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APPENDIX

Versions of draft legislation included in the Second and Third Reports of the Attorney General's Research Working Group are reprinted in this Appendix for convenience. Citations to the draft legislation in the articles published in this issue refer to the actual page numbers of each report. The aforementioned reports are on file with the Office of the Maryland Attorney General as well as the *Journal of Health Care Law & Policy.*

APPENDIX A
DRAFT
MAY 5, 1997
PART I

AN ACT concerning

RESEARCH — PROTECTION OF DECISIONALLY INCAPACITATED INDIVIDUALS

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

ARTICLE — HEALTH GENERAL

Title 20. Miscellaneous Health Provisions.

Subtitle 5. Research Involving Decisionally Incapacitated Individuals

20-501. LEGISLATIVE FINDINGS.

The General Assembly finds that:

(a) All research involving human subjects in this State, including research involving decisionally incapacitated individuals, should be conducted with the utmost respect for the well-being and dignity of each research subject.

(b) Except under the carefully limited circumstances set forth in this subtitle, all research involving human subjects in this State should be conducted only after each subject provides informed consent to participation in the research.

(c) Research involving decisionally incapacitated individuals may be essential under some circumstances if science is to understand and ultimately combat diseases of the brain, including Alzheimer's Disease, severe psychiatric disorders, severe trauma, stroke, and other causes of decisional incapacity.

(d) Researchers should seek to enroll decisionally incapacitated individuals as research subjects only if the research is likely to yield generalizable knowledge important to the understanding or amelioration of the subjects' disorder or condition, and the knowledge cannot be obtained without their participation.

20-502. DEFINITIONS.

(a) In this subtitle, the following terms have the meanings indicated.

(b) *"Advance directive authorizing research participation"* means an advance directive made in accordance with §5-602 of this article that states a desire of an individual to participate in research.

(c) *"Assent"* means an individual's affirmative agreement to participate in research.

(d) *"Common Rule"* means the federal regulations governing the protection of human subjects in research codified at 45 C.F.R. Part 46, Subpart A.

(e)(1) *"Decisionally incapacitated individual"* means an individual who is at least 18 years of age and who cannot give a valid informed consent for research participation because the individual cannot sufficiently understand the nature, extent, or probable consequences of the proposed research participation, cannot make a sufficient evaluation of burdens, risks, and benefits of the proposed research participation, or cannot communicate a decision.

(2) An individual who is able to communicate by means other than speech may not be considered incapable of giving informed consent solely by reason of the inability to speak.

(f) *"Health care agent"* means an adult appointed by an individual under an advance directive and authorized under the Health Care Decisions Act to make health care decisions for the individual.

(g) *"Health Care Decisions Act"* means Title 5, Subtitle 6 of this article.

(h) *"Informed consent"* means the voluntary agreement by an individual to participate in research following disclosure to the individual of all information required to be disclosed by the Common Rule.

(i) *"Investigator"* means a person who conducts research by means of:

(1) physical procedures by which data are gathered from a living individual;

(2) manipulation of an individual or the individual's environment;

(3) communication or interpersonal contact between an investigator and individual; or

(4) gathering individually identifiable private information, including 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.

(j) *"IRB"* means an institutional review board whose membership and processes comply with the requirements of the Common Rule.

(k) *"Legally authorized representative"* means an individual authorized under this subtitle to give consent to a decisionally incapacitated individual's participation in research.

(l) *"Medical best interest"* means that the potential medical benefits to the individual resulting from participation in research are determined by the legally authorized representative to be reasonable in relation to the burdens to the individual resulting from that participation in research, taking into account:

(1) the effect of the participation in research on the physical, emotional, and cognitive functions of the individual;

(2) the degree of physical pain or discomfort, psychological distress, or loss of dignity caused to the individual by the participation in research;

(3) the prognosis of the individual;

(4) the risks, side effects, and benefits of the participation in research, compared to the risks, side effects, and benefits of standard treatment, if any;

(5) the religious beliefs and basis values of the individual, to the extent these may assist the legally authorized representative in determining medical best interest.

