennessee is raised in this appeal as to whether Tennessee should adopt a mature minor exception to the common law rule that requires a physician to obtain parental consent before treating a minor. This case arose out of treatment administered by Defendant, Dr. E. L. Bechtol, to Sandra K. Cardwell, the daughter of Robert and Wilma Cardwell. Defendant is a doctor of osteopathy. At the time of treatment, Sandra Cardwell was a minor. The suit was instituted by the Plaintiffs, Sandra Cardwell, individually, and by her parents, both individual and as next friends on behalf of their daughter.

While Sandra Cardwell (Ms. Cardwell) was attending high school, she had suffered from persistent but intermittent back pain. She first saw her family physician in the summer of 1981 for this problem. Subsequently, in early October, 1981, she went to the Knoxville Orthopedic Clinic where she was seen by Dr. Stevens. His preliminary diagnosis was that she was displaying symptoms associated with a herniated disc; he recommended that she be hospitalized for further tests and therapy. Her parents decided to obtain a second opinion before acceding to hospitalization and she went to see Dr. McMahon, an orthopedic specialist, in Oak Ridge on October 15, 1981; he concurred in the diagnosis

and recommendation of Dr. Stevens.

On November 9, 1981, she was hospitalized at St. Mary's Medical Center in Knoxville. She was attended by Doctors Stevens and Wallace and underwent conservative treatment consisting primarily of physical therapy and injections. A recommended myelogram was rejected by her parents. A conservative course of treatment was continued following her discharge from the hospital on November 16, 1981. Dr. Sidney Wallace assumed treatment of Ms. Cardwell; he saw her several more times during the remainder of 1981 and in the early months of 1982. Apparently, both Ms. Cardwell and her parents hoped to avoid any necessity to resort to surgery.

Although her condition did not bother her continuously and she was usually able to participate in her normal high school activities, she was not obtaining any significant relief for her pain, despite the therapy and treatment she received under Dr. Wallace's care. In March, 1982, Dr. Wallace again recommended pre-surgical, diagnostic testing to identify definitely the nature of the problem, but Ms. Cardwell and her parents evidently continued to resist consideration of surgery. On April 26, 1982, having taken her mother's car to school, Ms. Cardwell left school early and went to see the family physician for treatment of a sore throat. With her mother's permission, she went to the family doctor's office alone. After her appointment with this doctor, she spontaneously decided that she would go to see Defendant, an osteopath who had treated her father's back condition on several occasions in the past. She had not told her parents that she was going to see Defendant but decided to do so on this day because her back was hurting her.

Defendant is a licensed osteopath but because he has been blind for most of his life, he limits his practice to manipulative treatments to adjust or realign the skeletal system. He conducts his sole practice with the assistance of his wife and daughter, who maintain his records. He was alone in his office when Ms. Cardwell came to see him. She told Defendant her name and that her father had been one of his patients; she also informed him of her symptoms and of the diagnoses of the orthopedic specialists she had seen. Defendant concluded, after examining her briefly, that a herniated disc was not her problem and treated her with manipulations involving [*742] her neck, spine, and legs for subluxation of the spine and bilateral sacroiliac slip. The treatment lasted for about 15 minutes, after which he asked her to return several times during the next few weeks for further manipulations. Ms. Cardwell wrote her name, age, and address down on a card Defendant supplied for this purpose and then paid his fee of \$25.00 with one of her father's blank, signed checks, which had been given to her to be used when she needed money.

After Ms. Cardwell left Defendant's office, she began to experience a tingling and numbing sensation in her legs. She drove to her aunt's house and lay down to take a nap. She was awakened by severe pain about an hour later. The pain was such that she had difficulty walking, but having driven her mother's car, she was obligated to pick her up from work. She found she had difficulty driving and when she reached her mother's place of employment, her pain had become very intense. By the time she and her mother arrived at home, she was no longer able to walk by herself. Later in the evening, she was driven to the emergency room at St. Mary's Medical Center in Knoxville and was subsequently admitted. Over the course of the evening, she also developed urinary retention problems and had to be catheterized.

During the next few days, she underwent diagnostic testing, which confirmed that she had a herniated disc, and a laminectomy was performed on April 29, 1982. Although no visible nerve damage was apparent, she continued to experience bladder and bowel retention and had continued difficulty walking as well as decreased sensation in her legs and buttocks. Her condition has improved gradually since her surgery, but she had not yet regained normal bowel control or complete sensation in her buttocks and one of her legs at the time of trial.

This action was filed on April 22, 1983, in Anderson County Circuit Court. The initial complaint alleged only medical malpractice (in the diagnosis and treatment of Ms. Cardwell's condition but the complaint was subsequently amended to include counts of battery (failure to obtain parental consent), negligent failure to obtain consent, and failure to obtain informed consent. The case was tried from September 25 to 27, 1984. At the close of the Plaintiffs' evidence, Defendant's Motion for a Directed Verdict on the medical malpractice issue was granted by the trial court because Plaintiffs had failed to carry their burden of proof under T.C.A. @29-26-115, which requires that a plaintiff in a medical malpractice suit produce expert testimony on the local standard of care of a physician in a practice or specialty relevant to the treatment performed by the defendant. The remaining issues of battery and informed consent were submitted to the jury; the jury instructions included the mature minor exception to the requirement of parental consent to perform medical treatment on a minor. A general verdict was returned for Defendant.

On appeal, the Eastern Section affirmed the trial court's directed verdict on the malpractice count, holding that Plaintiffs' expert witness, an orthopedic surgeon, was not qualified by his own admission to testify regarding the standard of care of an osteopath in this situation, and thus the trial court did not abuse its discretion in disqualifying his testimony. Nevertheless, the Court of Appeals reversed on the issue of battery because neither the Tennessee Legislature nor the Tennessee Supreme Court had adopted the mature minor exception to the established common law rule that a physician cannot treat minors without parental consent. Having directed a verdict on its finding of a technical battery, the intermediate court determined that it had no choice but to reverse and remand the case for a new trial solely on the issue of damages.

A timely Application for Permission to Appeal was filed by the Defendant and was granted by this Court. We now reverse the Court of Appeals on the issue of battery and reinstate the judgment of the trial court. The issues presented on appeal concern the capacity of a mature minor to give informed consent to medical treatment under the mature minor exception and the requirements of expert testimony under [*743] the Medical Malpractice Statute, T.C.A. @29-26-115 and 29-26-118.

I. The Mature Minor Exception

A.

On April 26, 1982, the date of Ms. Cardwell's treatment by Defendant, she was 17 years, 7 months of age, a senior in high school with good grades, and was planning to attend college. She had been licensed to drive since she was 16 years old. As a routine practice from the time she was 14 years old, she had permission to use her father's checking account; she carried several signed, blank checks in lieu of cash and had been very responsible in the exercise of this privilege. Testimony consistently characterized Ms. Cardwell as a mature

young woman who acted somewhat older than her age. Her parents permitted her substantial discretion because of her demonstrated maturity.

On the day she went to see Defendant, she had taken her mother's car so that she could go by herself to see the family physician about a sore throat. She had left school early and with her parents' permission had gone to this doctor's office alone, where she was examined and treated by the family doctor, who had not personally obtained parental consent. She decided to see Defendant on her own initiative because she knew her father had been to see him and she thought that Defendant might be able to provide some relief for her back pain. She had not told her parents that she was going to see Defendant and apparently had not been encouraged to do so by her parents. Although she did not know exactly what manipulative therapy involved, she was generally aware of the kind of practice an osteopath had. She also testified that Defendant did not treat her against her will.

Defendant testified that Ms. Cardwell seemed to him to be a mature young woman. While generally minors are accompanied by adults when they come to him for treatment, and parental consent is ordinarily obtained for treatment, Ms. Cardwell's demeanor led him to think that she was of age and that she had come to him because he had previously treated her father. He did not believe it was necessary to inquire about parental consent in this case.

B.

Plaintiffs argue that no effective consent was obtained by Defendant either from Ms. Cardwell herself or from her parents, actually or impliedly, resulting in a technical battery. Moreover, because no exception to the common law rule has been adopted by the Tennessee Legislature, except in specific statutes that are inapplicable to this case, Plaintiffs contend that the Legislature has implicitly fixed as the immutable law of this State the general common law rule that parental consent is required before a physician can treat a minor. Apparently, Plaintiffs' position is that the development of the common law has been arrested by these narrowly drawn statutory exceptions to the general common law rule embodied in the statutes.

That Tennessee is a common law state is clearly established. See, e.g., *State v. Alley*, 594 S.W.2d 381 (Tenn. 1980); *Powell v. Hartford Accident and Indemnity Co.*, 217 Tenn. 503, 398 S.W.2d 727 (1965); *Henley v. State*, 98 Tenn. 665, 41 S.W. 352 (1897). As a general principle, however, judicial development of the common law is not arrested by piece-meal legislative adoption of specific statutory exceptions to a general common law rule.

"If the statute does not include and cover such a case, it leaves the law as it was before its enactment. It is well settled that a statute will not be construed to alter the common law, further than the act expressly declares or than is necessarily implied from the fact that it covers the whole subject-matter." *State v. Cooper*, 120 Tenn. 549, 553, 113 S.W. 1048, 1049."

Olsen v. Sharpe, 191 Tenn. 503, 507, 235 S.W.2d 11, 12 (1950). This Court has consistently recognized that the "rule of reason is one of the bases of the common law and it is also founded on usages, habits and customs and will never be entirely statutory, but will be modified and extended by analogy, construction and custom so as to [*744] embrace new relations springing up from time to time to conform with the change and desire of society. *Jacob v.*

State, 22 Tenn. 493 (1842)." Powell v. Hartford Accident and Indemnity Co., supra, 217 Tenn. at 509-510, 398 S.W.2d at 730. Further,

"the common law binds courts only less firmly than statutes. Its rules are gradually, almost imperceptibly, enlarged or contracted by the courts, by construction, in the course of their application to new states of fact, to meet the needs of a progressive civilization but it is not allowable to change them per saltum. This can be done only by legislation."

