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APPENDIX B
DRAFT
AUGUST 1, 1997

AN ACT concerning

CONSENT TO 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. Consent for 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 as otherwise specifically authorized under federal or State law, 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, other causes of decisional incapacity, and the medical problems that are associated with these conditions and disorders.

(d) Researchers should seek to enroll decisionally incapacitated individuals as research subjects only if the research is expected to yield generalizable knowledge important to the understanding or amelioration of the subjects' disorder or condition and related medical problems, 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) "*Disinterested*" means:

(1) not participating in any way, including authorship of publications, in the research concerning which an individual performs duties under this subtitle; and

(2) not having any investment or other financial interest in any business entity sponsoring the research.

(g) "*Health care agent*" means a disinterested 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.

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

(i) "*Informed consent*" means:

(1) the voluntary agreement by an individual to participate in research following disclosure to the individual of all relevant information as determined by an IRB pursuant to the Common Rule and this subtitle; or

(2) if an individual is a decisionally incapacitated individual, the voluntary agreement by a legally authorized representative for the individual to participate in research following disclosure to the legally authorized representative of all relevant information as determined by an IRB pursuant to the Common Rule and this subtitle.

(j) "*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.

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

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

(m) *"Medical best interest"* means that the burdens to the individual resulting from participation in research are determined by the legally authorized representative to be acceptable in relation to the potential medical benefits to the individual resulting from the individual's 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 basic values of the individual, to the extent these may assist the legally authorized representative in determining medical best interest.

(n)(1) "*Minimal risk*" means that the probability and magnitude of harm or discomfort anticipated in the research, including psychological harm and loss of privacy or other aspects of personal 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.

(2) Research presenting "minimal risk" includes types of research that are:

(i) identified by the United States Department of Health and Human Services as suitable for expedited IRB review procedures; or

(ii) designated as "minimal risk" in a regulation of the Secretary of Health and Mental Hygiene.

(o)(1) "*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 privacy or other aspects of personal dignity, are only slightly greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(2) Research presenting a "minor increase over minimal risk" includes types of research designated as "minor increase over minimal risk" in a regulation of the Secretary of Health and Mental Hygiene.

(p) "*Monitor*" means a disinterested adult who is designated by an IRB, in accordance with this subtitle, to monitor the informed consent process when a research agent is considering whether to give informed consent to participation by decisionally incapacitated individual in research that, as determined by an IRB:

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

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

(q) "*Proxy decision maker*" means a disinterested adult who is designated by an IRB to consider whether to give informed consent, in accordance with this subtitle, for a decisionally incapacitated individual who had executed an advance directive authorizing research participation to participate in research that, as determined by an IRB, presents:

(1) a reasonable prospect of direct medical benefit; or

(2) minimal risk.

(r) "*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.

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

(t) "*Research agent*" means a disinterested 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.

(u) "*Surrogate*" means a disinterested adult who is neither a research agent nor a health care agent but who is authorized by the Health Care Decisions Act to make health care decisions for an individual.

20-503. SCOPE OF SUBTITLE.

(a)(1) Except as provided in subsection (b) of this section, all research in this State involving a decisionally incapacitated individual shall comply with this subtitle.

(2) Except as provided in subsection (b) of this section, research involving a decisionally incapacitated individual that is not expressly authorized in this subtitle is prohibited.

(b) An investigator need not comply with this subtitle if research involving a decisionally incapacitated individual:

(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) (i) is limited to the study of existing data, documents, records, pathological specimens, or diagnostic specimens;

(ii) will be conducted under procedures approved by an IRB sufficient to safeguard the privacy of the individual whose data, documents, or specimens are studied and any other identifiable individuals about whom personal information might be learned as a result of the research; and

(iii) is granted a waiver of informed consent by the IRB pursuant to 45 C.F.R. §46.116(d).

(c)(1) Except as provided in paragraph (2) of this subsection, nothing in this subtitle affects research that involves an individual with decisional capacity who has given informed consent to become a subject of the research.

(2) If an individual gave informed consent for research participation but becomes a decisionally incapacitated individual during the course of the research, the individual's further participation in the research is subject to this subtitle.

20-504. PERMISSIBLE RESEARCH — GENERAL CONDITIONS.

(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)(1) An investigator who plans to involve decisionally incapacitated individuals as research subjects shall obtain approval from an IRB to conduct the research with this group of subjects.

