Unofficial Copy 1999 Regular Session
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By: **Senator Frosh**
Introduced and read first time: February 5, 1999
Assigned to: Judicial Proceedings

A BILL ENTITLED

AN ACT concerning

The Decisionally Incapacitated Research Subject Protection Act

FOR the purpose of specifying certain requirements for research involving certain individuals with a potential or actual decisional incapacity; specifying certain general conditions for certain investigators concerning research involving certain decisionally incapacitated individuals and potentially decisionally incapacitated individuals; specifying certain standards for investigators and institutional review boards concerning the recruitment for certain purposes of individuals with a potentially incapacitating condition; providing for the execution and effect of a certain research advance directive under certain circumstances; specifying certain duties of an investigator, institutional review board, and medically responsible clinician concerning research involving a decisionally incapacitated individual; providing for a certain process of informed consent and assent concerning certain research involving a decisionally incapacitated individual; authorizing a certain research agent, health care agent, surrogate, proxy decision maker, or legally authorized representative to provide a consent to participation in certain research by a decisionally incapacitated individual under certain circumstances; providing for disclosure to the public of certain information concerning research approved by an institutional review board after a certain date; requiring a certain institutional review board to submit a certain annual report to the Secretary of Health and Mental Hygiene and the Attorney General; specifying certain powers and duties of the Secretary and certain duties of the Attorney General; providing for certain immunities, liabilities, disciplinary action, and penalties for certain persons; requiring the effectiveness of a certain advance research directive made before a certain date; making certain legislative findings; providing for the scope of this Act and of certain provisions of this Act; defining certain terms; and generally relating to certain research involving certain individuals with certain incapacities.

BY adding to
Article - Health - General
Section 20-701 through 20-766, inclusive, to be under the new subtitle "Subtitle 7. Research Involving Decisionally Incapacitated Individuals"
Annotated Code of Maryland

(1996 Replacement Volume and 1998 Supplement)

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

Article - Health - General

SUBTITLE 7. RESEARCH INVOLVING DECISIONALLY INCAPACITATED INDIVIDUALS.

PART I. GENERAL PROVISIONS.

20-701.

(A) IN THIS SUBTITLE THE FOLLOWING TERMS HAVE THE MEANINGS INDICATED.

(B) "ASSENT" MEANS AN AFFIRMATIVE AGREEMENT OF AN INDIVIDUAL TO PARTICIPATE IN RESEARCH.

(C) "COMMON RULE" MEANS THE FEDERAL REGULATIONS GOVERNING THE PROTECTION OF A HUMAN SUBJECT IN RESEARCH CODIFIED AT 45 C.F.R. PART 46, SUBPART A.

(D) "DECISIONAL INCAPACITY" MEANS A MEDICAL CONDITION THAT HAS CAUSED AN INDIVIDUAL TO BE UNABLE TO UNDERSTAND SUFFICIENTLY THE NATURE, EXTENT, OR PROBABLE CONSEQUENCES OF PARTICIPATION IN RESEARCH, MAKE A SUFFICIENT EVALUATION OF BURDENS, RISKS, AND BENEFITS OF PARTICIPATION IN RESEARCH, OR COMMUNICATE A DECISION ABOUT PARTICIPATION IN RESEARCH.

(E) "DECISIONALLY INCAPACITATED INDIVIDUAL" MEANS AN INDIVIDUAL WHO IS AT LEAST 18 YEARS OF AGE AND WHO CAN NOT GIVE A VALID INFORMED CONSENT FOR RESEARCH PARTICIPATION BECAUSE THE INDIVIDUAL HAS A DECISIONAL INCAPACITY.

(F) "DISINTERESTED INDIVIDUAL" MEANS AN INDIVIDUAL 18 YEARS OF AGE OR OLDER WHO:

(1) DOES NOT PARTICIPATE IN ANY WAY, INCLUDING AUTHORSHIP OF A PUBLICATION, IN RESEARCH ABOUT WHICH THE INDIVIDUAL PERFORMS A DUTY UNDER THIS SUBTITLE;

(2) IS NOT EMPLOYED BY:

(I) THE SAME INSTITUTION OR CORPORATION THAT EMPLOYS AN INVESTIGATOR INVOLVED IN THE RESEARCH; OR

(II) A HOSPITAL OR OTHER HEALTH CARE FACILITY IN WHICH A POTENTIAL RESEARCH SUBJECT IS A PATIENT OR RESIDENT;

(3) DOES NOT RECEIVE, DIRECTLY OR INDIRECTLY, FINANCIAL SUPPORT FROM FUNDS MANAGED OR DIRECTED BY AN INVESTIGATOR; AND

(4) DOES NOT HAVE ANY INVESTMENT OR OTHER FINANCIAL INTEREST IN ANY BUSINESS ENTITY THAT:

(I) IS A SPONSOR OF THE RESEARCH; OR

(II) MAY BENEFIT DIRECTLY FROM THE OUTCOME OF THE RESEARCH.

(G) "HEALTH CARE AGENT" MEANS A DISINTERESTED INDIVIDUAL APPOINTED BY AN INDIVIDUAL PURSUANT TO THE HEALTH CARE DECISIONS ACT TO MAKE A HEALTH CARE DECISION 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 AFTER DISCLOSURE TO THE INDIVIDUAL OF ALL MATERIAL INFORMATION AS DETERMINED BY AN IRB IN ACCORDANCE WITH THE COMMON RULE; OR

(2) IF AN INDIVIDUAL IS A DECISIONALLY INCAPACITATED INDIVIDUAL, THE VOLUNTARY AGREEMENT BY A LEGALLY AUTHORIZED REPRESENTATIVE FOR THE DECISIONALLY INCAPACITATED INDIVIDUAL TO PARTICIPATE IN RESEARCH AFTER DISCLOSURE TO THE LEGALLY AUTHORIZED REPRESENTATIVE OF ALL RELEVANT INFORMATION AS DETERMINED BY AN IRB IN ACCORDANCE WITH THE COMMON RULE AND THIS SUBTITLE.

(J) "INVESTIGATOR" MEANS A PERSON WHO CONDUCTS RESEARCH BY MEANS OF:

(1) A PHYSICAL PROCEDURE BY WHICH DATA ARE GATHERED FROM A LIVING INDIVIDUAL;

(2) MANIPULATION OF AN INDIVIDUAL OR THE ENVIRONMENT OF THE INDIVIDUAL;

(3) COMMUNICATION OR INTERPERSONAL CONTACT BETWEEN THE INVESTIGATOR AND AN INDIVIDUAL; OR

(4) COLLECTION OF INDIVIDUALLY IDENTIFIABLE PRIVATE INFORMATION, INCLUDING INFORMATION THAT:

(I) CONCERNS BEHAVIOR OCCURRING IN A CONTEXT IN WHICH AN INDIVIDUAL CAN REASONABLY EXPECT THAT NO OBSERVATION OR RECORDING IS TAKING PLACE; OR

(II) HAS OTHERWISE BEEN PROVIDED BY AN INDIVIDUAL UNDER CIRCUMSTANCES CAUSING THE INDIVIDUAL REASONABLY TO EXPECT THAT THE INFORMATION 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 A DISINTERESTED INDIVIDUAL AUTHORIZED UNDER THIS SUBTITLE TO GIVE CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH.

(M) "MEDICAL BEST INTEREST" MEANS THAT THE BURDEN TO THE INDIVIDUAL RESULTING FROM PARTICIPATION IN RESEARCH IS DETERMINED BY A LEGALLY AUTHORIZED REPRESENTATIVE TO BE ACCEPTABLE IN RELATION TO THE POTENTIAL MEDICAL BENEFIT TO THE INDIVIDUAL RESULTING FROM PARTICIPATION BY THE INDIVIDUAL IN RESEARCH, TAKING INTO ACCOUNT:

(1) THE EFFECT OF 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 PARTICIPATION IN RESEARCH;

(3) THE PROGNOSIS OF THE INDIVIDUAL;

(4) ANY RISK, SIDE EFFECT, AND BENEFIT OF PARTICIPATION IN RESEARCH, COMPARED TO ANY RISK, SIDE EFFECT, AND BENEFIT OF STANDARD TREATMENT; AND

(5) THE RELIGIOUS BELIEFS AND BASIC VALUES OF THE INDIVIDUAL, TO THE EXTENT THAT THESE MAY ASSIST A LEGALLY AUTHORIZED REPRESENTATIVE IN DETERMINING THE MEDICAL BEST INTEREST OF THE INDIVIDUAL.