Northcut v. Church, 135 Tenn. 541, 556, 188 S.W. 220, 223 (1916). To a great extent, the common law originated in court-fashioned rules, and inherent in the jurisprudence of the common law is the power of courts to develop and adapt the principles of its application.

In other areas, this Court has not failed to continue the evolution of the common law where the subject is not clearly covered by statutory law. See, e.g., Davis v. Davis, 657 S.W.2d 753 (Tenn. 1983) (Allegation of the prior common law doctrine of interspousal tort immunity); Arnold v. Hayslett, 655 S.W.2d 941 (Tenn. 1983) (A minor is capable of contributory fault); Powell v. Hartford Accident and Indemnity Co., supra (Same duty of care to be imposed on all persons operating motor vehicles, regardless of age); Walker v. Hamby, 503 S.W.2d 118 (Tenn. 1973) (Assumption of risk by minor recognized). Where the Legislature has not expressly acted to occupy the area held by the common law, nothing we have discovered in our jurisprudence requires "the closing of doors to changed conditions" as long as "the decisions of the court [are] so fashioned that the new truly grows out of the old as the product of a changed environment." Powell v. Hartford Accident and Indemnity Co., supra, 217 Tenn. at 513, 398 S.W.2d at 732. One of the great attributes of Anglo-American common law has been the flexibility demonstrated by the case by case judicial development of the principles and rules of the common law to adapt to the emerging conditions of society; this flexibility permits the law to remain relevant and reasonable, preventing "mindless obedience to [a] precept [that] can confound the search for truth and foster an attitude of contempt." Davis v. Davis, supra, at 758. Cf. Kilbourne v. Hanzelik, 648 S.W.2d 932, 934 (Tenn. 1983) ("[W]e abdicate our own function, in a field peculiarly non-statutory, when we refuse to consider an old and unsatisfactory court-made rule.") (citation omitted).

C.

While we acknowledge that the Legislature has enacted several statutes concerning medical treatment of minors without parental consent, see T.C.A. §§39-4-202, 68-34-104, 68-34-107, 63-6-220, 63-6-222, and 63-6-223, these statutes are either a "statutory enactment of the common law rule," State v. Alley, supra, at 382 (citation omitted), in the case of emergency treatment of minors, or are statutes in derogation of the common law and will thus be strictly construed and confined to their express terms. Austin v. County of Shelby, 640 S.W.2d 852, 854 (Tenn. App.), permission to appeal denied (Tenn. 1982). See also, e.g., Olsen v. Sharpe, supra, 191 Tenn. at 507, 235 S.W.2d at 12. We find no indication in any of the statutes of any intent on the part of the Legislature to establish a comprehensive statutory scheme to occupy the area of medical treatment of minors in its entirety. On the contrary, these statutes do no more than provide conditional immunities from certain types of liability in specific situations (where such immunities were not otherwise clear in the law) or promote certain social purposes, such as treatment of drug abuse or venereal disease in minors. We do not think that the conclusion that these

statutes are intended to abrogate judicial adoption of an exception to the general common law rule requiring parental consent to treat minors can be supported by the express terms of any of these provisions.

Furthermore, recognition that minors achieve varying degrees of maturity and responsibility (capacity) has been part of [*745] the common law for well over a century. See, e.g., *The Queen v. Smith*, 1 Cox C.C. 260 (1845); 42 Am. Jur.2d, Infants, @9, 45, 142. The rule of capacity has sometimes been known as the Rule of Sevens: under the age of seven, no capacity; between seven and fourteen, a rebuttable presumption of no capacity; between fourteen and twenty-one, a rebuttable presumption of capacity. In Tennessee and elsewhere, the rule of capacity of minors has been generally applied in criminal cases. See, e.g., *Colley v. State*, 179 Tenn. 651, 169 S.W.2d 848 (1943); *Juvenile Court of Shelby County v. State ex rel. Humphrey*, 139 Tenn. 549, 201 S.W. 771 (1918). The Rule of Sevens has been applied in the context of torts as well. See, e.g., *Walker v. Hambry*, supra; *Bailey v. Williams*, 48 Tenn. App. 320, 346 S.W.2d 285 (1960), cert. denied (Tenn. 1961). The competency of minors to testify as witnesses has also been measured by the common law Rule of Sevens. See, e.g., *State v. Fears*, 659 S.W.2d 370 (Tenn. Crim. App. 1983).

In addition, the Legislature has enacted several statutes that are consistent with or merely codify the Rule of Sevens established at common law. Under T.C.A. @37-1-134(a), a minor may be tried as an adult in criminal cases if the "child was sixteen (16) years or more of age at the time of the alleged conduct, or the child was more than fourteen (14) years of age if such child was charged with [certain violent crimes]." A minor may obtain a driver's license at 16, but may obtain a learner's permit at age 15 or a special restricted license between the ages of 14 and 16; however a chauffeur's license may not be given to anyone under 18. See T.C.A. @@55-7-104 and 55-7-105. These statutes clearly recognize the varying degrees of responsibility and maturity of minors 14 years and older.

T.C.A. @@1-3-105(1) and 1-3-113(a) now establish the age of majority in this State as 18 years old, except for the purpose of the purchase of alcoholic beverages. That the Legislature has adopted a lower age for attainment of majority indicates persuasively that conditions in society have changed to the extent that maturity is now reached at earlier stages of growth than at the time that the common law recognized the age of majority at 21 years. The conditions and reasons that made 21 the age of majority have been eroded over time. Moreover, the enactment of statutes establishing specific exceptions to the general common law regarding medical treatment of minors also tends to show that the attitudes and customs of society concerning the relative maturity of minors have changed. In any case, these statutory exceptions for medical treatment of minors without parental consent can apply whether the minor is 17 years, eight years, or one year old, although as a practical matter many such statutes will not usually be invoked except in cases of older minors. The mature minor exception, however, is limited by the application of the Rule of Sevens and is an exception to the general rule that parental consent is required to treat minors. n1

n1. T.C.A. @34-1-101 provides that parents are the natural guardians of their minor children, charged with their care, nurture welfare, education, and support.

D.

Adoption of the mature minor exception to the common law rule is by no means a general license to treat minors without parental consent and its application is dependent on the facts of each case. It must be seen in the context of the tort in question. At this point in the analysis, the issue is whether Ms. Cardwell had the capacity to consent to the treatment administered by Defendant. n2 If Ms. Cardwell had the capacity to consent, then her informed consent would be effective to negate any battery committed by Defendant in the course of his treatment of her. The Second Restatement of Torts, §892, states:

[*746] (1) Consent is willingness in fact for conduct to occur. It may be manifested by action or inaction and need not be communicated to the actor.

(2) If words or conduct are reasonably understood by another to be intended as consent, they constitute apparent consent and are as effective as consent in fact.

n2. For the purposes of this opinion, the related question of whether her consent was not effective, not because she lacked capacity but because she was not sufficiently informed, is considered as a separate issue, which is discussed below.

Plaintiffs contend that Ms. Cardwell failed to consent, even if she had the capacity to do so. A person may, however, consent by conduct. By presenting herself to Defendant for examination and treatment and then by submitting to treatment without protest or resistance, Defendant could reasonably conclude that he had Ms. Cardwell's consent to the treatment. "Consent is regarded as present, also, when one manifests a willingness that the defendant engage in conduct and the defendant acts in response to such a manifestation." Prosser and Keeton, Torts (5th edition, West 1984) §18, p. 113. From Ms. Cardwell's conduct in Defendant's office and by her own testimony, the jury could conclude that she had consented to the treatment. Thus, her capacity to give effective consent is determinative. If she had this capacity, the issue of whether parental consent, implied or actual, was given is pretermitted.

The trial court instructed the jury on the general rule that parental consent, whether implied or actual, is required to treat a minor; the mature minor exception was also included by the trial court and had been specifically requested by the Defendant; it was stated by the trial court as follows:

"One exception to the [general] rule has been recognized when the child is close to majority or maturity and knowingly gives an informed consent to the treatment. In this case, it is for you to determine whether the child in question was of sufficient maturity and judgment to give actual consent."

The Second Restatement of Torts, §892A, comment b, discusses the exception regarding mature minors:

"To be effective, the consent must be given by one who has the capacity to give it or by a person empowered to consent for him. If the person consenting is a child or one of deficient mental capacity, the consent may still be effective if he is capable of appreciating the nature, extent and probable consequences of the conduct consented to, although the consent of a parent, guardian or other person responsible is not obtained or is expressly refused."

Additionally, Prosser and Keeton include a discussion of the relative capacity

of a minor to consent, stating that "[a] minor acquires capacity to consent to different kinds of invasions and conduct at different stages in his development. Capacity exists when the minor has the ability of the average person to understand and weigh the risks and benefits." Prosser and Keeton, supra, @18, at 115. n3

n3. Effectiveness of consent can be attacked on two grounds i this situation: (1) lack of capacity to understand the risks and benefits of the treatment, or (2) lack of information to which to apply the capacity to understand such risks and benefits. The second assumes the first is present; the first precludes consideration of the second by definition.

Although no Tennessee case has previously dealt directly with this issue, courts in other states have adopted this exception to the general rule. n4 In *Younts v. St. Francis Hospital and School of Nursing, Inc.*, 205 Kan. 292, 469 P.2d 330 (1970), the parents of a 17 year old minor brought suit on theories of malpractice and battery when their daughter was treated without their consent by defendant's hospital staff. The daughter's finger had been injured in an accident that occurred in her mother's hospital room while she was attending her mother following surgery; her mother was semi-conscious after surgery, was unable to give consent and her father was unavailable to give consent to treatment of the daughter's injury. The Kansas Supreme Court stated the general rule:

[*747] "It is the settled general rule that in the absence of an emergency or unanticipated conditions arising during surgery a physician or surgeon before treating or operating must obtain the consent of the patient, or if the patient is incompetent the consent must be obtained from someone legally authorized to give it for him. A surgical operation on the body of a person is a technical battery or trespass, regardless of its result, unless the person or some authorized person consents to it. Generally, the surgeon is liable for damages if the operation is unauthorized."