(m) *"Minimal risk"* means that the probability and magnitude of harm or discomfort anticipated in the research, including psychological harm and loss of dignity, 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.

(n) *"Minor increase over minimal risk"* means that the probability and magnitude of harm or discomfort anticipated in the research, including psychological harm and loss of dignity, are only slightly greater in and of themselves than those ordinarily encountered in the daily life of the potential research subjects or during the performance or routine physical or psychological examinations or tests.

(o) *"Monitor"* means an adult who is not a health care agent, research agent, or surrogate for a decisionally incapacitated individual and who is designated by an IRB to carry out an action authorized under this subtitle.

(p) *"Reasonable prospect of direct medical benefit"* means that, on the basis of scientific evidence, a realistic possibility exists that an individual's medical condition would be improved as a direct result of participation in research, including ameliorating symptoms or avoiding side effects of standard therapy.

(q) *"Research"* means a systematic investigation including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

(r) *"Research agent"* means an adult who, under an advance directive authorizing research participation, is expressly authorized to make decisions regarding an individual's participation in research, whether or not the research agent is also a health care agent or surrogate.

(s) *"Surrogate"* means an adult authorized to make health care decisions for an individual under §5-605 of this article.

20-503. COMPLIANCE WITH SUBTITLE; EXCEPTIONS.

(a) Except for research identified in subsection (b) of this section, an investigator may not involve a decisionally incapacitated individual as a subject in research unless all applicable requirements of this subtitle are satisfied.

(b) This subtitle does not apply to research that:

(1) is exempt under 45 C.F.R. §46.101(b) from the requirements of the Common Rule;

(2) concerns treatment for a life-threatening emergency and is conducted in accordance with regulations of the United States Food and Drug Administration or a waiver of informed consent by the United States Department of Health and Human Services; or

(3) involves a decisionally incapacitated individual as a result of the consent of a court or guardian of the person, acting in accordance with Title 13, Subtitle 7 of the Courts and Judicial Proceedings Article.

20-504. DUTIES OF AN IRB.

(a) In considering whether to approve research in which decisionally incapacitated individuals are intended to be the subjects, an IRB shall comply with all requirements applicable to an IRB under the Common Rule and this subtitle.

(b)(1) An IRB may not approve research in which decisionally incapacitated individuals are intended to be the subjects unless the research relates directly to:

(i) the condition that has resulted in the decisional incapacity of the subjects; or

(ii) a demonstrated or reasonably predicted relationship between that condition and any other medical condition of those subjects.

(c) An IRB shall determine and state in its minutes whether or not research in which decisionally incapacitated individuals are in-

tended to be the subjects presents, to those subjects, a reasonable prospect of direct medical benefit.

(d)(1) An IRB shall determine and state in its minutes whether research in which decisionally incapacitated individuals are intended to be the subjects presents, to those subjects:

(i) minimal risk;

(ii) a minor increase over minimal risk; or

(iii) more than a minor increase over minimal risk.

(2) In determining the degree of risk to that class of subjects, the IRB shall take into account:

(i) the extent to which the research adds to the probability or magnitude of harm or discomfort that the subjects would experience if they did not participate in the research;

(ii) whether the research has been identified by the United States Department of Health and Human Services as a category for which expedited review procedures are authorized under the Common Rule; and

(iii) prior research of a similar kind, relevant laboratory and animal studies, and any other relevant information presented to the IRB.

(3) An IRB may not determine that research presents a minimal risk if the research would expose the class of subjects who are intended to be enrolled in the research to a loss of dignity greater than that ordinarily encountered by individuals who are not decisionally incapacitated in daily life or during the performance of routine physical or psychological examinations or tests.