(N) "MEDICALLY RESPONSIBLE CLINICIAN" MEANS A LICENSED PHYSICIAN OR INDIVIDUAL AUTHORIZED BY LAW TO ACT UNDER THE SUPERVISION OF A PHYSICIAN WHO CARRIES OUT THE DUTIES STATED IN § 20-721 OF THIS SUBTITLE.

(O) (1) "MINIMAL RISK" MEANS THAT THE PROBABILITY AND MAGNITUDE OF HARM OR DISCOMFORT ANTICIPATED IN 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 A ROUTINE PHYSICAL OR PSYCHOLOGICAL EXAMINATION OR TEST.

(2) "MINIMAL RISK" INCLUDES A TYPE OF RESEARCH THAT IS DESIGNATED AS "MINIMAL RISK" IN A REGULATION OF THE SECRETARY.

(P) (1) "MINOR INCREASE OVER MINIMAL RISK" MEANS THAT THE PROBABILITY AND MAGNITUDE OF HARM OR DISCOMFORT ANTICIPATED IN 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 A ROUTINE PHYSICAL OR PSYCHOLOGICAL EXAMINATION OR TEST.

(2) "MINOR INCREASE OVER MINIMAL RISK" INCLUDES A TYPE OF RESEARCH THAT IS DESIGNATED AS "MINOR INCREASE OVER MINIMAL RISK" IN A REGULATION OF THE SECRETARY.

(Q) "MONITOR" MEANS A DISINTERESTED INDIVIDUAL WHO IS DESIGNATED BY AN IRB TO:

(1) MONITOR THE INFORMED CONSENT PROCESS WHEN A RESEARCH AGENT IS CONSIDERING WHETHER TO GIVE INFORMED CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH GOVERNED BY PART VIII OF THIS SUBTITLE; OR

(2) PERFORM OTHER MONITORING DUTIES SPECIFIED BY THE IRB.

(R) "POTENTIALLY INCAPACITATING CONDITION" MEANS A MEDICAL CONDITION THAT, AS DETERMINED BY AN IRB, IN ITS NORMAL COURSE RESULTS IN A HIGHER RATE OF DECISIONAL INCAPACITY AMONG INDIVIDUALS WITH THE CONDITION THAN AMONG OTHERWISE COMPARABLE INDIVIDUALS WITHOUT THE CONDITION.

(S) "PROXY DECISION MAKER" MEANS A DISINTERESTED INDIVIDUAL WHO IS DESIGNATED BY AN IRB TO CONSIDER WHETHER TO GIVE INFORMED CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH GOVERNED BY PART VI OF THIS SUBTITLE.

(T) "REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT" MEANS THAT, ON THE BASIS OF SCIENTIFIC EVIDENCE, A REALISTIC POSSIBILITY EXISTS THAT THE MEDICAL CONDITION OF AN INDIVIDUAL WOULD BE IMPROVED AS A DIRECT RESULT OF PARTICIPATION IN RESEARCH, INCLUDING AMELIORATING SYMPTOMS OR AVOIDING SIDE EFFECTS OF STANDARD THERAPY.

(U) "RESEARCH" MEANS A SYSTEMATIC INVESTIGATION INCLUDING DEVELOPMENT, TESTING, AND EVALUATION, DESIGNED TO DEVELOP OR CONTRIBUTE TO GENERALIZABLE KNOWLEDGE.

(V) "RESEARCH ADVANCE DIRECTIVE" MEANS AN ADVANCE DIRECTIVE MADE IN ACCORDANCE WITH § 20-711 OF THIS SUBTITLE.

(W) "RESEARCH AGENT" MEANS A DISINTERESTED INDIVIDUAL WHO, UNDER A RESEARCH ADVANCE DIRECTIVE, IS EXPRESSLY AUTHORIZED TO MAKE A DECISION CONCERNING PARTICIPATION BY AN INDIVIDUAL IN RESEARCH.

(X) "RESEARCH PROTOCOL" MEANS A DETAILED, WRITTEN EXPLANATION BY AN INVESTIGATOR OF THE OBJECTIVES, RATIONALE, AND DESIGN OF PARTICULAR RESEARCH.

(Y) "SECRETARY" MEANS THE SECRETARY OF HEALTH AND MENTAL HYGIENE.

(Z) (1) "SURROGATE" MEANS A DISINTERESTED INDIVIDUAL WHO IS AUTHORIZED BY THE HEALTH CARE DECISIONS ACT TO MAKE A HEALTH CARE DECISION FOR AN INDIVIDUAL.

(2) "SURROGATE" DOES NOT INCLUDE AN INDIVIDUAL WHO IS A RESEARCH AGENT OR A HEALTH CARE AGENT.

20-702.

THE GENERAL ASSEMBLY FINDS THAT:

(1) ALL RESEARCH INVOLVING A HUMAN SUBJECT IN THIS STATE, INCLUDING RESEARCH INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL, SHOULD BE CONDUCTED WITH THE UTMOST RESPECT FOR THE WELL-BEING AND DIGNITY OF EACH RESEARCH SUBJECT;

(2) EXCEPT AS OTHERWISE SPECIFICALLY AUTHORIZED UNDER FEDERAL OR STATE LAW, ALL RESEARCH INVOLVING A HUMAN SUBJECT IN THIS STATE SHOULD BE CONDUCTED ONLY AFTER EACH SUBJECT PROVIDES INFORMED CONSENT TO PARTICIPATION IN THE RESEARCH;

(3) RESEARCH SHOULD NEVER INVOLVE A DECISIONALLY INCAPACITATED INDIVIDUAL AS A SUBJECT IF THE RESEARCH COULD BE DONE WITH A SUBJECT WHO PROVIDES INFORMED CONSENT;

(4) RESEARCH INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL 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;

(5) A RESEARCHER SHOULD SEEK TO ENROLL A DECISIONALLY INCAPACITATED INDIVIDUAL AS A RESEARCH SUBJECT ONLY IF THE RESEARCH IS EXPECTED TO YIELD GENERALIZABLE KNOWLEDGE IMPORTANT TO THE UNDERSTANDING OR AMELIORATION OF THE DISORDER OR CONDITION OF THE SUBJECT AND RELATED MEDICAL PROBLEMS, AND THE KNOWLEDGE CAN NOT BE OBTAINED WITHOUT PARTICIPATION OF THE SUBJECT; AND

(6) THE INFORMED CONSENT PROCESS PRECEDING RESEARCH PARTICIPATION SHOULD CONVEY ALL MATERIAL INFORMATION ABOUT THE RESEARCH IN A CLEAR AND UNDERSTANDABLE WAY AND EMPHASIZE, WHEN

APPROPRIATE, THAT THE RESEARCH IS NOT EXPECTED TO PROVIDE A DIRECT MEDICAL BENEFIT TO THE RESEARCH SUBJECT.

20-703.

(A) EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION:

(1) ALL RESEARCH IN THIS STATE INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL SHALL COMPLY WITH THIS SUBTITLE; AND

(2) RESEARCH INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL THAT IS NOT EXPRESSLY AUTHORIZED IN THIS SUBTITLE IS PROHIBITED.

(B) THIS SUBTITLE DOES NOT APPLY IF RESEARCH:

(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 A REGULATION 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 INDIVIDUAL 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 UNDER 45 C.F.R. § 46.116(D).

(C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, AND SUBJECT TO § 20-704(A) AND PART II OF THIS SUBTITLE, NOTHING IN THIS SUBTITLE AFFECTS RESEARCH THAT INVOLVES AN INDIVIDUAL WHO GIVES INFORMED CONSENT TO BECOME A SUBJECT OF THE RESEARCH.

(2) IF AN INDIVIDUAL WHO GIVES INFORMED CONSENT FOR PARTICIPATION IN RESEARCH BECOMES A DECISIONALLY INCAPACITATED INDIVIDUAL DURING THE COURSE OF THE RESEARCH, CONTINUED PARTICIPATION BY THE INDIVIDUAL IN THE RESEARCH IS SUBJECT TO § 20-728(B) OF THIS SUBTITLE.

(D) 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 AVERSIVE STIMULI THAT ARE PAINFUL OR INVASIVE.

(E) NOTHING IN THIS SUBTITLE AUTHORIZES AN INVESTIGATOR:

(1) TO INVOLVE AN INDIVIDUAL IN AN ACTION RELATED TO RESEARCH IF THE INVESTIGATOR IS AWARE THAT THE INDIVIDUAL HAS EXPRESSED DISAGREEMENT WITH THE ACTION; OR

(2) TO 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.