469 P.2d at 336 (citations omitted).

n4. For an early example of the application of this exception, See *Gulf & S.I.R.Co. v. Sullivan*, 155 Miss. 1, 119 So. 501 (1928).

The Court observed that in this case the minor "was seventeen years old, intelligent and capable for her age The [treatment]. . . was of a minor nature. The plaintiff remained conscious throughout the treatment and was fully aware of what was being done She raised no objection to the . . . procedure." 469 P.2d at 333. As an issue of first impression in Kansas, the Court recognized the mature minor exception as one of several exceptions regarding treatment of minors:

"Generally the consent of a parent to a surgical operation on a child is necessary. Certain exceptions are recognized . . . (1) whether an emergency exists, (2) when the child has been emancipated, (3) when the parents are so remote as to make it impracticable to obtain consent in time to accomplish proper results and (4) when the child is close to maturity and knowingly gives an informed consent."

469 P.2d at 337 (citation omitted). Nevertheless, "the sufficiency of a minor's consent depends upon his ability to understand and comprehend the nature of

the surgical procedure, the risks involved and the probability of attaining the desired results in the light of the circumstances which attend." Id.

While the age of majority was still 21 years in Ohio, another case arose involving treatment of a minor of 18. A plurality opinion was issued per curiam, but two concurring opinions accompanied the opinion of the Ohio Supreme Court. *Lacey v. Laird*, 166 Ohio St. 12, 139 N.E.2d 25 (1956) (per curiam). The concurring opinion of Justice Hart succinctly expresses the policy that underlies the general common law rule:

"The general rule seems to be that, unless there exists an emergency, which prevents any delay, or other exceptional circumstances, a surgeon who performs an operation upon a minor without the consent of his parents or guardian is guilty of a trespass and battery. This rule is not based upon the capacity of a minor to consent, so far as he is personally concerned, within the field of the law of torts or law of crimes, but is based upon the right of parents whose liability for support and maintenance of their child may be greatly increased by an unfavorable result from the operational procedures upon the part of the surgeon."

139 N.E.2d at 30.

In the concurring opinion of Justice Taft, the Rule of Sevens was stated, 139 N.E.2d at 33, and, recognizing that various stages of maturity are reached prior to attainment of majority, he then asked rhetorically about the logic of applying the strict common law rule to every case: "[D]oes any boy who kisses a girl under 21 with her consent but without the consent of her parents thereby expose himself to an action for assault and battery; and does every high school football player run the risk of assault and battery actions by boys under 21 with or against whom he plays?" Id., at 34.

Despite the lack of any cases directly on point in this State, Tennessee cases involving torts in which minors are either the tortfeasors or the victims of torts are relevant to determining whether the policy of this State compels the application of the strict view of the general common law rule regardless of the maturity of the minor or the circumstances and nature of the treatment involved. Consonant with the Rule of Sevens, the standards to which minors are held vary with the relative ability of the minor to appreciate his own conduct and the consequences of the conduct of others. [*748] Thus in *Arnold v. Hayslett*, supra, whether a minor would be capable of contributory fault is a question of fact in which "the fault of minors is to be judged by a standard somewhat different from that applicable to adults, and . . . the age, experience, training, education and maturity of the child must be taken into account." 655 S.W.2d at 947. See also *Standridge v. Godsey*, 189 Tenn. 522, 533, 226 S.W.2d 277, 282 (1949). Similarly, in *Prater v. Burns*, 525 S.W.2d 846 (Tenn. App.), cert. denied (Tenn. 1975), a child's capacity for negligence was relevant to whether the parents could be held liable for negligent entrustment of a firearm to a minor; the Court of Appeals held that "the proof of the minor's acts, demeanor and conduct at the time of the injury to another is material evidence on the minor's experience, training and judgment in the use of the firearm, and is therefore admissible on the issue of the parents' negligence in permitting the minor to use the weapon." Id., at 850. The Court of Appeals also applied the Rule of Sevens. Id., at 852. In *Cartwright v. Graves*, 182 Tenn. 114, 184 S.W.2d 373 (1944), a school bus driver was found liable for negligence when he failed to warn or restrain a six year old child alighting from the bus

that a truck was approaching at such a rate of speed that the child could not safely cross the street. The Court emphasized that six years old was "a wholly irresponsible age," 182 Tenn. at 124, 184 S.W.2d at 377, at which the child was unable to understand or foresee the danger, and found that consideration of the age of the child, the child's. experience and ability were appropriate in determining the degree of care required of persons who have charge of children. Id.

Cases in this State have consistently considered the relative maturity and ability of a minor to appreciate his own conduct's consequences and the consequences of the conduct of others in assessing the extent of responsibility to which a child will be held. Walker v. Hambry, supra, recognized that a minor may be charged with assumption of the risk. n5 In that case, the record showed that the minor.

"aged fifteen, [was] an honor student in high school, with no known physical or mental defects. She is therefore charged, as a matter of law, with the same degree of care as an adult, there being no evidence whatever to submit to the jury in rebuttal of the prima facie presumption that a minor over fourteen is capable of the same degree of care as an adult."

503 S.W.2d at 122. In contrast, Bailey v. Williams, supra, involved an injury to an eight year old playmate by a seven year old, and the Court of Appeals, recognizing the presumptions of the Rule of Sevens, stated that "the rule with respect to a minor's capacity for negligence is that the question is to be judged in the light of his age, ability, intelligence, training and experience and the complexity of the danger with which he is confronted. 48 Tenn. App. at 324, 346 S.W.2d at 287. As previously noted, in criminal cases, the Rule of Sevens has been applied to the capacity of a minor to commit a crime; essentially, this has now been codified at T.C.A. @37-1-134. See, e.g., Colley v. State, supra; Juvenile Court of Shelby County v. State ex rel. Humphrey, supra.

n5. Justice Taft in Lacey v. Laird, supra, compared capacity to consent to medical treatment to the ability of a minor to assume the risk. 139 N.E.2d at 32.

Several relevant principles from these cases may be stated for this case. Whether a minor has the capacity to consent to medical treatment depends upon the age, ability, experience, education, training, and degree of maturity or judgment obtained by the minor, as well as upon the conduct and demeanor of the minor at the time of the incident involved. Moreover, the totality of the circumstances, the nature of the treatment and its risks or probable consequences, and the minor's ability to appreciate the risks and consequences are to be considered. Guided by the presumptions in the Rule of Sevens, these are questions of fact for the jury to decide.

In our opinion, adoption of the mature minor exception to the general common law rule at issue would be wholly [*749] consistent with the existing statutory and tort law in this State as part of "the normal course of the growth and development of the law." Powell v. Hartford Accident and Indemnity Co., supra, 217 Tenn. at 513, 398 S.W.2d at 732. Accordingly, we hold that the mature minor exception is part of the common law of Tennessee. Its application is a question of fact for the jury to determine whether the minor has the capacity to consent to and appreciate the nature, the risks, and the consequences of the

medical treatment involved. In the circumstances of this case, and based on the evidence presented at trial, we think that the jury was justified in concluding that Ms. Cardwell had the ability, maturity, experience, education and judgment at her 17 years, 7 months of age to consent knowingly to medical treatment. "In this case, therefore, the reason for the common law rule does not exist. Where the reason fails the rule should not apply." Brown v. Selby, 206 Tenn. 71, 78, 332 S.W.2d 166, 169 (1960).

We do not, however, alter the general rule requiring parental consent for the medical treatment of minors. We observe here that under the Rule of Sevens, it would rarely, if ever, be reasonable, absent an applicable statutory exception, for a physician to treat a minor under seven years, and that between the ages of seven and fourteen, the rebuttable presumption is that a minor would not have the capacity to consent; moreover, while between the ages of fourteen and eighteen, a presumption of capacity does arise, that presumption may be rebutted by evidence of incapacity, thereby exposing a physician or care provider to an action for battery.

II. Informed Consent

A complete analysis of the issue of the effectiveness of consent cannot be made without considering whether Ms. Cardwell had sufficient information concerning the risks and consequences of the treatment administered, regardless of her capacity to give actual consent under the mature minor exception. Whether the information she had was sufficient depends on the nature of the treatment, the extent of the risks involved, and the standard of care of the treating physician. The burden of proof on the issue of standard of care is controlled by T.C.A. §29-26-118 of the Medical Malpractice Act.

A.

Ms. Cardwell testified that she was not fully cognizant of the nature of spinal manipulative therapy, that she had never undergone such treatment, and that she had never discussed it in any detail with anyone, including Defendant, as of April, 26, 1982. She did have a general idea of what the practice of an osteopath involved, considering it similar to that of a chiropractor. She knew that manipulations were involved and that this treatment was the reason she decided to see Defendant. She stated that Defendant did not discuss the nature of the treatment or tell her of any risks, although she did seek Defendant's treatment and manifestly consented to the manipulations. She did tell Defendant the diagnosis of the orthopedic specialists who had previously seen her.

Dr. Michael Eisenstadt, a neurologist, testified as an expert for Plaintiffs. He stated that he was familiar with the standard of care required to obtain informed consent and that older children have a greater capacity to comprehend the nature of the treatment. He was of the opinion that the effectiveness of consent depends on the risks involved in the proposed treatment. He admitted, however that he was not familiar with the standard of care for an osteopath in informing a patient as to the risks of manipulative treatments.

For Defendant, Dr. James Carson, an osteopath, testified as an expert on the standard of care of osteopaths in informing patients of the attendant risks of manipulative treatment and regarding the standard of care in administering such treatment. His opinion was that the effectiveness of consent depends on the treatment and the risks involved. In the case of manipulative treatment, the

need to explain is minimal because the treatment is of a minor nature with few risks. He was also [*750] of the opinion that the standard of care of osteopaths and medical doctors were not identical. In addition, Defendant testified in his own behalf. He stated that relatively little risk is usually involved in manipulative therapy. He generally did not find it necessary to explain the risks of manipulations unless the patient expressed concern; Ms. Cardwell did not express any apprehension about the treatment at the time he examined and treated her.