(4) An IRB may not certify research as presenting a minimal risk or a minor increase over minimal risk if the research would expose the class of subjects who are intended to be enrolled in the research to the reasonable possibility of:

(i) severe or prolonged pain or discomfort; or

(ii) deterioration in a medical condition.

(e) An IRB may not approve research in which decisionally incapacitated individuals are intended to be the subjects unless the IRB has reviewed and approved:

(1) informed consent procedures and documents consistent with the Common Rule, including, as appropriate, an explanation of randomization, the use of a placebo, or other aspects of the control element of a research design; and

(2) a procedure for soliciting assent from each decisionally incapacitated individual who is capable of providing assent.

(f) An IRB may not approve research in which decisionally incapacitated individuals are intended to be the subjects if the IRB is aware that an investigator involved in the research has, within the preceding five years, been found by an agency of the United States or this State to have knowingly and willfully involved a decisionally incapacitated individual in research in violation of this subtitle.

(g) An IRB shall establish standards and procedures under which a health care agent shall document, in accordance with § 20-509(c)(2), the direct and explicit evidence of a decisionally incapacitated individual's wish to participate in research.

(h)(1) An IRB shall assure that any member of the public may obtain, upon request, the following documents related to research involving decisionally incapacitated individuals that is approved by the IRB on or after October 1, 1998:

(i) the relevant portions of the IRB's minutes;

(ii) if not included in the IRB's minutes, a summary or precis of the research; and

(iii) written consent documents approved by the IRB.

(2) Disclosure of these documents may be made by the IRB, or, by agreement with the IRB, an investigator, a sponsor of research, or an institution with which the IRB is affiliated.

(3) The person responsible for disclosure may charge a reasonable fee for copies.

(4) The disclosure required by this subsection is in addition to any disclosure of information or documents related to research that is required or authorized by:

(i) federal or State law or policy; or

(ii) the policy of the IRB, a sponsor of research, an institution with which the IRB is affiliated, or an institution at which research occurs.

20-505. DUTIES OF AN INVESTIGATOR.

(a) An investigator who conducts research involving decisionally incapacitated individuals shall comply with all requirements applicable to an investigator under the Common Rule and this subtitle.

(b) Before involving a decisionally incapacitated individual as a subject in research, an investigator shall:

(1) obtain approval from an IRB to conduct the research;

(2) determine that the individual may participate in the research because:

(i) the individual is one of a class of decisionally incapacitated individuals whose participation in the research has been approved by the IRB;

(ii) the research presents a reasonable prospect of direct medical benefit to the individual; or

(iii) the research falls within a category of research identified in an advance directive of the individual authorizing research participation;

(3) in accordance with procedures and documents approved by an IRB, provide a legally authorized representative with all of the information required under the Common Rule for informed consent; and

(4) obtain permission form a legally authorized representative of the individual; and

(c) unless the individual is unconscious, prior to the participation in research of a decisionally incapacitated individual, the investigator shall tell the individual, in a manner appropriate to the individual's capacity for understanding, that:

(i) he or she is to participate in research; and

(ii) a legally authorized representative has consented to the individual's participation.

(d)(1) Except as otherwise authorized by law, an investigator may not compel a decisionally incapacitated individual to perform an action related to the research if the individual refuses to take the action after being asked to do so.

(2) An investigator may take reasonable, noncoercive steps to encourage a decisionally incapacitated individual to perform an action.

(e) An investigator who seeks IRB approval of research involving decisionally incapacitated individuals shall inform the IRB whether:

(1) any other IRB has failed to approve the research or substantially equivalent research proposed by the investigator; and

(2) any investigator involved in the research has, within the preceding five years, been found by an agency of the United States or this State to have knowingly and willfully involved a decisionally incapacitated individual in research in violation of this subtitle.

20-506. PRIORITY TO GUARDIANSHIP.

Nothing in this subtitle authorizes a legally authorized representative to consent to a decisionally incapacitated individual's participation in research if a guardian of the person has been appointed for the individual and has been granted authority to made decisions about research participation.