(F) EXCEPT AS PROVIDED IN § 20-727(B) OF THIS SUBTITLE, THIS SUBTITLE MAY NOT AFFECT THE AUTHORITY OF A COURT OR A GUARDIAN OF THE PERSON APPOINTED UNDER TITLE 13, SUBTITLE 7 OF THE ESTATES AND TRUSTS ARTICLE.

20-704.

(A) AN INVESTIGATOR WHO PLANS TO RECRUIT A POTENTIAL RESEARCH SUBJECT FROM AMONG INDIVIDUALS WITH A POTENTIALLY INCAPACITATING CONDITION SHALL COMPLY WITH ALL REQUIREMENTS APPLICABLE TO AN INVESTIGATOR UNDER THE COMMON RULE AND PART II OF THIS SUBTITLE.

(B) AN INVESTIGATOR WHO CONDUCTS RESEARCH INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL SHALL COMPLY WITH ALL REQUIREMENTS APPLICABLE TO AN INVESTIGATOR UNDER THE COMMON RULE AND THIS SUBTITLE.

(C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, AN INVESTIGATOR MAY INVOLVE A DECISIONALLY INCAPACITATED INDIVIDUAL AS A RESEARCH SUBJECT ONLY IN RESEARCH THAT RELATES DIRECTLY TO:

(I) THE CONDITION THAT HAS RESULTED IN THE DECISIONAL INCAPACITY OF THAT INDIVIDUAL;

(II) A DEMONSTRATED OR REASONABLY PREDICTED RELATIONSHIP BETWEEN THAT CONDITION AND ANY OTHER MEDICAL CONDITION OF THE DECISIONALLY INCAPACITATED INDIVIDUAL; OR

(III) AN ASSESSMENT OF THE EFFICACY OF AN INTERVENTION ALREADY USED IN CLINICAL PRACTICE TO TREAT A CONDITION OR RELATIONSHIP DESCRIBED IN SUBPARAGRAPH (I) OR (II) OF THIS PARAGRAPH.

(2) IF RESEARCH DOES NOT MEET THE CRITERIA SPECIFIED IN PARAGRAPH (1) OF THIS SUBSECTION, AN INVESTIGATOR MAY INVOLVE A DECISIONALLY INCAPACITATED INDIVIDUAL AS A RESEARCH SUBJECT ONLY IF:

(I) THE RESEARCH, AS APPROVED BY AN IRB, HOLDS OUT A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO THE DECISIONALLY INCAPACITATED INDIVIDUAL;

(II) THE INVESTIGATOR DID NOT DESIGN THE RESEARCH TO INVOLVE A DECISIONALLY INCAPACITATED INDIVIDUAL;

(III) THE DECISIONALLY INCAPACITATED INDIVIDUAL MEETS ALL APPLICABLE CRITERIA FOR PARTICIPATION IN THE RESEARCH;

(IV) IN ACCORDANCE WITH PART VI OF THIS SUBTITLE, THE INVESTIGATOR OBTAINS THE INFORMED CONSENT OF A LEGALLY AUTHORIZED REPRESENTATIVE OF THE DECISIONALLY INCAPACITATED INDIVIDUAL OR OF A COURT OR GUARDIAN OF THE DECISIONALLY INCAPACITATED INDIVIDUAL; AND

(V) THE INVESTIGATOR PROMPTLY NOTIFIES THE IRB THAT THE DECISIONALLY INCAPACITATED INDIVIDUAL IS PARTICIPATING IN THE RESEARCH.

20-705. RESERVED.

20-706. RESERVED.

PART II. CAPACITY ASSESSMENT - INDIVIDUALS WITH POTENTIALLY INCAPACITATING CONDITIONS.

20-707.

(A) THIS SECTION APPLIES IF AN INVESTIGATOR INTENDS TO RECRUIT A RESEARCH SUBJECT AMONG INDIVIDUALS WITH A POTENTIALLY INCAPACITATING CONDITION, WHETHER OR NOT PARTICIPATION IN RESEARCH WILL BE BASED ON THE INFORMED CONSENT OF THE INDIVIDUALS OR OF THE LEGALLY AUTHORIZED REPRESENTATIVES OF THE INDIVIDUALS.

(B) THE INVESTIGATOR SHALL:

(1) AS PART OF THE RESEARCH PROTOCOL, DESCRIBE TO THE IRB:

(I) THE PROCEDURE THAT THE INVESTIGATOR PLANS TO USE TO ASSESS WHETHER OR NOT THE INDIVIDUAL IS ABLE TO GIVE INFORMED CONSENT TO PARTICIPATION IN RESEARCH, INCLUDING THE PROCEDURE FOR DOCUMENTING THE ASSESSMENT;

(II) THE REASONABLE ACCOMMODATION THAT THE INVESTIGATOR PLANS TO PROVIDE SO AS TO ENABLE AS MANY INDIVIDUALS AS POSSIBLE TO DECIDE PERSONALLY ABOUT PARTICIPATION IN RESEARCH;

(III) ANY PROCEDURE THAT THE INVESTIGATOR PLANS TO USE TO REASSESS THE CAPACITY OF AN INDIVIDUAL DURING THE COURSE OF THE RESEARCH; AND

(IV) THE STEPS THAT THE INVESTIGATOR INTENDS TO TAKE IF AN INDIVIDUAL WHO GAVE INFORMED CONSENT BECOMES DECISIONALLY INCAPACITATED DURING THE COURSE OF THE RESEARCH, INCLUDING THE PROCEDURE FOR NOTIFYING THE LEGALLY AUTHORIZED REPRESENTATIVE OF THE INDIVIDUAL; AND

(2) AS PART OF AN ANNUAL REVIEW OR MORE FREQUENTLY IF DIRECTED BY THE IRB, INFORM THE IRB WHETHER ANY INDIVIDUAL WHO INITIALLY WAS DETERMINED BY THE INVESTIGATOR TO BE ABLE TO GIVE INFORMED CONSENT BECAME DECISIONALLY INCAPACITATED DURING THE COURSE OF THE RESEARCH AND, IF SO, WHAT STEPS THE INVESTIGATOR TOOK CONCERNING THE CONTINUED PARTICIPATION OF THAT INDIVIDUAL IN THE RESEARCH.

(C) 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.

20-708.

AFTER AN INVESTIGATOR PROVIDES AN IRB WITH THE DESCRIPTION REQUIRED BY § 20-707(B)(1) OF THIS SUBTITLE, THE IRB SHALL:

(1) CONSIDER WHETHER TO APPROVE, AS REASONABLE UNDER THE CIRCUMSTANCES, THE PROCEDURE THE INVESTIGATOR INTENDS TO USE;

(2) IN LIGHT OF THE POTENTIALLY INCAPACITATING CONDITION, CONSIDER WHETHER THE RISK TO WHICH A RESEARCH SUBJECT WOULD BE EXPOSED, AND ANY OTHER RELEVANT CIRCUMSTANCE, REQUIRES THAT A MONITOR CONDUCT OR OBSERVE THE PROCEDURE; AND

(3) DOCUMENT ITS DECISION IN ITS MINUTES.

20-709. RESERVED.

20-710. RESERVED.

PART III. RESEARCH ADVANCE DIRECTIVES.

20-711.

(A) AN INDIVIDUAL WHO HAS THE CAPACITY TO EXECUTE AN ADVANCE DIRECTIVE FOR HEALTH CARE UNDER THE HEALTH CARE DECISIONS ACT MAY EXECUTE A RESEARCH ADVANCE DIRECTIVE.

(B) A RESEARCH ADVANCE DIRECTIVE SHALL BE EXECUTED AND WITNESSED IN ACCORDANCE WITH § 5-602 OF THIS ARTICLE.

(C) A RESEARCH ADVANCE DIRECTIVE IS NOT EFFECTIVE UNLESS IT:

(1) DESIGNATES A RESEARCH AGENT; AND

(2) DESCRIBES, BY REFERENCE TO A PARTICULAR MEDICAL CONDITION, LEVEL OF RISK, OR OTHER PERTINENT FACTORS, THE RESEARCH IN WHICH AN INDIVIDUAL IS WILLING TO PARTICIPATE IF THE INDIVIDUAL IS OR BECOMES UNABLE TO GIVE INFORMED CONSENT TO PARTICIPATION IN THE RESEARCH.

(D) AFTER CONSULTATION WITH INTERESTED PERSONS, THE OFFICE OF THE ATTORNEY GENERAL SHALL PREPARE AND DISTRIBUTE A MODEL FORM OF A RESEARCH ADVANCE DIRECTIVE, THE USE OF WHICH SHALL BE OPTIONAL.