B.

T.C.A. §29-26-118 provides that

"the plaintiff shall prove by evidence as required by §29-26-115(b) that the defendant did not supply appropriate information to the patient in obtaining his informed consent (to the procedure out of which plaintiffs claim allegedly arose) in accordance with the recognized standard of acceptable professional practice in the profession and in the specialty, if any, that the defendant practices in the community in which he practices and in similar communities."

Incorporating the common law controlling the effectiveness of consent, the statute explicitly requires as part of the plaintiff's burden of proof that the standard of care for obtaining informed consent must be shown by expert evidence in the same manner as provided in T.C.A. §29-26-115(b). As stated in *Baldwin v. Knight*, 569 S.W.2d 450, 453 (Tenn. 1978), T.C.A. §29-26-115(b) "adds . . . to the present case law requirements relating to expert testimony, (1) the necessity that a medical expert be licensed in this state or a contiguous bordering state; (2) the relevant specialty requirement; and (3) judicial discretion to waive those requirements upon a showing of the unavailability of such witnesses." Where a person has the capacity to consent, consent may not be effective because the person was not sufficiently aware of the extent of the risks or the nature of the treatment involved.

"Counsel insists that simply because plaintiff testified that no one told her of any possible risks prior to receiving the injection, a prima facie case based on lack of informed consent was made out In matters of informed consent the plaintiff has the burden of proving by expert medical evidence, (a) what a reasonable medical practitioner of the same or similar communities under the same or similar circumstances would have disclosed to the patient about attendant risks incident to a proposed diagnosis or treatment and (b) that the defendant departed from the norm."

German v. Nichopoulos, 577 S.W.2d 197, 204 (Tenn. App. 1978), cert. denied (Tenn. 1979).

Although this provision is part of the malpractice statute and while determining whether the Defendant failed to obtain informed consent is dependent upon the standard of care of the profession or specialty, if informed consent is not effectively obtained, the defendant's departure from the standard of care is not negligence but battery because "the doctrine of battery [is] applicable to cases involving [treatment] performed without informed or knowledgeable consent." *Ray v. Scheibert*, 484 S.W.2d 63, 71 (Tenn. App.), cert. denied (Tenn. 1972) (emphasis in original As observed in *Lanford v. York*, 224 Tenn. 503, 457 S.W.2d 525 (1970), malpractice "'is based on lack of care or skill in the performance of services contracted for, and [battery] on wrongful trespass on

the person regardless of the skill employed. The assertion of one is the denial of the other.'" 224 Tenn. at 510-511, 457 S.W.2d at 528 (citation omitted).

We found it necessary to note this because the Plaintiffs alleged and the trial court instructed the jury on "negligent failure to obtain informed consent." T.C.A. §29-26-118 does not codify or otherwise create such a cause of action. n6 While the determination of the effectiveness of consent cannot be made without expert testimony [*751] on the standard of care concerning what information is usually supplied to enable a patient to give informed consent, considering both the seriousness of the treatment and any expressio of concern by the patient, failure to give such information is not the type of omission that results in negligence, but rather it negates consent for the treatment. Without consent, the treatment constitutes a battery.

n6. This provision incorporates only subsection (b) of T.C.A. §29-26-115 and does not impose the negligence requirements of T.C.A. §29-26-115(a) on a plaintiff alleging failure to obtain informed consent in a malpractice action.

Under the case law, the correct analysis in our opinion is that if the evidence shows that the person had the capacity to consent, then the question becomes whether the consent given was effective because it was based upon adequate information on which to make the decision to submit to treatment; if not, then a battery results, but if so, then the question becomes whether the defendant subsequently did anything negligent in the administration of the treatment for which consent was obtained, proof of which is controlled by T.C.A. §29-26-115. The trial court's instruction on negligent failure to obtain informed consent was, therefore, error, but in view of the verdict and our decision in this case, it was harmless error. Rule 36, T.R.A.P.

These theories, battery and malpractice, are not ordinarily inconsistent, and no election of remedies is generally required; if a battery exists, then malpractice may not necessarily be reached, but if no battery can be shown, then the issue clearly emerges as one of malpractice. This distinction between battery and malpractice (as a form of negligence) is consistently recognize in the case law. See, e.g., *Ray v. Scheibert*, supra; *Langford v. York*, supra; *Butler v. Molinski*, 198 Tenn. 124, 277 S.W.2d 448 (1955). As the Kansas Supreme Court noted in *Younts v. St. Francis Hospital and School of Nursing, Inc.*, supra, "a malpractice claim based upon negligence in the care and treatment of a patient is not concerned with the consent of the patient. The consent of the patient or of his parent is immaterial in such a case because consent does not free the hospital or the doctor from the consequences of negligence." 469 P.2d at 333 (citations omitted). Thus "whenever a physician performs [treatment] upon a person, not being authorized by consent and not being protected by the exception made in cases of emergency, the physician is liable to such person for consequent injuries, regardless of whether such injuries resulted from negligence or otherwise." *Ray v. Scheibert*, supra, at 71.

C.

In this case, expert testimony was advanced by Plaintiffs regarding the general standard of care of physicians in obtaining informed consent, but this expert was not familiar with the type of treatment administered to Ms. Cardwell. Considering that Ms. Cardwell did not express any concern to Defendant regarding the treatment and in view of the Defendant's testimony and that of his expert that the manipulations involved in this case are usually a relatively minor

form of treatment for which little, if any information is needed to obtain effective consent, we think the jury was warranted in concluding that Ms. Cardwell was adequately informed to give effective consent.

Under T.C.A. @29-26-118, the standard of relevancy is that provided by T.C.A. @29-26-115(b). A recent case of this Court has construed the standard of relevancy embodied in T.C.A. @29-26-115(b) as not requiring "that the witness practice in the same specialty as the defendant," *Searle v. Bryant*, 713 S.W.2d 62, 65 (Tenn. 1986) but the witness must demonstrate sufficient familiarity with the standard of care and the testimony must be probative of the issue involved. Dr. Eisenstadt stated he was generally familiar with the standard of care of physicians in obtaining informed consent, testifying that in general the amount of information to be supplied would be a function of the risks of the treatment, but being unfamiliar with the nature of the treatment in this case, his opinion might very well be less persuasive to a jury than that of experts who were both knowledgeable of the standard of care generally (and who agreed with Dr. Eisenstadt regarding this general standard and [*752] of the nature of the particular treatment administered. As the Supreme Court of Arizona noted in *Fridena v. Evans*, 127 Ariz. 516, 622 P.2d 463, 467 (1980) (citations omitted):

"Historically, it has been held that a member of one 'school' of medicine is not competent to testify against a member of another school This rule has been eroded in a number of ways, and it has been held that where standards of different schools are or should be the same with respect to a particular condition, experts from such schools should be fungible in terms of their competency to testify regarding those specific standards. . . . Here, there has not been shown to exist any material differences between the two schools that would make any difference"

T.C.A. @29-26-115(b) recognizes this fungibility of experts as long as the expert practices in "a profession or specialty which would make his expert testimony relevant to the issues" and the other competency requirements of this provision are met. See *Sutphin v. Platt*, 720 S.W.2d 455 (Tenn. 1986); *Searle v. Bryant*, supra. Essentially, aside from its procedural restrictions, T.C.A. @29-26-118 states the rule, as expressed by the Younts court, that, "'the duty of the physician to disclose . . . is limited to those disclosures which a reasonable medical practitioner [in the locality] would make under the same or similar circumstances,'" 469 P.2d at 336 (citation omitted), and "what is a reasonable disclosure upon which an informed consent may rest must depend upon the facts and circumstances of each case." 469 P.2d at 337 (citation omitted).

III. Medical Malpractice

The final issue presented for resolution is whether the trial court erred in directing a verdict on the malpractice count because Plaintiffs failed to produce expert testimony on the standard of care required of Defendant in diagnosing Ms. Cardwell's condition and in administering manipulative treatment under the circumstances of this case. This issue is governed by the requirements of T.C.A. @29-26-115.

A.

Several experts testified for Plaintiffs regarding causation and the extent of Ms. Cardwell's injuries; two of these offered to testify concerning the standard of care of an osteopath in administering manipulative treatment to a

person in Ms. Cardwell's condition. While Dr. Sidney Wallace, an orthopedic specialist, testified that the manipulations (and to some extent a delay from April 26 to the surgery on April 29) exacerbated Ms. Cardwell's pre-existing back condition and precipitated the immediate need to perform surgery (although he also believed surgery would have likely become necessary at some point anyway), the trial court did not permit Dr. Wallace to testify to the standard of care required of an osteopath in the circumstances of this case. By his own admission, Dr. Wallace was not familiar with the practice and types of treatments administered by osteopaths. Dr. Michael Eisenstadt, a neurologist, testified as to the general standard of care in the medical profession regarding obtaining informed consent, and attempted to testify regarding Defendant's standard of care in diagnosing Ms. Cardwell's problem and in administering manipulative treatment, but he also conceded that he was not an osteopath, had no training in the field, and was unfamiliar with the standard of care of that profession. Consequently, neither expert could render a relevant opinion on this issue.

Dr. James Carson and Defendant both testified as experts on the standard of care for osteopaths in performing manipulative treatments on a person in Ms. Cardwell's condition. Dr. Carson expressed the opinion that Defendant's treatment did not cause or exacerbate Ms. Cardwell's condition. He testified that the symptom of Ms. Cardwell were consistent with the diagnoses both of Defendant and of Ms. Cardwell's orthopedic specialists. As noted previously, he stated that the standards of care of osteopaths and medical doctors were not generally the same. Defendant testified that manipulations are generally considered a conservative treatment and [*753] that from what Ms. Cardwell told him and from his examination he made his diagnosis.