20-507. EXPECTED BENEFIT RESEARCH.

(a) This section applies to research that:

(1) presents a reasonable prospect of direct medical benefit to the class of decisionally incapacitated individuals who have been authorized by an IRB to be enrolled in the research; or

(2) pertains to a disorder or condition of a decisionally incapacitated individual and presents a reasonable prospect of direct medical benefit to that individual.

(b) A research agent may consent to a decisionally incapacitated individual's participation in research described in this section if, after taking into account treatment alternatives outside of the research, the research agent concludes that participation in the research is in the individual's medical best interest.

(c) A health care agent may consent to a decisionally incapacitated individual's participation in research described in this section if:

(1) a research agent is not available; and

(2) after taking into account treatment alternatives outside of the research, the health care agent concludes that participation in the research is in the individual's medical best interest.

(d)(1) A surrogate may consent to a decisionally incapacitated individual's participation in research described in this section if:

(i) neither a research agent nor a health care agent is available; and

(ii) after taking into account treatment alternatives outside of the research, the surrogate concludes that participation in the research is in the individual's medical best interest.

(2) If surrogates with equal decision making priority under the Health Care Decisions Act disagree about the individual's participation in the research, the disagreement shall be resolved in accordance with §5-605(b) of this article.

(e) A monitor designated in accordance with §20-511 may consent to a decisionally incapacitated individual's participation in research described in this section if:

(1) no health care agent, research agent, or surrogate is available;

(2) the research is unambiguously included in the individual's advance directive authorizing research participation; and

(3) after taking into account treatment alternatives outside of the research, the monitor concludes that participation in the research is in the individual's medical best interest.

(f) Nothing in this section authorizes a surrogate or a monitor to consent to:

(1) the admission of a decisionally incapacitated individual to a mental health facility; or

(2) a behavior modification program involving aversive stimuli.

20-508. NO EXPECTED BENEFIT RESEARCH — MINIMAL RISK.

(a) This section applies to research involving a decisionally incapacitated individual that, as determined by an IRB:

(1) does not provide a reasonable prospect of direct medical benefit; and

(2) presents no greater than minimal risk to the class of subjects who are authorized to be enrolled in the research.

(b) A research agent, if available, may consent to a decisionally incapacitated individual's participation in research described in this section if the research agent concludes, on the basis of the advance directive and other pertinent information, that the individual would consent to participate in the research were the individual able to give informed consent.

(c) A health care agent may consent to a decisionally incapacitated individual's participation in research described in this section if:

(1) a research agent is not available; and

(2) the health care agent concludes that the individual would consent to participate in the research were the individual able to give informed consent.

(d)(1) A surrogate may consent to a decisionally incapacitated individual's participation in research described in this section if:

(i) neither a research agent nor a health care agent is available; and

(ii) the surrogate concludes that the individual would consent to participate in the research were the individual able to give informed consent.

(2) If two or more surrogates with equal decision making priority under the Health Care Decisions Act are available, the individual may participate in the research only if all surrogates agree to consent to the individual's participation.

(e) A monitor may consent to a decisionally incapacitated individual's participation in research described in this section if:

(1) no research agent, health care agent, or surrogate is available; and

(2) the research is unambiguously included in the individual's advance directive authorizing research participation.

(f) Nothing in this section authorizes a surrogate or a monitor to consent to:

(1) the admission of a decisionally incapacitated individual to a mental health facility; or

(2) a behavior modification program involving aversive stimuli.

20-509. NO EXPECTED BENEFIT RESEARCH — MINOR INCREASE OVER MINIMAL RISK.

(a) This section applies to research involving a decisionally incapacitated individual that, as determined by an IRB:

(1) does not provide a reasonable prospect of direct medical benefit; and

(2) present no more than a minor increase over minimal risk to the class of subjects who are authorized to be enrolled in the research.