(E) (1) THIS SUBSECTION DOES NOT PROHIBIT AN INVESTIGATOR, IN ACCORDANCE WITH THIS SUBTITLE, FROM REQUESTING AN INDIVIDUAL TO EXECUTE A RESEARCH ADVANCE DIRECTIVE.

(2) A HEALTH CARE FACILITY MAY NOT REQUEST, AS A ROUTINE MATTER, THAT A PATIENT EXECUTE A RESEARCH ADVANCE DIRECTIVE.

20-712.

(A) IF AN INVESTIGATOR INTENDS TO REQUEST THAT AN INDIVIDUAL WITH A POTENTIALLY INCAPACITATING CONDITION EXECUTE A RESEARCH ADVANCE DIRECTIVE, THE INVESTIGATOR SHALL, AS PART OF THE RESEARCH PROTOCOL, DESCRIBE TO THE IRB THE PROCEDURE THAT THE INVESTIGATOR INTENDS TO USE TO ASSESS WHETHER THE INDIVIDUAL HAS THE CAPACITY TO EXECUTE A RESEARCH ADVANCE DIRECTIVE, INCLUDING THE PROCEDURE FOR DOCUMENTING THE ASSESSMENT.

(B) THE IRB SHALL:

(1) CONSIDER WHETHER TO APPROVE, AS REASONABLE UNDER THE CIRCUMSTANCES, THE PROCEDURE INTENDED TO BE USED BY THE INVESTIGATOR;

(2) IN LIGHT OF THE POTENTIALLY INCAPACITATING CONDITION, CONSIDER WHETHER THE RISK TO WHICH A RESEARCH SUBJECT WOULD BE EXPOSED, AND ANY OTHER RELEVANT CIRCUMSTANCE, REQUIRES THAT A MONITOR CONDUCT OR OBSERVE THE PROCEDURE; AND

(3) DOCUMENT ITS DECISION IN ITS MINUTES.

20-713.

(A) EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION, A RESEARCH ADVANCE DIRECTIVE MAY BE GIVEN EFFECT IN ACCORDANCE WITH ITS TERMS.

(B) (1) THIS SUBSECTION APPLIES TO A RESEARCH ADVANCE DIRECTIVE THAT AN INDIVIDUAL EXECUTES AFTER AN INVESTIGATOR:

(I) APPROACHES THE INDIVIDUAL ABOUT PARTICIPATION IN RESEARCH; AND

(II) DETERMINES THAT, ALTHOUGH THE INDIVIDUAL LACKS THE CAPACITY TO GIVE INFORMED CONSENT TO PARTICIPATION IN RESEARCH, THE INDIVIDUAL NEVERTHELESS RETAINS THE CAPACITY TO EXECUTE A RESEARCH ADVANCE DIRECTIVE.

(2) UNLESS THE PROCEDURE SPECIFIED IN PARAGRAPH (3) OF THIS SUBSECTION IS FOLLOWED, A RESEARCH ADVANCE DIRECTIVE EXECUTED UNDER THE CIRCUMSTANCES SPECIFIED IN PARAGRAPH (1) OF THIS SUBSECTION MAY BE APPLIED ONLY TO RESEARCH THAT, AS DETERMINED BY AN IRB:

(I) PRESENTS A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO A RESEARCH PARTICIPANT; OR

(II) PRESENTS NO MORE THAN A MINIMAL RISK TO A RESEARCH PARTICIPANT.

(3) SUBJECT TO THE TERMS OF A RESEARCH ADVANCE DIRECTIVE, THE RESEARCH ADVANCE DIRECTIVE DESCRIBED IN THIS SUBSECTION MAY BE GIVEN EFFECT IN OTHER RESEARCH IF THE RESEARCH ADVANCE DIRECTIVE IS EXECUTED IN THE PRESENCE OF A MONITOR WHO DETERMINES THAT THE INDIVIDUAL:

(I) UNDERSTANDS THE NATURE AND EXTENT OF THE RESEARCH ADVANCE DIRECTIVE AND THE PROBABLE CONSEQUENCES OF EXECUTING IT; AND

(II) INTENDS TO AUTHORIZE THE RESEARCH AGENT TO CONSENT TO THE TYPE OF RESEARCH DESCRIBED IN THE RESEARCH ADVANCE DIRECTIVE.

20-714. RESERVED.

20-715. RESERVED.

PART IV. RESEARCH INVOLVING DECISIONALLY INCAPACITATED INDIVIDUALS - INVESTIGATOR AND IRB RESPONSIBILITIES.

20-716.

IF AN INVESTIGATOR PLANS TO INVOLVE A DECISIONALLY INCAPACITATED INDIVIDUAL AS A RESEARCH SUBJECT, THE INVESTIGATOR SHALL, AS PART OF THE RESEARCH PROTOCOL:

(1) DESCRIBE TO AN IRB THE CATEGORY OF DECISIONALLY INCAPACITATED INDIVIDUALS WHO WILL BE ELIGIBLE TO BE INVOLVED IN THE RESEARCH;

(2) EXPLAIN TO THE IRB WHY THE PROPOSED RESEARCH CANNOT BE CONDUCTED WITHOUT THE INVOLVEMENT OF A DECISIONALLY INCAPACITATED INDIVIDUAL;

(3) PROVIDE THE IRB WITH THE RESULTS OF ANY PRIOR REVIEW OF THE SCIENTIFIC MERITS OF THE PROPOSED RESEARCH OR EXPLAIN TO THE IRB WHY 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 EVER BEEN:

(I) FOUND BY AN AGENCY OF THE UNITED STATES, THIS STATE, OR ANOTHER STATE TO HAVE VIOLATED ANY FEDERAL OR STATE STATUTE OR REGULATION OR IRB REQUIREMENT PROTECTING THE RIGHTS AND WELFARE OF A RESEARCH SUBJECT; OR

(II) INVOLVED IN RESEARCH FOR WHICH IRB APPROVAL WAS WITHDRAWN BECAUSE OF NONCOMPLIANCE WITH ANY FEDERAL OR STATE STATUTE OR REGULATION OR IRB REQUIREMENT PROTECTING THE RIGHTS AND WELFARE OF A RESEARCH SUBJECT;

(6) DESCRIBE TO THE IRB THE PROCEDURE THAT THE INVESTIGATOR INTENDS TO FOLLOW TO ACHIEVE COMPLIANCE WITH THE REQUIREMENTS OF THIS SUBTITLE;

(7) DESCRIBE TO THE IRB THE PROCEDURE BY WHICH THE HEALTH AND SAFETY OF A RESEARCH SUBJECT IS TO BE MONITORED DURING THE COURSE OF THE RESEARCH, INCLUDING:

(I) WHETHER A DISINTERESTED, EXPERT BOARD OR COMMITTEE WILL REVIEW INTERIM DATA RESULTING FROM THE RESEARCH AND EVALUATE THE DATA IN TERMS OF THE SAFETY OF A RESEARCH SUBJECT; AND

(II) WHETHER THE ATTENDING PHYSICIAN OF A RESEARCH SUBJECT IS TO BE CONSULTED ABOUT THE POTENTIAL EFFECT OF THE RESEARCH ON THE RESEARCH SUBJECT AND, IF NOT, HOW PROPER COORDINATION WITH THE CLINICAL CARE OF THE SUBJECT IS TO BE ACHIEVED;

(8) DESCRIBE TO THE IRB:

(I) HOW A LEGALLY AUTHORIZED REPRESENTATIVE MAY OBSERVE THE RESEARCH OR OTHERWISE LEARN ABOUT THE EXPERIENCE OF A DECISIONALLY INCAPACITATED INDIVIDUAL IN THE RESEARCH;

(II) WHETHER CONSENT FOR FURTHER PARTICIPATION IN RESEARCH WILL BE SOUGHT FROM A LEGALLY AUTHORIZED REPRESENTATIVE AT ANY POINT DURING THE RESEARCH; AND

(III) WHAT PROCEDURE IS TO BE USED FOR PERIODIC CONFIRMATION THAT THE INDIVIDUAL REMAINS WILLING TO PARTICIPATE IN THE RESEARCH;

(9) IF THE DESIGN OF THE RESEARCH INCLUDES THE USE OF A PLACEBO CONTROL, DESCRIBE TO THE IRB:

(I) WHY A CONTROL PROCEDURE OTHER THAN PLACEBO CONTROL COULD NOT BE USED;