(2) Research that is planned to involve a group of decisionally incapacitated individuals as research subjects shall relate directly to:

(i) the condition that has resulted in the decisional incapacity of those individuals;

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

(iii) an assessment of the efficacy of an intervention already used in clinical practice to treat a condition or relationship described in subparagraphs (i) or (ii) of this paragraph.

(c)(1) An investigator who did not plan to involve decisionally incapacitated individuals as research subjects and therefore did not obtain approval from an IRB to do so nevertheless may involve a particular decisionally incapacitated individual as a research subject if:

(i) the research, as approved by the IRB, holds out a reasonable prospect of direct medical benefit to the research subjects;

(ii) the individual meets all applicable criteria for participation in the research;

(iii) in accordance with §20-510, the investigator obtains the informed consent of a legally authorized representative of the individual or of a court or guardian of the person; and

(iv) the investigator promptly notifies the IRB that the individual is participating in the research.

(2) If, in light of the criteria for participation in the research, the investigator anticipates that other decisionally incapacitated individuals may become involved in the research in the future, the investigator shall obtain approval from an IRB for their participation.

20-505. INVESTIGATOR'S DISCLOSURE TO IRB.

When an investigator plans to involve decisionally incapacitated individuals as research subjects, the investigator shall:

(1) describe to an IRB the group of decisionally incapacitated individuals who will be eligible to be involved;

(2) explain to the IRB why the proposed research cannot be conducted without the involvement of this group of decisionally incapacitated individuals;

(3) provide the IRB with the results of any prior review of the scientific merits of the proposed research or state to the IRB that the scientific merits of the proposed research have not been reviewed;

(4) inform the IRB whether any other IRB has failed to approve the research or substantially equivalent research proposed by the investigator;

(5) inform the IRB whether any investigator involved in the research has, within the preceding five years, been found by an agency of the United States, this State, or another state to have knowingly violated this subtitle or any federal or state law protecting the rights and welfare of decisionally incapacitated individuals in research;

(6) describe to the IRB the procedures by which the health and safety of the research subjects are to be monitored during the course of the research, including appropriate consultation with the attending physicians of the research subjects;

(7) describe to the IRB:

(i) how legally authorized representatives may observe the research or otherwise learn about the experience of decisionally incapacitated individuals in the research;

(ii) whether a consent for further research participation will be sought from legally authorized representatives at any point during the research; and

(iii) what procedures are to be used for periodic confirmation that the individual remains willing to participate in the research; and

(8) obtain approval from the IRB to conduct the research.

20-506. RESPONSIBILITIES OF AN IRB — IN GENERAL.

In considering whether to approve research in which an investigator plans to involve decisionally incapacitated individuals, an IRB shall:

(1) comply with all requirements applicable to an IRB under the Common Rule, including its requirements for membership, and under this subtitle;

(2) consider whether additional safeguards, beyond those generally required by the Common Rule, should be adopted to protect the rights and welfare of the decisionally incapacitated individuals who will be research subjects;

(3) review the research to determine that the proposed procedures do not unnecessarily expose decisionally incapacitated individuals to risk; and

(4) verify that the investigator has provided the IRB with the information required by §20-505.

20-507. RESPONSIBILITIES OF AN IRB — DETERMINATION AND DESCRIPTION OF BENEFITS AND RISKS.

(a)(1) (i) If an investigator seeks approval for research in which a group of decisionally incapacitated individuals are planned to be involved, an IRB shall determine and state in its minutes whether the research presents a reasonable prospect of direct medical benefit to the group of subjects as a whole.

(ii) In considering whether the research presents a reasonable prospect of direct medical benefit to the group of subjects as a whole, the IRB shall take into account the relevant scientific evidence available to it and the nature of the research design, including the effect of any placebo control.

(2) If research presents a reasonable prospect of direct medical benefit to the group of subjects, the IRB shall ensure that materials to be made available to legally authorized representatives as part of the informed consent process fairly describe the risks and benefits of research participation, including the extent to which the research adds to the probability or magnitude of harm or discomfort that the individuals could be expected to experience if they did not participate in the research.

(b)(1) If the IRB determines that the research presents no reasonable prospect of direct medical benefit to a group of research subjects, the IRB shall further determine and state in its minutes whether the research presents, to that group as a whole, a level of risk that is:

(i) minimal risk;

(ii) a minor increase over minimal risk; or

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

(2) An IRB shall determine that research presents more than a minor increase over minimal risk if, as a result of research participation, the subjects would be exposed to more than a remote possibility of:

(i) severe or prolonged pain or discomfort; or

(ii) clinically significant deterioration in a medical condition.