B.

T.C.A. §29-26-115 affirmatively places the burden of proof in a malpractice case upon the plaintiff:

"(a) In a malpractice action, the claimant shall have the burden of proving by evidence as provided by subsection (b):

(1) The recognized standard of acceptable professional practice in the profession and the specialty thereof, if any, that the defendant practices in the community in which he practices or in a similar community at the time the alleged injury or wrongful action occurred;

(2) That the defendant acted with less than or failed to act with ordinary and reasonable care in accordance with such standard; and

(3) As a proximate result of the defendant's negligent act or omission, the plaintiff suffered injuries which would not otherwise have occurred.

(b) No person in a health care profession requiring licensure under the laws of this state shall be competent to testify in any court of law to establish the facts required to be established by subsection (a) unless he was licensed to practice in the state or a contiguous bordering state a profession or specialty which would make his expert testimony relevant to the issues in the case and had practiced this profession or specialty in one of these states during the year preceding the date that the alleged injury or wrongful act occurred. This rule shall apply to expert witnesses testifying for the defendant as rebuttal

witnesses. The court may waive this subsection when it determines that the appropriate witnesses otherwise would not be available.

(c) In a malpractice action as described in subsection (a) of this section there shall be no presumption of negligence on the part of the defendant. Provided, however, there shall be a rebuttable presumption that the defendant was negligent where it is shown by the proof that the instrumentality causing injury was in the defendant's (or defendants') exclusive control and that the accident or injury was one which ordinarily doesn't occur in the absence of negligence.

(d) In a malpractice action as described in subsection (a) of this section, the jury shall be instructed that the claimant has the burden of proving, by a preponderance of the evidence, the negligence of the defendant. The jury shall be further instructed that injury alone does not raise a presumption of the defendant's negligence."

Tennessee courts have construed these provisions and their predecessors in a number of cases. See, e.g., *Sutphin v. Platt*, supra; *Tutton v. Patterson*, 714 S.W.2d 268 (Tenn. 1986); *Searle v. Bryant*, supra; *Baldwin v. Knight*, supra; *Lanford v. York*, supra; *Pyle v. Morrison*, 716 S.W.2d 930 (Tenn. App.), permission to appeal denied (Tenn. 1986); *Stokes v. Leung*, 651 S.W.2d 704 (Tenn. App.), permission to appeal denied (Tenn. 1983); *Dolan v. Cunningham*, 648 S.W.2d 652 (Tenn. App. 1982), permission to appeal denied (Tenn. 1983). Cf., e.g., *Ison v. McFall*, 55 Tenn. App. 326, 400 S.W.2d 243, cert. denied (Tenn. 1964); *Merryman v. Bunch*, 24 Tenn. App. 408, 145 S.W.2d 559, cert. denied (Tenn. 1940) (Consistent "'common law cases with comparable results). T.C.A. @29-26-115 essentially codifies the common law elements of negligence without substantive modification:

"The plaintiffs have the burden of proving, by expert testimony (1) the standard of care, (2) that defendant deviated from that standard, and (3) that as a proximate result of the defendant's negligent act or omission, the plaintiff suffered injuries which would not otherwise have occurred. See T.C.A. @29-26-115."

Dolan v. Cunningham, supra, at 654 (emphasis in original). See also *Pyle v. Morrison*, supra, at 936. Nevertheless, it does impose more rigorous procedural requirements on the plaintiff in a malpractice action, but, as this Court has previously observed in this regard, "the conclusion is inevitable that the Legislature has sanctioned [*754] existing case law governing both substantive and evidentiary requirements, merely adding thereto . . . the additional expert witness requirements." *Baldwin v. Knight*, supra, at 453. The requirements found in T.C.A. @29-26-115(b) make it clear (1) that a modified locality rule is the law of this State, see *Sutphin v. Platt*, supra, and (2) read with T.C.A. @29-26-115(c), (d), that "the mere fact that the professional service rendered was not a success does not in any sense justify the conclusion that the defendant was guilty of actionable negligence." *Butler v. Molinski*, supra, 198 Tenn. at 130, 277 S.W.2d at 451.

C.

Under the terms of this statute and the law of evidence generally, the trial court exercises broad discretion to determine the qualifications of experts and its determination will not ordinarily be reversed absent some abuse of

discretion. See, e.g., *Pyle v. Morrison*, supra, at 933; *Stokes v. Leung*, supra, at 706. At the close of Plaintiff's evidence, no admissible expert testimony existed on the record relevant to the standard of care in the locality of an osteopath in similar circumstances. The trial court, therefore, committed no error in granting Defendant's Motion for a Directed Verdict on the issue of malpractice. See, e.g., *Sutphin v. Platt*, supra; *Stokes v. Leung*, supra, at 706-707; *German v. Nichopoulos*, supra, at 202; *Butler v. Molinski*, supra, 198 Tenn. at 128, 277 S.W.2d at 450. Cf. *Dolan v. Cunningham*, supra, at 654 ("If the issue is one upon which expert testimony is necessary, and the non-moving party cannot produce an expert . . . summary judgment may be appropriate. . . .").

Plaintiffs argue that the trial court should have exercised its discretion under T.C.A. §29-26-115(b) to permit their experts to testify under the waiver provision of the statute. They also contend that the standard of care under the Medical Malpractice Act is the same for osteopaths as it is for medical doctors because all of the healing arts are subsumed in the practice of medicine and thus a minimum standard of care regarding matters of common observation and experience in the healing arts can be established by the expert testimony of medical doctors for all professions covered by the Medical Malpractice Act.

Although the standard of care may be established by the defendant's own admissions, *Tutton v. Patterson*, supra, at 270, that is not the case here. Moreover, *Searle v. Bryant*, supra, at 65, held that T.C.A. §29-26-115(b) "contains no requirement that the witness practice the same specialty as the defendant," but, as previously noted, the witness must be sufficiently familiar with the standard of care of the profession or specialty and be able to give relevant testimony on the issue in question. Cf. *Ison v. McFall*, supra. Without the requisite threshold evidence of the standard of care in the locality, regardless of the other requirements of the statute, Plaintiffs were not able to demonstrate "a breach of duty to the patient to use that degree of skill and learning which is ordinarily used under similar circumstances by members in good standing in his profession." *Merryman v. Bunch*, supra, 24 Tenn. App. at 410-411, 145 S.W.2d at 561 (citations omitted).

The record does not reflect that Plaintiffs sought to make any timely motion or any showing that a waiver under T.C.A. §29-26-115(b) would be appropriate. See, e.g., *Pyle v. Morrison*, supra, at 933; *Ayers v. Rutherford Hospital, Inc.*, 689 S.W.2d 155, 161 (Tenn. App. 1984), permission to appeal denied (Tenn. 1985). The trial court's decision to disqualify Plaintiff's experts is, thus, fully supported by the record. Having found no abuse of discretion, we also think that adoption of the Plaintiffs' contentions concerning the general standard of care to which medical doctors could testify is contrary to the express provisions of T.C.A. §29-26-115(b) and would be a significant departure from the case law of this State. The statute was enacted in part to prevent further erosion of the competency requirements for expert witnesses in malpractice actions. Cf. *Sutphin v. Platt*, supra. The statute and cases currently permit some fungibility of [*755] experts, but where an expert is unfamiliar with the practice of another field and with its standard of care or "where material differences between . . . schools," *Fridena v. Evans*, supra, 622 P.2d at 467, have been shown, we do not think it would be consistent with the terms or the policy of the Medical Malpractice Act to permit the kind of generalized evidence as that proposed by Plaintiffs in this case.

"The trial judge and the court of appeal ruled correctly that the plaintiff had not met her burden of proof as to malpractice. The only evidence as to

that standard consisted of the testimony of two orthopedic surgeons. Both of these admitted they had no formal training in the manipulatory techniques of chiropractors and that they were at best familiar with those techniques. This is not sufficient to establish a standard of chiropractic care."

Boudreaux v. Panger, 490 So.2d 1083, 1085 (La. 1986).

IV.

Addition of the mature minor exception to the general common law that requires parental consent to treat a minor is consistent with the evolution of the common law of torts in this State and flows as a consequence of those changed conditions that, among other things, have justified the lowering of the age of majority to 18 years of age. We have not found any State policy, legislative or otherwise, that would preclude adoption of the mature minor exception. On the contrary, the statutory law both is generally consistent with the common law on the capacity of minors and supports our conclusion that adoption of this exception undermines no express or apparent legislative policy. Furthermore, this exception is circumscribed by the rebuttable presumptions of the Rule of Sevens and limited by the facts and circumstances of each case; thus, little chance exists that the exception will swallow the rule.

The mature minor exception pretermits the issue of parental consent and we do not address that issue. Ms. Cardwell was only five months short of the age of majority at the time of this incident; the presumption of capacity, therefore, attached under the Rule of Sevens. The jury's verdict, based on instructions incorporating the mature minor exception and the evidence in this case, implicitly found that Ms. Cardwell did have the judgment, ability, education, and training at her 17 years, 7 months to have the capacity to consent and did in fact consent to the Defendant's treatment. The same capacity to consent entails the ability to appreciate and weigh the risks and benefits of the treatment she sought and thus to give informed consent to it. The jury also found that the Defendant complied with the standard of care of his practice in providing her with sufficient information upon which Ms. Cardwell could give informed consent. The treatment was relatively minor, with a minimum risks of injury, and Ms. Cardwell expressed no concern about the treatment at the time it was to be administered. The jury could reasonably have found that Plaintiffs did not show that Defendant had deviated from the standard of care concerning the information ordinarily supplied to obtain informed consent to Defendant's treatment. Consequently, having the capacity to consent and having given informed consent, no battery occurred because Ms. Cardwell's consent was effective on the facts of this case.