(II) IF A STANDARD THERAPY EXISTS, WHY THE USE OF A PLACEBO CONTROL IS CONSISTENT WITH THE WELL-BEING OF A SUBJECT IN THE PLACEBO CONTROL ARM; AND

(III) WHETHER A RESEARCH SUBJECT INITIALLY RANDOMIZED TO THE PLACEBO CONTROL ARM CAN RECEIVE A DRUG UNDER STUDY AT ANY TIME DURING OR AFTER THE RESEARCH;

(10) IF THE DESIGN OF THE RESEARCH REQUIRES THAT NEITHER THE INVESTIGATOR NOR A LEGALLY AUTHORIZED REPRESENTATIVE KNOW WHETHER A SPECIFIC RESEARCH SUBJECT IS RECEIVING A DRUG UNDER STUDY OR SOME OTHER SUBSTANCE, DESCRIBE TO THE IRB THE PROCEDURE FOR DETERMINING THAT INFORMATION IF IT BECOMES NECESSARY FOR THE CLINICAL CARE OF A RESEARCH SUBJECT; AND

(11) IF THE RESEARCH PROTOCOL INVOLVES USE OF A SUBSTANCE OR PROCEDURE DESIGNED TO PROVOKE OR AGGRAVATE A SYMPTOM OF A MEDICAL CONDITION, EXPLAIN TO THE IRB WHY THE SUBSTANCE OR PROCEDURE IS CONSISTENT WITH THE WELL-BEING OF A RESEARCH SUBJECT.

20-717.

(A) IN DECIDING WHETHER TO APPROVE RESEARCH IN WHICH AN INVESTIGATOR PLANS TO INVOLVE A DECISIONALLY INCAPACITATED INDIVIDUAL, AN IRB SHALL:

(1) 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 INDIVIDUAL WHO WILL BE A RESEARCH SUBJECT;

(2) CONSIDER WHETHER, IN LIGHT OF THE RISK PRESENTED BY PARTICIPATION IN RESEARCH, TO REQUIRE THAT A MONITOR PARTICIPATE IN OR OBSERVE THE INFORMED CONSENT PROCESS REQUIRED BY § 20-724 OF THIS SUBTITLE;

(3) REVIEW THE RESEARCH PROTOCOL TO DETERMINE THAT THE PROPOSED PROCEDURE DOES NOT UNNECESSARILY EXPOSE A DECISIONALLY INCAPACITATED INDIVIDUAL TO RISK, ESPECIALLY IF THE RESEARCH PROTOCOL INCLUDES THE USE OF A PLACEBO CONTROL OR INVOLVES THE USE OF A

SUBSTANCE OR PROCEDURE DESIGNED TO PROVOKE OR AGGRAVATE THE SYMPTOM OF A MEDICAL CONDITION; AND

(4) VERIFY THAT THE INVESTIGATOR HAS PROVIDED THE IRB WITH THE INFORMATION REQUIRED BY § 20-716 OF THIS SUBTITLE.

(B) (1) AN IRB MAY DESIGNATE ONE OR MORE PROXY DECISION MAKERS, MONITORS, AND MEDICALLY RESPONSIBLE CLINICIANS FOR RESEARCH CONDUCTED IN AN INSTITUTION SERVED BY THE IRB.

(2) (I) EXCEPT AS PROVIDED IN SUBPARAGRAPHS (II) AND (III) OF THIS PARAGRAPH, AN IRB MAY ONLY DESIGNATE A DISINTERESTED INDIVIDUAL AS A PROXY DECISION MAKER, MONITOR, OR MEDICALLY RESPONSIBLE CLINICIAN.

(II) IN EXCEPTIONAL CIRCUMSTANCES DOCUMENTED IN THE MINUTES OF AN IRB, THE IRB MAY DESIGNATE AS A PROXY DECISION MAKER OR MONITOR AN INDIVIDUAL WHO DOES NOT MEET THE EMPLOYMENT RESTRICTION SPECIFIED IN § 20-701(F)(2) OF THIS SUBTITLE BUT WHO IS OTHERWISE A DISINTERESTED INDIVIDUAL AND IS EMPLOYED IN A PART OF AN INSTITUTION, CORPORATION, HOSPITAL, OR HEALTH CARE FACILITY THAT IS ORGANIZATIONALLY DISTINCT FROM THAT OF THE INVESTIGATORS.

(III) AN IRB MAY DESIGNATE AS A MEDICALLY RESPONSIBLE CLINICIAN AN INDIVIDUAL WHO DOES NOT MEET THE EMPLOYMENT RESTRICTION IN § 20-701(F)(2) OF THIS SUBTITLE BUT WHO IS OTHERWISE A DISINTERESTED INDIVIDUAL AND IS EMPLOYED IN A PART OF AN INSTITUTION, CORPORATION, HOSPITAL, OR HEALTH CARE FACILITY THAT IS ORGANIZATIONALLY DISTINCT FROM THAT OF THE INVESTIGATORS.

(C) IF AN IRB LEARNS THAT AN INVESTIGATOR PARTICIPATING IN RESEARCH IN WHICH A DECISIONALLY INCAPACITATED INDIVIDUAL IS INTENDED TO BE INVOLVED HAS EVER BEEN FOUND BY AN AGENCY OF THE UNITED STATES, THIS STATE, OR ANOTHER STATE TO HAVE VIOLATED ANY FEDERAL OR STATE STATUTE OR REGULATION OR IRB REQUIREMENT PROTECTING THE RIGHTS AND WELFARE OF A RESEARCH SUBJECT, THE IRB SHALL:

(1) DISAPPROVE THE CONDUCT OF THE RESEARCH; OR

(2) IF IT APPROVES THE CONDUCT OF THE RESEARCH:

(I) IMPLEMENT APPROPRIATE MEASURES FOR STRICT SCRUTINY OF THE CONDUCT OF THE RESEARCH; AND

(II) PROVIDE THE SECRETARY AND THE ATTORNEY GENERAL WITH THE INFORMATION AVAILABLE TO THE IRB CONCERNING THE VIOLATION AND THE ACTION TAKEN BY THE IRB UNDER PARAGRAPH (1) OF THIS SUBSECTION.

20-718.

(A) (1) IF AN INVESTIGATOR SEEKS APPROVAL FOR RESEARCH IN WHICH A DECISIONALLY INCAPACITATED INDIVIDUAL IS TO BE INVOLVED, AN IRB SHALL DETERMINE AND STATE IN ITS MINUTES WHETHER THE RESEARCH PROTOCOL PRESENTS A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO THE DECISIONALLY INCAPACITATED INDIVIDUAL.

(2) IN CONSIDERING WHETHER THE RESEARCH PROTOCOL PRESENTS A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO A DECISIONALLY INCAPACITATED INDIVIDUAL, AN IRB SHALL TAKE INTO ACCOUNT THE RELEVANT SCIENTIFIC EVIDENCE AVAILABLE TO IT CONCERNING THE NATURE AND LIKELIHOOD OF A DIRECT MEDICAL BENEFIT.

(3) IF THE RESEARCH PROTOCOL INVOLVES THE USE OF A PLACEBO CONTROL, THE IRB SHALL TAKE INTO ACCOUNT WHETHER A DECISIONALLY INCAPACITATED INDIVIDUAL INITIALLY RANDOMIZED TO THE PLACEBO CONTROL ARM CAN RECEIVE THE DRUG UNDER STUDY AT ANY TIME DURING OR AFTER THE RESEARCH.

(4) IF THE RESEARCH PROTOCOL PRESENTS A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO A DECISIONALLY INCAPACITATED INDIVIDUAL, THE IRB SHALL ENSURE THAT WRITTEN MATERIALS:

(I) ARE MADE AVAILABLE TO A LEGALLY AUTHORIZED REPRESENTATIVE AS PART OF THE INFORMED CONSENT PROCESS;

(II) EMPHASIZE THAT THE PROCEDURE INVOLVES RESEARCH, NOT STANDARD THERAPY; AND

(III) DESCRIBE FAIRLY THE RISKS AND BENEFITS OF PARTICIPATION IN RESEARCH, INCLUDING THE EXTENT TO WHICH THE RESEARCH ALTERS THE PROBABILITY OR MAGNITUDE OF HARM OR DISCOMFORT THAT A DECISIONALLY INCAPACITATED INDIVIDUAL COULD BE EXPECTED TO EXPERIENCE IF THE DECISIONALLY INCAPACITATED INDIVIDUAL DID NOT PARTICIPATE IN THE RESEARCH.