(3) The IRB shall ensure that materials to be made available to legally authorized representatives as part of the informed consent process fairly describe the risks of research participation, including

the extent to which the research adds to the probability or magnitude of harm or discomfort that the individuals could be expected to experience if they did not participate in the research.

20-508. RESPONSIBILITIES OF AN IRB — OTHER SAFEGUARDS.

(a) If the IRB learns that an investigator involved in research in which decisionally incapacitated individuals are intended to be the subject has, within the preceding five years, been found by an agency of the United States, this State, or another state to have knowingly violated this subtitle or any federal or state law protecting the rights and welfare of decisionally incapacitated individuals in research, the IRB shall:

(1) decline to approve the research; and

(2) provide the Secretary of Health and Mental Hygiene and the Attorney General with the information available to the IRB concerning the violation.

(b) An IRB shall establish standards and procedures under which a health care agent shall document, in accordance with §20-515(c), the direct and explicit evidence of a decisionally incapacitated individual's wish to participate in research.

(c) In addition to the review of research at periodic intervals required by the Common Rule, an IRB may at any time suspend or withdraw its approval of research or suspend the accrual of additional research subjects if the IRB concludes that:

(1) continuation of research may result in unanticipated harm to research subjects; or

(2) an investigator has failed to:

(i) carry out properly the investigator's responsibilities under the Common Rule and this subtitle; or

(ii) comply with the determinations of the IRB.

20-509. CONFORMING RESEARCH TO IRB DETERMINATIONS.

(a) If an IRB has determined that research presents a reasonable prospect of direct medical benefit to a group of research subjects, an investigator shall:

(1) involve in the research only individuals who fall within that group; and

(2) discontinue the involvement in the research of any individual for whom the research no longer presents a reasonable prospect of direct medical benefit.

(b) If an IRB has determined that research presents a particular level of risk to a group of research subjects, an investigator shall:

(1) involve in the research only individuals who fall within that group; and

(2) immediately discontinue the involvement in the research of any individual for whom the research has presented a higher level of risk.

(c) An investigator shall immediately report to the IRB any unexpected serious harm to a research subject resulting from participation in the research.

20-510. INFORMED CONSENT.

(a) An investigator shall provide a legally authorized representative with all of the information deemed necessary by an IRB for informed consent.

(b) As part of the informed consent process, an investigator shall fairly describe:

(1) all material risks and direct medical benefits, if any, reasonably foreseeable from participation in the research;

(2) if the research involves an alternative to a standard form of treatment, the risks and benefits of the research alternative compared to the standard treatment; and

(3) randomization, the use of a placebo, or other aspects of the control element of a research design.

(c)(1) Prior to involving a decisionally incapacitated individual in research, an investigator shall obtain the informed consent of a legally authorized representative of an individual, as provided in this subtitle, or of a court or guardian of the person.

(2) Unless documentation requirements have been waived by the IRB under 45 C.F.R. §46.117(c), the investigator shall document the consent by obtaining a written consent form signed by the legally authorized representative.

(d) If a research subject was a decisionally incapacitated individual when first involved in research, but later is able to give informed consent, the investigator may not involve the individual in further research without the individual's informed consent.

20-511. SUBJECT ASSENT.

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

(i) the fact that he or she is being asked to participate in research; and

(ii) the name of the legally authorized representative who has consented to the individual's participation.

(b) An investigator shall obtain the assent of any decisionally incapacitated individual who is capable of giving assent prior to involving the individual in research.

(c)(1) Nothing in this subtitle authorizes an investigator to:

(i) involve an individual in an action related to research if the investigator is aware that the individual has expressed disagreement with the action; or

(ii) 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 reconsider a refusal of assent or refusal to perform an action related to the research.

20-512. EFFECT OF GUARDIANSHIP.

(a) Except as provided in subsection (c), nothing in this subtitle affects the authority of a court or a guardian of the person appointed under Title 13, Subtitle 7 of the Courts and Judicial Proceedings Article.

(b) Notwithstanding the authority given in this subtitle to a legally authorized representative, if a guardian of the person has been appointed for the individual and has specifically been granted authority to make decisions about a decisionally incapacitated individual's participation in research, the guardian, subject to the court's supervision, shall have exclusive authority to make these decisions.

(c) A guardian of the person may not give informed consent for a decisionally incapacitated individual to participate in research unless the research, as approved by the IRB, presents:

(1) a reasonable prospect of direct medical benefit to the individual; or

(2) no more than a minor increase over minimal risk to the individual.