(b) A research agent may consent to a decisionally incapacitated individual's participation in research described in this section if the research agent concludes, based on the advance directive authorizing research participation and other pertinent information, that the individual would consent to participate in the research were the individual able to give informed consent.

(c) A health care agent may consent to a decisionally incapacitated individual's participation in research described in this section if:

(1) a research agent is not available; and

(2) the health care agent determines, based on direct and explicit evidence of the individual's wish to participate in this research, as documented in accordance with standards and procedures determined by the IRB, that the individual would consent to participate in the research were the individual able to give informed consent.

(d) The individual's prior participation in similar research, when the individual was able to give informed consent, may be taken into account by the research agent or health care agent but may not be the sole basis on which permission is granted for the individual to participate in the research.

20-510. NO EXPECTED BENEFIT RESEARCH — MORE THAN MINOR INCREASE OVER MINIMAL RISK.

(a) This section applies to research involving a decisionally incapacitated individual that, as determined by an IRB:

(1) does not provide a reasonable prospect of direct medical benefit; and

(2) presents more than a minor increase over minimal risk.

(b) A research agent may consent to a decisionally incapacitated individual's participation in research described in this section if:

(1) a monitor confirms that:

(i) the research is unambiguously included in the individual's advance directive authorizing research participation; and

(ii) the research agent understands the goals and risks of the research; and

(2) the research agent concludes that the individual would consent to participate in the research were the individual able to give informed consent.

20-511. DESIGNATION AND DUTIES OF MONITOR.

(a) An IRB may designate one or more monitors for research conducted in the institution served by the IRB.

(b)(1) A monitor may not participate in any way, including authorship of publications, in the research concerning which the monitor performs duties under this subtitle.

(2) If feasible, an IRB shall designate as a monitor an individual who is not employed by the same institution that employs any investigator in the research about which the monitor will carry out a duty.

(c) Upon request of an IRB, a monitor shall:

(1) consider whether to consent to research participation by a decisionally incapacitated individual, in accordance with §20-507(e) or §20-508(e); and

(2) verify, in accordance with §20-510(b)(1), that:

(i) research is unambiguously included in an individual's advance directive authorizing research participation; and

(ii) a research agent understands the goals and risks of the research.

20-512. WITHDRAWAL FROM RESEARCH.

A legally authorized representative who consents to a decisionally incapacitated individual's participation in research shall:

(1) take reasonable steps to learn whether the experience of the individual in the research is consistent with the expectations of the legally authorized representative at the time that consent was granted; and

(2) withdraw consent if continued participation by the individual would, considering all relevant circumstances, be detrimental to the well-being of the individual.

20-513. IMMUNITY FROM LIABILITY; UNPROFESSIONAL CONDUCT.

(a) If research involving decisionally incapacitated individuals is authorized under this subtitle, an investigator is not subject to criminal prosecution or civil liability or deemed to have engaged in unprofessional conduct as a result of conducting that research without the informed consent of the research subjects.

(b) A member of an IRB or a monitor is not subject to criminal prosecution or civil liability or deemed to have engaged in unprofessional conduct as a result of actions done in accordance with this subtitle.

(c) A legally authorized representative who consents to a decisionally incapacitated individual's participation in research as provided in this subtitle is not subject to:

(1) criminal prosecution or civil liability for that action; or

(2) liability for any costs associated with the research participation based solely on the consent.

(d) The immunity provisions of this section shall apply unless it is shown by a preponderance of the evidence that the person did not, in good faith, comply with the provisions of this subtitle.

(e) An investigator who knowingly and willfully involves a decisionally incapacitated individual in research in violation of this subtitle shall be deemed to have engaged in unprofessional conduct for purposes of disciplinary action by a licensing authority.

20-514. ADVANCE DIRECTIVES EXECUTED BEFORE EFFECTIVE DATE.

An advance directive authorizing research participation made prior to October 1, 1998 shall be given effect as provided in this article.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect on October 1, 1998.