Absent any actionable battery, the Plaintiffs' remaining theory was the allegation of medical malpractice. The trial court did not err in directing a verdict on this issue. By their own admissions, both of Plaintiffs' experts were not sufficiently familiar with the standard of care for osteopaths and could thus not offer any probative opinion testimony concerning the Defendant's diagnosis or the administration of manipulative treatments in the circumstances of this case. The trial court did not abuse its discretion in disallowing the testimony of these experts on this record. Absent any relevant expert testimony on the standard of care of Defendant, the Plaintiffs could not carry their burden of proof under T.C.A. §29-26-115. We decline to adopt a more expansive reading of this statute on [*756] the facts of this case than is already permitted in the case law.

Accordingly, we reverse the Court of Appeals on the issue of battery and reinstate the judgment of the trial court. The Court of Appeals and the trial court are affirmed on the issue of competency of an expert under T.C.A. §29-26-115. Costs of this appeal are taxed equally to the parties. The case is dismissed.

Concur: Brock, C.J., Fones, Harbison and Cooper, JJ.

MEDICAL EXPERIMENT AND MATURE MINOR

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ERICA MAE STILL, by her next friend and grandmother,
FLORENCE FAYE ERLANDSON, Plaintiff-Appellant, VS. BAPTIST
HOSPITAL, INC. and JAMES W. JOHNSON, M.D.,
Defendants-Appellees

STILL v. BAPTIST HOSP., INC.

No. 87-381-II

Court of Appeals of Tennessee, Middle Section

755 S.W.2d 807; 1988 Tenn. App. LEXIS 315

May 20, 1988, Filed

DISPOSITION: AFFIRMED AND REMANDED

OPINION:

... [*812] [**16] recognized); Kilbourne v. Hanzelik, 648 S.W.2d 932 (Tenn. 1983) (allowing a wife to recover medical expenses paid on behalf of a tortiously injured husband); Cardwell v. Bechtol, 724 S.W.2d 739 (Tenn. 1987) ("mature minors" need not obtain parental consent before receiving treatment from doctors); Arnold v. Hayslett, 655 S.W.2d 941 (Tenn. 1983) (minors capable of contributory fault). Of course, many more such ...

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*** THIS SECTION IS CURRENT THROUGH THE 1994 SUPPLEMENT ***
*** (1994 SESSION OF THE GENERAL ASSEMBLY) ***

TITLE 1. CODE AND STATUTES
CHAPTER 3. CONSTRUCTION OF STATUTES

Tenn. Code Ann. @ 1-3-105 (1994)

1-3-105. Definition of terms used in code

As used in this code, unless the context otherwise requires:

(1) "Age of majority" means eighteen (18) years of age or older; except that when purchasing, consuming or possessing alcoholic beverages, wine or beer as those terms are defined in title 57, "age of majority" means twenty-one (21) years of age. "Minor" means any person who has not attained eighteen (18) years of age; except that where used in title 57 with respect to purchasing, consuming or possessing alcoholic beverages, wine or beer, "minor" means any person who has not attained twenty-one (21) years of age. This subdivision shall not be construed as prohibiting any person eighteen (18) years of age or older from selling, transporting, possessing or dispensing alcoholic beverages, wine or beer in the course of employment;

(2) "Code" includes the Tennessee Code and all amendments and revisions thereof and all additions and supplements thereto;

(3) "Collector" includes any person entrusted with the collection of public revenue;

(4) "Constable," or other word used for an executive or ministerial officer, includes any person performing the duties of such officer, either generally or in special cases;

(5) "Coroner," or other word used for an executive or ministerial officer, includes any person performing the duties of such officer, either generally or in special cases;

(6) "County executive" also means and includes "county mayor" unless the context clearly indicates otherwise;

(7) "Executor" includes an administrator, where the subject matter applies to an administrator;

(8) "Federal census," "federal census of population," or references to the federal decennial census, are deemed to be references to the federal decennial censuses of population as defined in @ 1-3-116, and contained in the "Tables" volume of this code, Volume 13, or its replacement volume;

(9) "Funeral and burial expenses" includes, but is not limited to, the cost of preparing the body for burial or other disposition, the funeral service, any funeral merchandise, flowers, honoraria, acknowledgment cards, postage,

transporting the body to the place of burial or disposition, the burial space, crypt, mausoleum or other final resting place, the opening and closing thereof and any marker;

(10) "Highway" includes public bridges and may be held equivalent to the words "county way," "county road" or "state road";

(11) "Insane" includes all persons of unsound mind;

(12) "Lands" includes lands, tenements and hereditaments, and all rights thereto and interests therein, equitable as well as legal;

(13) "Lunatic" includes all persons of unsound mind;

(14) "Month" means a calendar month;

(15) "Non compos mentis" includes all persons of unsound mind;

(16) "Oath" includes affirmation;

(17) "Person" includes a corporation, firm, company or association;

(18) "Personal property" includes money, goods, chattels, things in action, and evidences of debt;

(19) "Personal representative," when applied to those who represent a decedent, includes executors and administrators, unless the context implies heirs and distributees;

(20) "Probate court" means the court having jurisdiction over the administration of the estates of decedents;

(21) "Property" includes both personal and real property;

(22) "Real estate" and "real property" include lands, tenements and hereditaments, and all rights thereto and interests therein, equitable as well as legal;

(23) "Representative," when applied to those who represent a decedent, includes executors and administrators, unless the context implies heirs and distributees;

(24) "Road" includes public bridges and may be held equivalent to the words "county way," "county road" or "state road";

(25) "Savings and loan association" includes a building and loan association, a federal or state savings and loan association, a federal savings bank, and any other financial institution, the accounts of which are insured by the federal savings and loan insurance corporation (FSLIC) or any successor of such corporation;

(26) "Sheriff," or other word used for an executive or ministerial officer, includes any person performing the duties of such officer, either generally or in special cases;

Tenn. Code Ann. @ 1-3-105 (1994)

(27) "Signature" includes a mark, the name being written near the mark and witnessed;

(28) "State," when applied to the different parts of the United States, includes the District of Columbia and the several territories of the United States;

(29) "Subscription" includes a mark, the name being written near the mark and witnessed;

(30) "Tennessean" denotes a permanent resident of the state, and the recognized spelling of the word is as above;

(31) "United States" includes the District of Columbia and the several territories of the United States;

(32) "Writing" or "written" includes printing, typewriting, engraving, lithography, and any other mode of representing words and letters; and

(33) "Year" means a calendar year, unless otherwise expressed; but "year," in reference to any appropriation from the state treasury, means fiscal year, unless otherwise expressed or implied.

HISTORY: Code 1858, @@ 50-52, 54-57, 59; Shan., @@ 62-64, 65-68, 70; Code 1932, @@ 14-16, 18-21, 23-25; C. Supp. 1950, @ 27.2; modified; Acts 1969, ch. 76, @ 1; 1972, ch. 612, @ 1; 1972, ch. 740, @ 2; 1979, ch. 413, @ 1; T.C.A. (orig. ed.), @ 1-305; Acts 1983, ch. 304, @ 1; 1984, ch. 705, @ 1; 1984, ch. 1006, @ 1; 1985, ch. 134, @ 1; 1985, ch. 140, @ 2; 1990, ch. 655, @ 1; 1992, ch. 951, @ 1.

NOTES:

COMPILER'S NOTES. The federal savings and loan insurance corporation, referred to in (25), was abolished, effective February 1, 1992. See the Historical and Statutory Notes under 12 U.S.C. @ 1437.

CROSS-REFERENCES. Alcoholic beverage limitations on persons under 21, @ 1-3-113.

Entities included within definition of savings and loan association, @ 45-3-104.

"Minor" defined for purposes of municipal motion picture regulatory boards, @ 6-54-404.

Penalty for sale of alcoholic beverages to minor, @@ 57-4-203, 57-5-303.

SECTION TO SECTION REFERENCES. This section is referred to in @@ 1-3-115, 8-34-101, 32-11-110.

TEXTBOOKS. Gibson's Suits in Chancery (7th ed., Inman), @ 44.

Pritchard on Wills and Administration of Estates (4th ed., Phillips and Robinson), @@ 16, 151, 193, 418, 453, 611.

Tennessee Jurisprudence, 2 Tenn. Juris., Animals, @@ 3, 4; 3 Tenn. Juris., Attachment and Garnishment, @ 4; 5 Tenn. Juris., Bridges, @ 3; 7 Tenn. Juris., Corporations, @@ 3, 101; 18 Tenn. Juris., Mechanics' Liens, @ 8; 18 Tenn. Juris., Minors, @ 2; 22 Tenn. Juris., Signatures, @ 1; 23 Tenn. Juris., Time, @ 1; 25 Tenn. Juris., Wills, @ 117.

LAW REVIEWS. Selection and Removal of Fiduciaries (Robert L. McMurray), 26 No. 3, Tenn. B.J. 22 (1990).

CITED: Round Mt. Lumber & Coal Co. v. Bass, 136 Tenn. 687, 191 S.W. 341 (1916); Frazier v. Nashville Veterinary Hosp., 139 Tenn. 440, 201 S.W. 751 (1917); Haverty Furn. Co. v. Foust, 174 Tenn. 203, 124 S.W.2d 694 (1939); Burns v. Kinzer, 161 F.2d 806 (6th Cir. 1947); Southeastern Aviation, Inc. v. Hurd, 209 Tenn. 639, 355 S.W.2d 436 (1962); Williams v. Estep, 431 F. Supp. 75 (E.D. Tenn. 1976); First Nat'l Bank v. Charles Blalock & Sons (In re Just For Fun of It of Tenn., Inc.), 7 Bankr. 166 (Bankr. E.D. Tenn. 1980); Brookins v. Round Table, Inc., 624 S.W.2d 547 (Tenn. 1981); State v. Gardner, 626 S.W.2d 721 (Tenn. Crim. App. 1981); Metropolitan Gov't v. Ashland Oil, Inc., 535 F. Supp. 328 (M.D. Tenn. 1982); Cardwell v. Bechtol, 724 S.W.2d 739 (Tenn. 1987); Nichols v. Atnip, 844 S.W.2d 655 (Tenn. Ct. App. 1992).