20-513. AUTHORITY TO GIVE INFORMED CONSENT — DIRECT MEDICAL BENEFIT.

(a) This section applies to research that, as determined by an IRB, presents a reasonable prospect of direct medical benefit to the research subjects.

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

(1) after taking into account the risks and benefits of research participation compared to the risks and benefits of any treatment alternatives outside of the research, the research agent concludes that participation in the research is in the individual's medical best interest; and

(2) the research agent does not have reason to believe that the individual would have declined 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 subsection (a) if:

(1) a research agent is not available;

(2) after taking into account the risks and benefits of research participation compared to the risks and benefits of any treatment alternatives outside of the research, the health care agent concludes that participation in the research is in the individual's medical best interest; and

(3) the health care agent does not have reason to believe that the individual would have declined 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 subsection (a) if:

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

(ii) after taking into account the risks and benefits of research participation compared to the risks and benefits of any treatment alternatives outside of the research, the surrogate concludes that participation in the research is in the individual's medical best interest; and

(iii) the surrogate does not have reason to believe that the individual would have declined to participate in the research were the individual able to give informed consent.

(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 proxy decision maker designated by an IRB in accordance with §20-519 may consent to a decisionally incapacitated individual's participation in research described in subsection (a) 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 the risks and benefits of research participation compared to the risks and benefits of any treatment alternatives outside of the research, the proxy decision maker concludes that participation in the research is in the individual's medical best interest.

(f) In considering whether an individual would have declined to participate in research were the individual able to give informed consent, a research agent, health care agent, surrogate, or proxy decision maker may take into account any relevant information, including:

(1) any expressed preferences of the individual regarding participation in the kind of research at issue;

(2) any expressed preferences of the individual about research participation generally;

(3) any religious or moral beliefs or personal values of the individual in relation to research participation;

(4) any behavioral or other manifestations of the attitude of the individual toward research participation, including prior participation in research;

(5) any reactions of the individual to another individual's research participation; and

(6) any statements of the individual about the effect of research participation on the individual's family or on others who have the same medical condition.

20-514. AUTHORITY TO GIVE INFORMED CONSENT — NO DIRECT MEDICAL BENEFIT, MINIMAL RISK.

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

(1) does not present a reasonable prospect of direct medical benefit to the research subjects; and

(2) presents no greater than minimal risk to the research subjects.

(b) A research agent, if available, may consent to a decisionally incapacitated individual's participation in research described in subsection (a) if the research agent has reason to believe that the individual would have consented to participate in the research were the individual able to give informed consent.

(c) If a research agent is not available, a health care agent may consent to a decisionally incapacitated individual's participation in research described in subsection (a) if the health care agent has

reason to believe that the individual would have consented to participate in the research were the individual able to give informed consent.

(d)(1) If neither a research agent nor a health care agent is available, a surrogate may consent to a decisionally incapacitated individual's participation in research described in subsection (a) if the surrogate has reason to believe that the individual would have consented 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 jointly consent to the individual's participation.

(e) If no research agent, health care agent, or surrogate is available, a proxy decision maker may consent to a decisionally incapacitated individual's participation in research described in subsection (a) if the research is unambiguously included in the individual's advance directive authorizing research participation.

(f) In considering whether an individual would have consented to participate in research were the individual able to give informed consent, a research agent, health care agent, surrogate, or proxy decision maker may take into account any relevant information, including:

(1) any expressed preferences of the individual regarding participation in the kind of research at issue;

(2) any expressed preferences of the individual about research participation generally;

(3) any religious or moral beliefs or personal values of the individual in relation to research participation;

(4) any behavioral or other manifestations of the attitude of the individual toward research participation, including prior participation in research;

(5) any reactions of the individual to another individual's research participation; and

(6) any statements of the individual about the effect of research participation on the individual's family or on others who have the same medical condition.

20-515. AUTHORITY TO GIVE INFORMED CONSENT — NO DIRECT MEDICAL BENEFIT, MINOR INCREASE OVER MINIMAL RISK.

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

(1) does not present a reasonable prospect of direct medical benefit to the research subjects; and

(2) presents a minor increase over minimal risk to the research subjects.

(b) A research agent may consent to a decisionally incapacitated individual's participation in research described in subsection (a) if the research agent concludes, based on the advance directive authorizing research participation and other pertinent information, as set forth in §20-514(f), that the individual would consent to participate in the research were the individual able to give informed consent.

(c) If a research agent is not available, a health care agent may consent to a decisionally incapacitated individual's participation in research described in subsection (a) if the health care agent concludes, 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.