(B) (1) THE IRB SHALL DETERMINE AND STATE IN ITS MINUTES WHETHER THE RESEARCH PROTOCOL PRESENTS TO A DECISIONALLY INCAPACITATED INDIVIDUAL A LEVEL OF RISK THAT IS:

(I) A MINIMAL RISK;

(II) A MINOR INCREASE OVER A MINIMAL RISK; OR

(III) MORE THAN A MINOR INCREASE OVER A MINIMAL RISK.

(2) IN CONSIDERING WHETHER THE RESEARCH PROTOCOL PRESENTS A MINIMAL RISK, THE IRB MAY TAKE INTO ACCOUNT WHETHER THE RESEARCH

INVOLVES A PROCEDURE THAT THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES HAS IDENTIFIED AS SUITABLE FOR EXPEDITED IRB REVIEW.

(3) IN DETERMINING THE LEVEL OF RISK OF THE RESEARCH, THE IRB SHALL CONSIDER WHETHER THE CHARACTERISTICS OF A DECISIONALLY INCAPACITATED INDIVIDUAL WOULD RESULT IN A GREATER RISK TO THE DECISIONALLY INCAPACITATED INDIVIDUAL THAN TO AN INDIVIDUAL DRAWN FROM THE GENERAL POPULATION.

(4) AN IRB SHALL DETERMINE THAT A RESEARCH PROTOCOL PRESENTS MORE THAN A MINOR INCREASE OVER A MINIMAL RISK IF, AS A RESULT OF PARTICIPATION IN RESEARCH, A DECISIONALLY INCAPACITATED INDIVIDUAL WOULD BE EXPOSED TO MORE THAN A REMOTE POSSIBILITY OF:

(I) SUBSTANTIAL OR PROLONGED PAIN, DISCOMFORT, OR DISTRESS; OR

(II) CLINICALLY SIGNIFICANT DETERIORATION OF A MEDICAL CONDITION.

20-719.

(A) AN INVESTIGATOR MAY NOT INVOLVE A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH UNLESS:

(1) THE RESEARCH PROTOCOL HAS BEEN APPROVED BY AN IRB; AND

(2) THE INVESTIGATOR CONDUCTS THE RESEARCH IN CONFORMITY WITH ALL CONDITIONS IMPOSED BY THE IRB IN CONNECTION WITH ITS APPROVAL.

(B) (1) THIS SUBSECTION APPLIES IF A DECISIONALLY INCAPACITATED INDIVIDUAL IS INVOLVED IN RESEARCH THAT, AS DETERMINED BY AN IRB, PRESENTS A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO THE DECISIONALLY INCAPACITATED INDIVIDUAL.

(2) IF THE INVESTIGATOR DETERMINES THAT PARTICIPATION IN RESEARCH NO LONGER PRESENTS A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO A DECISIONALLY INCAPACITATED INDIVIDUAL, THE INVESTIGATOR SHALL:

(I) ADVISE THE LEGALLY AUTHORIZED REPRESENTATIVE OF THE DETERMINATION OF THE INVESTIGATOR; AND

(II) DISCONTINUE PARTICIPATION BY THE DECISIONALLY INCAPACITATED INDIVIDUAL IN THE RESEARCH.

(C) (1) THIS SUBSECTION APPLIES WHEN A DECISIONALLY INCAPACITATED INDIVIDUAL PARTICIPATES IN RESEARCH THAT, AS DETERMINED BY AN IRB, PRESENTS A PARTICULAR LEVEL OF RISK TO THE DECISIONALLY INCAPACITATED INDIVIDUAL.

(2) IF THE INVESTIGATOR DETERMINES THAT RESEARCH PRESENTS A HIGHER LEVEL OF RISK TO A DECISIONALLY INCAPACITATED INDIVIDUAL THAN THAT ORIGINALLY DETERMINED BY THE IRB, THE INVESTIGATOR SHALL:

(I) ADVISE THE LEGALLY AUTHORIZED REPRESENTATIVE OF THE DETERMINATION OF THE INVESTIGATOR; AND

(II) DISCONTINUE PARTICIPATION BY THE DECISIONALLY INCAPACITATED INDIVIDUAL IN THE RESEARCH.

(D) AN INVESTIGATOR IMMEDIATELY SHALL REPORT TO THE IRB ANY UNEXPECTED SERIOUS HARM TO A DECISIONALLY INCAPACITATED INDIVIDUAL RESULTING FROM PARTICIPATION IN THE RESEARCH.

(E) IN ADDITION TO THE REVIEW OF RESEARCH AT PERIODIC INTERVALS REQUIRED BY THE COMMON RULE, AN IRB SHALL PROMPTLY CONSIDER WHETHER TO SUSPEND OR WITHDRAW ITS APPROVAL OF RESEARCH OR SUSPEND THE ACCRUAL OF AN ADDITIONAL RESEARCH SUBJECT IF THE IRB CONCLUDES THAT:

(1) CONTINUATION OF RESEARCH MAY RESULT IN UNANTICIPATED HARM TO A DECISIONALLY INCAPACITATED INDIVIDUAL; OR

(2) AN INVESTIGATOR HAS FAILED TO:

(I) CARRY OUT PROPERLY THE RESPONSIBILITIES OF THE INVESTIGATOR UNDER THE COMMON RULE AND THIS SUBTITLE; OR

(II) COMPLY WITH A DETERMINATION OF THE IRB.

(F) IF AN IRB SUSPENDS OR WITHDRAWS ITS APPROVAL OF RESEARCH OR SUSPENDS THE ACCRUAL OF AN ADDITIONAL RESEARCH SUBJECT, THE IRB SHALL NOTIFY THE SECRETARY AND THE ATTORNEY GENERAL OF ITS ACTION.

20-720.

IF A DECISIONALLY INCAPACITATED INDIVIDUAL MUST BE WITHDRAWN FROM A STANDARD TREATMENT TO RECEIVE A TREATMENT UNDER INVESTIGATION OR BE WITHDRAWN FROM A TREATMENT UNDER INVESTIGATION TO RETURN TO A STANDARD TREATMENT, AN INVESTIGATOR SHALL:

(1) DESIGN THE TREATMENT WITHDRAWAL PHASE OF THE RESEARCH, INCLUDING ITS DURATION, SO AS TO MINIMIZE THE RISK TO THE DECISIONALLY INCAPACITATED INDIVIDUAL FROM THE WITHDRAWAL;

(2) IF THE PERIOD OF WITHDRAWAL OCCURS WHILE THE DECISIONALLY INCAPACITATED INDIVIDUAL IS AN IN-PATIENT IN A HOSPITAL OR A RESIDENT OF A HEALTH CARE FACILITY, ASSURE THE PROMPT AVAILABILITY OF MEDICAL CARE THAT MAY BE NEEDED BY THE RESEARCH SUBJECT IN THE EVENT OF A MEDICALLY SERIOUS SIDE EFFECT OF WITHDRAWAL; AND

(3) IN OTHER CIRCUMSTANCES, INFORM THE DECISIONALLY INCAPACITATED INDIVIDUAL, THE LEGALLY AUTHORIZED REPRESENTATIVE, AND ANY INDIVIDUAL WHO THE INVESTIGATOR KNOWS WILL BE PROVIDING CARE TO THE DECISIONALLY INCAPACITATED INDIVIDUAL OF:

(I) ANY SPECIAL PRECAUTION THAT NEEDS TO BE TAKEN DURING THE COURSE OF THE RESEARCH; AND

(II) THE MEANS TO OBTAIN TIMELY MEDICAL CARE THAT IS APPROPRIATE TO THE NEEDS OF THE DECISIONALLY INCAPACITATED INDIVIDUAL IN THE EVENT OF A MEDICALLY SERIOUS SIDE EFFECT OF WITHDRAWAL FROM A TREATMENT.

20-721.

(A) THIS SECTION APPLIES IF A RESEARCH PROTOCOL:

(1) INVOLVES WITHDRAWING A GROUP OF DECISIONALLY INCAPACITATED INDIVIDUALS FROM A STANDARD TREATMENT; OR

(2) HAS BEEN DETERMINED BY AN IRB TO PRESENT A LEVEL OF RISK GREATER THAN A MINIMAL RISK.