NOTES TO DECISIONS

ANALYSIS

1. Application of definitions.
2. Collectors.
3. Executors and administrators.
4. Highways and roads.
5. Month.
6. Person.
7. Personal property.
8. Property.
9. Real property and lands.
10. --Leasehold estates.
11. Sheriff.
12. Signature.
13. Year.

1. APPLICATION OF DEFINITIONS.

The code definitions were not intended to be limited to the words as used by the code, but extend to the words whenever used in subsequent statutes. Wiley v. State, 43 Tenn. 362 (1866); Cowan v. Murch, 97 Tenn. 590, 37 S.W. 393, 34 L.R.A. 538 (1896); Carroll v. Alsup, 107 Tenn. 257, 64 S.W. 193 (1901); State v. Erwin, 139 Tenn. 341, 200 S.W. 973 (1917); Dunn v. Archer, 150 Tenn. 440, 265 S.W. 678 (1924).

These definitions are not applicable to common-law terms not embraced in the statutory system. Lewis v. Glass, 92 Tenn. 147, 20 S.W. 571 (1892).

The definitions apply not only to the statutes in the code as enacted, but to all amendments thereof, which include all statutes passed since its enactment, in the absence of a contrary intention or purpose expressed in the statutes themselves. Standard Oil Co. v. State, 117 Tenn. 618, 100 S.W. 705, 10 L.R.A. (n.s.) 1015 (1906).

2. COLLECTORS.

Under a law making the state comptroller a collector of the state taxes due from railroads and conferring general powers upon him in the premises, he was authorized to assess omitted railroads for taxes. State v. Railroad, 96 Tenn. 385, 34 S.W. 1023 (1896); Railroad v. Williams, 101 Tenn. 146, 46 S.W. 448 (1898).

The remedies against the delinquent revenue collectors provided in the statutes may be used against county trustees entrusted with the collection of public revenue. McHenderson v. Anderson County, 105 Tenn. 591, 59 S.W. 1016

(1900).

3. EXECUTORS AND ADMINISTRATORS.

An administrator de bonis non is embraced and described in our statutes by the general description of administrator, whether by such statutes powers are given, or duties imposed. *Shackelford v. Runyan*, 26 Tenn. 140 (1846); *Coleman v. Raynor*, 43 Tenn. 25 (1866); *Minor v. Webb*, 48 Tenn. 395 (1870); *Whitaker v. Whitaker*, 80 Tenn. 393 (1883).

An act of the general assembly passed after the adoption of the code, empowering a bank to act as executor, includes power to act as administrator. This section applies to later enactments. *Union Bank & Trust Co. v. Wright*, 58 S.W. 755 (Tenn. Ch. App. 1900).

4. HIGHWAYS AND ROADS.

Public bridges are included within the general words "roads and highways," and may be held to be equivalent to the words "county roads." *Ledbetter v. Turnpike Co.*, 110 Tenn. 92, 73 S.W. 117 (1902), overruled in part on other grounds, *Knierim v. Leatherwood*, 542 S.W.2d 806 (Tenn. 1976); *Cannon County v. McConnell*, 152 Tenn. 555, 280 S.W. 24 (1926); *Boshears v. Foster*, 154 Tenn. 494, 290 S.W. 387 (1926).

5. MONTH.

A lunar month is not intended. *Cook v. Shute*, 3 Tenn. 67 (1812).

The period of 30 days, within which time the execution issued by a justice of the peace is required by statute to be returned, does not mean a calendar month, and is not equivalent thereto, except when such month happens to contain 30 days. *Cowan, McClung & Co. v. Sloan*, 95 Tenn. 424, 32 S.W. 388 (1895).

6. PERSON.

The word "person" includes a corporation, but the word as here used means a private corporation and not a public or municipal corporation. *City of Memphis v. Laski*, 56 Tenn. 511, 24 Am. R. 327 (1872); *Adams v. City of Memphis*, 3 Shannon's Cases 392 (1875); *Parsons v. McGavock*, 2 Cooper's Tenn. Ch. 581 (1875); *Daly v. State*, 81 Tenn. 228 (1884); *Turcott v. Yazoo & M.V.R.R.*, 101 Tenn. 102, 45 S.W. 1067, 40 L.R.A. 768, 70 Am. St. R. 661 (1898); *Standard Oil Co. v. State*, 117 Tenn. 618, 100 S.W. 705, 10 L.R.A. (n.s.) 1015 (1906).

While the word "person" includes a "corporation," within the purview of the statute that excludes absence from the state in computing the time for the running of the statute of limitations, a foreign corporation that has never complied with our statutes for its domestication, but has continually, for the period requisite for the running of the statute, operated its business within the state, maintaining an office, with officers and agents subject, under our statutes, to service of process that binds it, is entitled to plead and rely upon the statute of limitations to the same extent as a domestic corporation. *Turcott v. Yazoo & M.V.R.R.*, 101 Tenn. 102, 45 S.W. 1067, 40 L.R.A. 768, 70 Am. St. R. 661 (1898); *Boro v. Hidell*, 122 Tenn. 80, 120 S.W. 961, 135 Am. St. R. 857 (1909).

Corporations are not included in the words "a person or persons" used in a statute the indictment provisions of which show a contrary intention. *Standard Oil Co. v. State*, 117 Tenn. 618, 100 S.W. 705, 10 L.R.A. (n.s.) 1015 (1906).

7. PERSONAL PROPERTY.

Dogs, having owners, are personal property. *Wheatley v. Harris*, 36 Tenn. 468, 70 Am. Dec. 258 (1857); *State v. Brown*, 68 Tenn. 53, 40 Am. R. 81 (1876); *Phillips v. Lewis*, 3 Shannon's Cases 230 (1877); *Citizens' Rapid Transit Co.*

v. Dew, 100 Tenn. 317, 45 S.W. 790, 40 L.R.A. 518, 66 Am. St. R. 754 (1898).

"Personal property" includes "money, goods, chattels, things in action, and evidences of debt." Duke v. Hall, 68 Tenn. 282 (1878).

Suits by city and contractor to recover damages from defendants for purchase of manufactured products of defendants at exorbitant price due to monopoly exercised by defendants were suits involving "personal property" since suits were to recover for money unlawfully demanded and paid. City of Atlanta v. Chattanooga Foundry & Pipe Co., 101 F. 900 (6th Cir. 1900).

8. PROPERTY.

The right to litigate in the courts is a common right, and a species of incorporeal property. Harrison, Pepper & Co. v. Willis, 54 Tenn. 35, 19 Am. R. 604 (1871); Lawyers' Tax Cases, 55 Tenn. 565 (1875).

The word "property" includes both personal and real property, Woolridge v. Page, 68 Tenn. 325 (1878), and all rights and interests, therein, equitable as well as legal. Woolridge v. Page, 68 Tenn. 325 (1878); Alexander v. Miller, 54 Tenn. 65 (1871); Hooberry v. Harding, 3 Cooper's Tenn. Ch. 677 (1878).

9. REAL PROPERTY AND LANDS.

A right to or interest in land is precisely the same thing as land and the course of descent of the one and the other is regulated by the same law. Alexander v. Miller, 54 Tenn. 65 (1871).

Fences, apple trees, timber and forest trees, and corn in the field are part of the realty. Nashville, C. & St. L.R.R. v. Weak, 81 Tenn. 148 (1884).

An interest in realty, purely contingent, is not by this section made leviable. Nichols v. Guthrie, 109 Tenn. 535, 73 S.W. 107 (1902).

The terms "real estate," "real property," and "lands," as defined in this section, expressly include every species of realty which a railroad company may own. State ex rel. Stewart v. Louisville & N.R.R., 139 Tenn. 406, 201 S.W. 738 (1917).

Regulation of the use of land includes regulation of the use to which buildings on the land may be put. Spencer-Sturla Co. v. City of Memphis, 155 Tenn. 70, 290 S.W. 608 (1927).

10. --LEASEHOLD ESTATES.

A leasehold estate or an estate for a term of years is subject to the mechanic's lien, because it is "land." Alley & Bush v. Lanier, 41 Tenn. 540 (1860); Kay v. Smith, 57 Tenn. 41 (1872); Burr v. Graves, 72 Tenn. 552 (1880); H.E. Daniel & Co. v. Weaver, 73 Tenn. 392 (1880); Truxall v. Williams, 83 Tenn. 427 (1885); Steger v. Arctic Refrigerator Co., 89 Tenn. 453, 14 S.W. 1087, 11 L.R.A. 580 (1891); Lewis v. Glass, 92 Tenn. 147, 20 S.W. 571 (1892).

A leasehold estate in land is real estate. Kelley v. Schultz, 59 Tenn. 218 (1873); Steers v. Daniel, 4 F. 587 (6th Cir. 1880), aff'd, 110 U.S. 264, 4 S. Ct. 94 28 L. Ed. 141 (1884); Burr v. Graves, 72 Tenn. 552 (1880); Lewis v. Glass, 92 Tenn. 147, 20 S.W. 571 (1892); Matthews v. Crofford, 129 Tenn. 541, 167 S.W. 695 (1914); Growers Warehousing Corp. v. W.E. Sawyer Tobacco Co., 5 Tenn. App. 619 (1927); American Ry. Express Co. v. City of Chattanooga, 10 Tenn. App. 63 (1929).

A statute which protects the interest of a husband in real estate of the wife from his creditors protects a like interest in the wife's leasehold. Burr v. Graves, 72 Tenn. 552 (1880).

This section does not change the common-law rule that curtesy does not attach to the wife's leasehold. Lewis v. Glass, 92 Tenn. 147, 20 S.W. 571 (1892).

A lease of an upper story of a building is not personalty, but is an interest in real estate, and contracts therefor are governed by the law relating to

real estate. *Mason v. City of Nashville*, 155 Tenn. 256, 291 S.W. 1074 (1926).