(e) No legally authorized representative other than a research agent or a health care agent may consent to a decisionally incapacitated individual's participation in research described in this section.

20-516. AUTHORITY TO GIVE INFORMED CONSENT — NO DIRECT MEDICAL BENEFIT, MORE THAN MINOR INCREASE OVER MINIMAL RISK.

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

(1) does not present a reasonable prospect of direct medical benefit to the research subjects; and

(2) presents more than a minor increase over minimal risk to the research subjects.

(b) A research agent may consent to a decisionally incapacitated individual's participation in research described in subsection (a) 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, based on the advance directive authorizing research participation and other pertinent information, as set forth in §20-514(f), that the individual would consent to participate in the research were the individual able to give informed consent.

(c) The monitor shall witness the process by which an investigator provides the research agent with the information required by an IRB for informed consent.

(d) No legally authorized representative other than a research agent may consent to a decisionally incapacitated individual's participation in research described in this section.

20-517. AUTHORITY TO GIVE INFORMED CONSENT — LIMITATION.

Nothing in this subtitle authorizes a surrogate or a proxy decision maker to consent to:

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

(2) a behavior modification program involving painful or invasive aversive stimuli.

20-518. 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, including expectations about potential benefits, if any, and risks presented by the research; and

(2) withdraw consent if:

(i) the research was initially determined to present a reasonable prospect of direct medical benefit to the research subjects but no longer does so for the individual;

(ii) the research presents a higher level of risk to the individual than initially expected; or

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

20-519. DESIGNATION AND DUTIES OF PROXY DECISION MAKERS AND MONITORS.

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

(b)(1) Except as provided in paragraph (2), an IRB shall designate as a proxy decision maker or monitor a disinterested 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.

(2) In exceptional circumstances documented in the IRB's minutes, an IRB may designate as a proxy decision maker or monitor a disinterested individual who is employed in a part of the institution organizationally distinct from that of the investigators.

(c) Upon request of an IRB, a proxy decision maker shall consider whether to consent to research participation by a decisionally incapacitated individual, in accordance with §20-513(e) or §20-514(e).

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

(1) verify, in accordance with §20-516(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; and

(2) witness the process by which an investigator provides the research agent with the information required by an IRB for informed consent.

20-520. DISCLOSURE OF DOCUMENTS AND INFORMATION.

(a)(1) An IRB shall assure that any member of the public may obtain, upon request, a copy of 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 informed consent documents approved by the IRB.

(2) Disclosure of these documents may be made by the IRB, or, under an agreement with the IRB, by 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.

(b) Not later than February 15 of each year, an IRB that, during the preceding calendar year, approved research in which decisionally incapacitated individuals were intended to be subjects shall report to the Secretary of Health and Mental Hygiene and the Attorney General:

(1) the number of these research protocols approved; and

(2) for each research protocol, the number of decisionally incapacitated individuals who were authorized to become subjects.

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

(1) federal or State statute, regulation, or policy; or

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

20-521. IMMUNITY FROM LIABILITY; PRESERVATION OF 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 the research without the informed consent of the research subjects.

(b) 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.

(c) A member of an IRB or 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.

(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)(1) Notwithstanding any other provision of this section, an investigator who knowingly involves a decisionally incapacitated individual in research in violation of this subtitle shall remain subject to criminal prosecution or civil liability as otherwise provided by law.

(2) An investigator who knowingly 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.

20-522. AUTHORITY OF SECRETARY OF HEALTH AND MENTAL HYGIENE.

The Secretary may:

(1) in accordance with the Administrative Procedure Act, adopt regulations to:

(i) designate the level of risk of a particular type of research;

(ii) require additional disclosures to a legally authorized representative or to the public; and

(iii) clarify other aspects of this subtitle;

(2) order the immediate suspension of any research involving decisionally incapacitated individuals that, in the judgment of the Secretary, endangers the health or safety of these individuals; and

(3) in cooperation with the Office of the Attorney General, study the effects of this subtitle on the protection of decisionally incapacitated individuals and the conduct of research involving decisionally incapacitated individuals.

20-523. OFFICE OF THE ATTORNEY GENERAL — MODEL FORM.

After consultation with interested persons, the Office of the Attorney General shall prepare and distribute a model form of an advance directive authorizing research participation, the use of which shall be optional.

20-524. 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 subtitle.

20-525. SHORT TITLE.

This subtitle may be cited as "The Maryland Research Consent Act."

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