(B) FOR A RESEARCH PROTOCOL SPECIFIED IN SUBSECTION (A) OF THIS SECTION, A MEDICALLY RESPONSIBLE CLINICIAN SHALL BE DESIGNATED BY:

(1) THE IRB, IN ACCORDANCE WITH § 20-717(B) OF THIS SUBTITLE; OR

(2) THE INVESTIGATOR, IF THE IRB HAS NOT DESIGNATED A MEDICALLY RESPONSIBLE CLINICIAN AND THE MEDICALLY RESPONSIBLE CLINICIAN IS:

(I) A DISINTERESTED INDIVIDUAL; AND

(II) APPROVED BY THE IRB.

(C) THE MEDICALLY RESPONSIBLE CLINICIAN SHALL, IN ACCORDANCE WITH A PROCEDURE OR A REQUIREMENT SPECIFIED BY THE IRB:

(1) FOR A RESEARCH PROTOCOL THAT INVOLVES WITHDRAWING A GROUP OF DECISIONALLY INCAPACITATED INDIVIDUALS FROM A STANDARD TREATMENT:

(I) EVALUATE THE MEDICAL CONDITION OF EACH DECISIONALLY INCAPACITATED INDIVIDUAL IN THAT GROUP BEFORE ENROLLMENT AND AT APPROPRIATE INTERVALS DURING THE RESEARCH; AND

(II) CONSIDER WHETHER INVOLVEMENT IN THE RESEARCH PRESENTS A RISK TO THE HEALTH OF THE DECISIONALLY INCAPACITATED INDIVIDUAL THAT THE MEDICALLY RESPONSIBLE CLINICIAN CONSIDERS MEDICALLY INADVISABLE;

(2) FOR A RESEARCH PROTOCOL THAT AN IRB DETERMINES TO PRESENT A LEVEL OF RISK GREATER THAN A MINIMAL RISK:

(I) EVALUATE THE MEDICAL CONDITION OF EACH DECISIONALLY INCAPACITATED INDIVIDUAL BEFORE ENROLLMENT AND AT APPROPRIATE INTERVALS DURING THE RESEARCH; AND

(II) CONSIDER WHETHER INVOLVEMENT IN THE RESEARCH PRESENTS A RISK TO THE HEALTH OF THE DECISIONALLY INCAPACITATED INDIVIDUAL THAT THE MEDICALLY RESPONSIBLE CLINICIAN CONSIDERS MEDICALLY INADVISABLE.

(D) IF THE MEDICALLY RESPONSIBLE CLINICIAN DETERMINES THAT PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN THE RESEARCH IS MEDICALLY INADVISABLE, THE MEDICALLY RESPONSIBLE CLINICIAN SHALL REPORT THAT DETERMINATION TO THE INVESTIGATOR AND THE LEGALLY AUTHORIZED REPRESENTATIVE AND RECOMMEND THAT THE DECISIONALLY INCAPACITATED INDIVIDUAL NOT PARTICIPATE IN THE RESEARCH.

(E) (1) IF THE INVESTIGATOR AND LEGALLY AUTHORIZED REPRESENTATIVE DECLINE TO FOLLOW THE RECOMMENDATION OF THE MEDICALLY RESPONSIBLE CLINICIAN, THE INVESTIGATOR SHALL PROMPTLY REPORT THE MATTER TO THE IRB FOR ITS DETERMINATION CONCERNING PARTICIPATION BY THE DECISIONALLY INCAPACITATED INDIVIDUAL IN THE RESEARCH.

(2) THE DECISIONALLY INCAPACITATED INDIVIDUAL MAY NOT PARTICIPATE IN THE RESEARCH WITHOUT THE EXPRESS WRITTEN APPROVAL OF THE IRB.

20-722. RESERVED.

20-723. RESERVED.

PART V. CONSENT AND ASSENT - IN GENERAL.

20-724.

(A) AN INVESTIGATOR SHALL PROVIDE A LEGALLY AUTHORIZED REPRESENTATIVE WITH:

(1) ALL INFORMATION REQUIRED UNDER THE COMMON RULE OR BY AN IRB AS A BASIS FOR INFORMED CONSENT; AND

(2) A SUMMARY OF THIS SUBTITLE, AS PREPARED BY THE ATTORNEY GENERAL UNDER § 20-763 OF THIS SUBTITLE.

(B) AS PART OF THE INFORMED CONSENT PROCESS, AN INVESTIGATOR SHALL FAIRLY DESCRIBE:

(1) ANY MATERIAL RISK AND DIRECT MEDICAL BENEFIT REASONABLY FORESEEABLE FROM PARTICIPATION IN THE RESEARCH;

(2) IF THE RESEARCH PROTOCOL INVOLVES AN ALTERNATIVE TO A STANDARD FORM OF TREATMENT, THE RISK AND BENEFIT 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) BEFORE INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH, AN INVESTIGATOR SHALL OBTAIN THE INFORMED CONSENT OF A LEGALLY AUTHORIZED REPRESENTATIVE AS PROVIDED IN THIS SUBTITLE, A COURT, OR A GUARDIAN OF THE DECISIONALLY INCAPACITATED INDIVIDUAL.

(2) UNLESS AN IRB WAIVES DOCUMENTATION REQUIREMENTS UNDER 45 C.F.R. § 46.117(C), AN INVESTIGATOR SHALL DOCUMENT THE CONSENT BY OBTAINING A WRITTEN CONSENT FORM SIGNED BY THE LEGALLY AUTHORIZED REPRESENTATIVE.

(D) IF AN INDIVIDUAL IS A DECISIONALLY INCAPACITATED INDIVIDUAL WHEN FIRST INVOLVED IN RESEARCH, BUT SUBSEQUENTLY IS ABLE TO GIVE INFORMED CONSENT, THE INVESTIGATOR MAY NOT CONTINUE TO INVOLVE THE INDIVIDUAL IN THE RESEARCH WITHOUT THE INFORMED CONSENT OF THE INDIVIDUAL.

20-725.

(A) BEFORE PARTICIPATING IN RESEARCH INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL, AN INVESTIGATOR SHALL TELL THE DECISIONALLY INCAPACITATED INDIVIDUAL, UNLESS THE DECISIONALLY INCAPACITATED INDIVIDUAL IS UNCONSCIOUS, IN A MANNER APPROPRIATE TO THE CAPACITY OF THE DECISIONALLY INCAPACITATED INDIVIDUAL FOR UNDERSTANDING:

(1) THE FACT THAT THE DECISIONALLY INCAPACITATED INDIVIDUAL IS BEING ASKED TO PARTICIPATE IN RESEARCH;

(2) THE NATURE OF THE RESEARCH AND ITS LIKELY EFFECT ON THE DECISIONALLY INCAPACITATED INDIVIDUAL;

(3) THE NAME OF THE LEGALLY AUTHORIZED REPRESENTATIVE WHO HAS CONSENTED TO PARTICIPATION BY THE DECISIONALLY INCAPACITATED INDIVIDUAL;

(4) THE FACT THAT, EXCEPT AS OTHERWISE ORDERED BY A COURT, THE DECISIONALLY INCAPACITATED INDIVIDUAL MAY DECLINE TO PARTICIPATE IN THE RESEARCH WITHOUT PENALTY OR LOSS OF BENEFITS TO WHICH THE DECISIONALLY INCAPACITATED INDIVIDUAL IS OTHERWISE ENTITLED; AND

(5) THE FACT THAT, EXCEPT AS OTHERWISE ORDERED BY A COURT, IF THE DECISIONALLY INCAPACITATED INDIVIDUAL AGREES TO PARTICIPATE IN THE RESEARCH, THE DECISIONALLY INCAPACITATED INDIVIDUAL SUBSEQUENTLY MAY WITHDRAW FROM THE RESEARCH WITHOUT PENALTY OR LOSS OF BENEFITS TO WHICH THE DECISIONALLY INCAPACITATED INDIVIDUAL IS OTHERWISE ENTITLED.

(B) BEFORE INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH, AN INVESTIGATOR SHALL OBTAIN THE ASSENT OF THE DECISIONALLY INCAPACITATED INDIVIDUAL IF THE DECISIONALLY INCAPACITATED INDIVIDUAL IS CAPABLE OF GIVING ASSENT.

(C) AN INVESTIGATOR MAY TAKE REASONABLE, NONCOERCIVE STEPS TO REQUEST A DECISIONALLY INCAPACITATED INDIVIDUAL TO RECONSIDER A REFUSAL OF ASSENT OR REFUSAL TO PERFORM AN ACTION RELATED TO THE RESEARCH.

20-726.