11. SHERIFF.

A deputy sheriff is not included in @ 25-3-101 giving remedy by motion against "any sheriff, coroner, or constable, or other executive officer, to whom an execution is directed and by him received," for certain defaults as to same. An execution is never directed to the deputy sheriff, but to the sheriff. *Robertson v. Lessan & Dougan*, 47 Tenn. 158 (1869); *State ex rel. Little v. Slagle*, 115 Tenn. 336, 89 S.W. 326 (1905).

12. SIGNATURE.

A person whose name is written by another, and who makes his mark thereto, may be a good attesting witness to a will. *Ford v. Ford*, 26 Tenn. 91 (1846); *Rose v. Allen*, 41 Tenn. 23 (1860); *Tate v. City of Lawrence*, 58 Tenn. 503 (1872); *Simmons v. Leonard*, 91 Tenn. 183, 18 S.W. 280 (1892).

A mark, with name written near it and witnessed, constitutes a "signature" or "subscription." A party may bind himself by making his mark or signing his initials with the intent thereby to be bound. *Brown v. McClanahan*, 68 Tenn. 347 (1878).

The name of a witness written by another, without the witness touching the pen or making his mark, is not sufficient. *McFarland v. Bush*, 94 Tenn. 538, 29 S.W. 899 (1895).

13. YEAR.

The definition of "year" means that a year shall be 12 calendar months, regardless of the time of commencement. It does not mean that the year must commence with the month of January, for it may commence at any time. *McClellan v. Memphis & C.R.R.*, 79 Tenn. 336 (1883).

In computing interest a year is not to be treated as 360 days, or 12 periods of 30 days each. *Dowler v. Georgia Enters., Inc.*, 162 Tenn. 59, 34 S.W.2d 445 (1931).

COLLATERAL REFERENCES. What 12-month period constitutes "year" or "calendar year" as used in public enactment, contract, or other written instrument. 5 A.L.R.3d 584.

Statutory change of age of majority as affecting pre-existing status or rights. 75 A.L.R.3d 228.

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*** THIS SECTION IS CURRENT THROUGH THE 1994 SUPPLEMENT ***
*** (1994 SESSION OF THE GENERAL ASSEMBLY) ***

TITLE 1. CODE AND STATUTES
CHAPTER 3. CONSTRUCTION OF STATUTES

Tenn. Code Ann. @ 1-3-113 (1994)

1-3-113. Eighteen-year-olds -- Legal responsibility -- Alcoholic beverage restrictions on persons under twenty-one

(a) Notwithstanding any laws to the contrary, any person who is eighteen (18) years of age or older shall have the same rights, duties, and responsibilities as a person who is twenty-one (21) years of age, except as provided in subsection (b) relative to the rights to purchase, possess, transport, and consume alcoholic beverages, wine, or beer as those terms are defined in title 57.

(b) Notwithstanding the provisions of subsection (a), it is unlawful for any person under twenty-one (21) years of age to purchase, possess, transport or consume alcoholic beverages, wine, or beer, with the following exceptions:

(1) Any person eighteen (18) years of age or older may transport, possess, sell, or dispense alcoholic beverages, wine, or beer in the course of such person's employment; and

(2) The provisions of @ 39-6-910(1) [repealed], shall not be affected by any provision of this subsection, it being the intent of the general assembly that such provisions remain lawful and in full force and effect. Any such priest or minister may utilize and administer alcohol or wine at a communion service, bar mitzvah, bat mitzvah, or other similar religious service or ceremony, in accordance with the practices of such denomination or sect.

HISTORY: Acts 1971, ch. 162, @ 3; 1979, ch. 413, @ 2; T.C.A., @ 1-313; Acts 1984, ch. 1006, @@ 2, 9, 13-16; 1985, ch. 375, @@ 1-4; 1987, ch. 95, @ 1.

NOTES:

COMPILER'S NOTES. Section 39-6-910(1), referred to in this section, was repealed by Acts 1989, ch. 591.

CROSS-REFERENCES. Age of majority for alcoholic beverage and legal purposes, @ 1-3-105.

Alcoholic beverage definitions, @@ 57-2-101, 57-3-101.

Juvenile alcohol abuse, title 68, ch. 27, part 4.

Minimum age for fire protection sprinkler system certification and licensing, @ 62-32-107.

Removal of disability of minor veterans and spouses for receipt of benefits, @ 58-3-103.

Sale of alcoholic beverages to minors, @@ 57-4-203, 57-5-301.

Support of child over 18 in high school, @ 34-11-102.

Lodging establishments, conduct of guests, title 68, ch. 14, part 6.

SECTION TO SECTION REFERENCES. This section is referred to in @@ 1-3-115, 37-2-105, 68-14-601, 68-14-603, 68-14-605.

TEXTBOOKS. Tennessee Criminal Practice and Procedure (Raybin), @ 16.56.

Tennessee Jurisprudence, 18 Tenn. Juris., Limitations of Actions, @@ 3, 34; 18 Tenn. Juris., Minors, @ 2; 20 Tenn. Juris., Parent and Child, @ 18.

LAW REVIEWS. Criminal Law in Tennessee in 1971 -- A critical Survey (Joseph G. Cook), 39 Tenn. L. Rev. 247.

CITED: Parker v. Parker, 497 S.W.2d 572 (Tenn. 1973); State v. Gardner, 626 S.W.2d 721 (Tenn. Crim. App. 1981); Cardwell v. Bechtol, 724 S.W.2d 739 (Tenn. 1987); Nichols v. Atnip, 844 S.W.2d 655 (Tenn. Ct. App. 1992).

NOTES TO DECISIONS

ANALYSIS

1. Constitutionality.
2. Duty to support.
3. Jury selection.
4. Federal laws.
5. Limitations of actions.
6. Construction with other statutes.
7. Legal capacity of minors.

1. CONSTITUTIONALITY.

The Legal Responsibility Act of 1971 is not unconstitutional as being retrospective. Arnold v. Davis, 503 S.W.2d 100 (Tenn. 1973).

2. DUTY TO SUPPORT.

By lowering the age of majority from 21 to 18 years of age the general assembly completely emancipated such persons from the control of the parents and relieved the parents of their attendant legal duty of support. Garey v. Garey, 482 S.W.2d 133 (Tenn. 1972).

Father's legal obligation to maintain, support, and educate his two sons terminated as of May 11, 1971, for son over the age of 18 years old and on the date of the eighteenth birthday of the younger son. Weinstein v. Heimberg, 490 S.W.2d 692 (Tenn. Ct. App. 1972).

Where divorce decree provided for child support by father "until each child reaches twenty-one (21) years of age or is otherwise emancipated" passage of this section relieved father of obligation to make support payments for 18-year-old child. Garey v. Garey, 482 S.W.2d 133 (Tenn. 1972).

Where divorce decree provided for child support by father until children completed education or reached age 22 and would be reduced if child permanently left custody of mother, father was liable to support 18-year-old daughter who had not left custody of mother regardless of this section. Jones v. Jones, 503 S.W.2d 924 (Tenn. Ct. App. 1973).

Separation agreement between husband and wife providing that husband pay support for the children until they reached the age of 21 was within the husband's legal obligations and therefore lost its contractual nature when approved by the court and could be enforced only so long as he had a legal duty to support his children. Blackburn v. Blackburn, 526 S.W.2d 463 (Tenn. 1975).

The statute by lowering the age of majority to 18 cut short support

obligations. Blackburn v. Blackburn, 526 S.W.2d 463 (Tenn. 1975).

Absent a specific contractual undertaking going further, the parental duty to support the child terminates when the child reaches 18 years of age, the age of majority. Deatherage v. Wallace, 55 Bankr. 268 (Bankr. E.D. Tenn. 1985).

A parent has no legal duty to support a child who has attained majority. Hawkins v. Hawkins, 797 S.W.2d 897 (Tenn. Ct. App. 1990).

3. JURY SELECTION.

There was no basis for contention that persons 18, 19, and 20 years old, who were extended the elective franchise on May 11, 1971, were systematically excluded from grand jury where the jury list from which the defendant's grand jury was empaneled was selected and compiled and placed in the jury box long before that date. Shadden v. State, 488 S.W.2d 54 (Tenn. 1972), cert. denied, 411 U.S. 909, 93 S. Ct. 1538, 36 L. Ed. 2d 199 (1973).

4. FEDERAL LAWS.

The enactment of this statute by Tennessee did not prevent a federal court from sentencing a juvenile under the federal Juvenile Delinquency Act (18 U.S.C. @@ 5031-5042) to custody until the age of 21. United States v. Minor, 455 F.2d 937 (6th Cir.), cert. denied, 406 U.S. 975, 92 S. Ct. 2426, 32 L. Ed. 2d 675 (1972).

5. LIMITATIONS OF ACTIONS.

The Legal Responsibility Act of 1971 is not a statute of limitations although its effect shortens the time minors have to commence actions. Arnold v. Davis, 503 S.W.2d 100 (Tenn. 1973).

6. CONSTRUCTION WITH OTHER STATUTES.

Upon a finding that a child is delinquent, has committed any act designated a crime by @ 37-1-103, the court has the discretion to "retain jurisdiction and control ... until he or she shall have reached the age of twenty-one (21) years," notwithstanding the Legal Responsibility Act of 1971 lowering the age of minority to age 18. State ex rel. Anglin v. Mitchell, 596 S.W.2d 779 (Tenn. 1980).

7. LEGAL CAPACITY OF MINORS.

A six-year-old child, as a matter of law, has no capacity to enter into an agreement of joint venture involving the hauling of livestock in a trailer being pulled by a pickup truck owned by his alleged coadventurer. Bennett v. Sanders, 685 S.W.2d 1 (Tenn. Ct. App. 1984).

COLLATERAL REFERENCES. Burden of proof of defendant's age, in prosecution where attainment of particular age is statutory requisite of guilt. 49 A.L.R.3d 526.

Statutory change of age of majority as affecting pre-existing status or rights. 75 A.L.R.3d 228.

Validity and construction of covenant restricting occupancy of premises to person over or under specified age. 68 A.L.R.3d 1239.