(A) IF A LEGALLY AUTHORIZED REPRESENTATIVE IS REQUIRED UNDER THIS SUBTITLE TO CONSIDER WHETHER OR NOT A DECISIONALLY INCAPACITATED INDIVIDUAL WOULD CONSENT TO PARTICIPATE IN RESEARCH IF THE DECISIONALLY INCAPACITATED INDIVIDUAL WERE ABLE TO GIVE INFORMED CONSENT, THE LEGALLY AUTHORIZED REPRESENTATIVE MAY TAKE INTO ACCOUNT ANY RELEVANT INFORMATION, INCLUDING:

(1) ANY EXPRESSED PREFERENCE OF THE DECISIONALLY INCAPACITATED INDIVIDUAL REGARDING PARTICIPATION IN THE TYPE OF RESEARCH AT ISSUE;

(2) ANY EXPRESSED PREFERENCE OF THE DECISIONALLY INCAPACITATED INDIVIDUAL ABOUT PARTICIPATION IN RESEARCH GENERALLY;

(3) ANY RELIGIOUS OR MORAL BELIEF OR PERSONAL VALUES OF THE DECISIONALLY INCAPACITATED INDIVIDUAL CONCERNING PARTICIPATION IN RESEARCH;

(4) ANY BEHAVIORAL OR OTHER MANIFESTATION OF THE ATTITUDE OF THE DECISIONALLY INCAPACITATED INDIVIDUAL TOWARD PARTICIPATION IN RESEARCH;

(5) ANY REACTION OF THE DECISIONALLY INCAPACITATED INDIVIDUAL TO PARTICIPATION BY ANOTHER INDIVIDUAL IN RESEARCH; AND

(6) ANY STATEMENT OF THE DECISIONALLY INCAPACITATED INDIVIDUAL ABOUT THE EFFECT OF PARTICIPATION IN RESEARCH BY THE DECISIONALLY INCAPACITATED INDIVIDUAL ON THE FAMILY OF THE INDIVIDUAL OR ON ANOTHER INDIVIDUAL WHO HAS THE SAME MEDICAL CONDITION.

(B) PRIOR PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN SIMILAR RESEARCH, IF THE DECISIONALLY INCAPACITATED INDIVIDUAL WAS

ABLE TO GIVE INFORMED CONSENT, MAY BE TAKEN INTO ACCOUNT BY A LEGALLY AUTHORIZED REPRESENTATIVE BUT MAY NOT BE THE SOLE BASIS ON WHICH PERMISSION IS GRANTED FOR THE DECISIONALLY INCAPACITATED INDIVIDUAL TO PARTICIPATE IN THE RESEARCH.

20-727.

(A) NOTWITHSTANDING THE AUTHORITY OF A LEGALLY AUTHORIZED REPRESENTATIVE UNDER THIS SUBTITLE, IF A GUARDIAN OF THE PERSON IS APPOINTED FOR A DECISIONALLY INCAPACITATED INDIVIDUAL AND HAS SPECIFIC AUTHORITY TO MAKE A DECISION ABOUT PARTICIPATION BY THE DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH, THE GUARDIAN, SUBJECT TO THE SUPERVISION OF A COURT, HAS EXCLUSIVE AUTHORITY TO MAKE THE DECISION.

(B) 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 DECISIONALLY INCAPACITATED INDIVIDUAL; OR

(2) NO MORE THAN A MINOR INCREASE OVER A MINIMAL RISK TO THE DECISIONALLY INCAPACITATED INDIVIDUAL.

20-728.

(A) A LEGALLY AUTHORIZED REPRESENTATIVE WHO CONSENTS TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH SHALL:

(1) TAKE REASONABLE STEPS TO LEARN WHETHER THE EXPERIENCE OF THE DECISIONALLY INCAPACITATED INDIVIDUAL IN THE RESEARCH IS CONSISTENT WITH THE EXPECTATION OF THE LEGALLY AUTHORIZED REPRESENTATIVE AT THE TIME THE CONSENT WAS GRANTED, INCLUDING AN EXPECTATION ABOUT ANY POTENTIAL BENEFIT OR RISK PRESENTED BY THE RESEARCH; AND

(2) WITHDRAW CONSENT IF:

(I) THE RESEARCH PROTOCOL WAS INITIALLY DETERMINED TO PRESENT A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO A DECISIONALLY INCAPACITATED INDIVIDUAL BUT PARTICIPATION IN RESEARCH NO LONGER DOES SO FOR THE DECISIONALLY INCAPACITATED INDIVIDUAL;

(II) PARTICIPATION IN RESEARCH PRESENTS A HIGHER LEVEL OF RISK TO THE DECISIONALLY INCAPACITATED INDIVIDUAL THAN INITIALLY EXPECTED; OR

(III) CONSIDERING ALL RELEVANT CIRCUMSTANCES, CONTINUED PARTICIPATION WOULD BE DETRIMENTAL TO THE WELL-BEING OF THE DECISIONALLY INCAPACITATED INDIVIDUAL.

(B) IF AN INDIVIDUAL GIVES INFORMED CONSENT TO PARTICIPATION IN RESEARCH BUT BECOMES A DECISIONALLY INCAPACITATED INDIVIDUAL DURING THE COURSE OF THE RESEARCH, A LEGALLY AUTHORIZED REPRESENTATIVE SHALL WITHDRAW CONSENT FOR THE CONTINUED PARTICIPATION BY THE DECISIONALLY INCAPACITATED INDIVIDUAL IN THE RESEARCH IF, CONSIDERING ALL RELEVANT CIRCUMSTANCES, CONTINUED PARTICIPATION WOULD BE DETRIMENTAL TO THE WELL-BEING OF THE DECISIONALLY INCAPACITATED INDIVIDUAL.

20-729. RESERVED.

20-730. RESERVED.

PART VI. CONSENT - RESEARCH INVOLVING DIRECT MEDICAL BENEFIT OR MINIMAL RISK.

20-731.

THIS PART APPLIES TO RESEARCH CONDUCTED UNDER A RESEARCH PROTOCOL THAT, AS DETERMINED BY AN IRB, PRESENTS:

(1) A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO A DECISIONALLY INCAPACITATED INDIVIDUAL WHO IS A RESEARCH SUBJECT; OR

(2) A MINIMAL RISK TO A DECISIONALLY INCAPACITATED INDIVIDUAL WHO IS A RESEARCH SUBJECT.

20-732.

(A) A RESEARCH AGENT MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH SPECIFIED IN § 20-730 OF THIS SUBTITLE IF THE RESEARCH AGENT HAS REASON TO BELIEVE THAT THE DECISIONALLY INCAPACITATED INDIVIDUAL WOULD HAVE AGREED TO PARTICIPATE IN THE RESEARCH IF THE DECISIONALLY INCAPACITATED INDIVIDUAL WERE ABLE TO GIVE INFORMED CONSENT.

(B) (1) THIS SUBSECTION APPLIES IF:

(I) A RESEARCH AGENT CAN NOT GIVE CONSENT UNDER SUBSECTION (A) OF THIS SECTION; AND

(II) THE RESEARCH PRESENTS A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT.

(2) THE RESEARCH AGENT MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH IF THE RESEARCH AGENT

CONCLUDES THAT PARTICIPATION IN THE RESEARCH IS IN THE MEDICAL BEST INTEREST OF THE DECISIONALLY INCAPACITATED INDIVIDUAL.

20-733.

(A) A HEALTH CARE AGENT MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH SPECIFIED IN § 20-731 OF THIS SUBTITLE IF:

(1) A RESEARCH AGENT IS NOT AVAILABLE; AND

(2) THE HEALTH CARE AGENT HAS REASON TO BELIEVE THAT THE DECISIONALLY INCAPACITATED INDIVIDUAL WOULD HAVE AGREED TO PARTICIPATE IN THE RESEARCH IF THE DECISIONALLY INCAPACITATED INDIVIDUAL WERE ABLE TO GIVE INFORMED CONSENT.

(B) (1) THIS SUBSECTION APPLIES IF:

(I) A HEALTH CARE AGENT CAN NOT GIVE CONSENT UNDER SUBSECTION (A)(2) OF THIS SECTION; AND

(II) THE RESEARCH PRESENTS A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT.

(2) THE HEALTH CARE AGENT MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH IF THE HEALTH CARE AGENT CONCLUDES THAT PARTICIPATION IN THE RESEARCH IS IN THE MEDICAL BEST INTEREST OF THE DECISIONALLY INCAPACITATED INDIVIDUAL.

20-734.

(A) A SURROGATE MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH SPECIFIED IN § 20-731 OF THIS SUBTITLE IF:

(1) NEITHER A RESEARCH AGENT NOR A HEALTH CARE AGENT IS AVAILABLE; AND

(2) THE SURROGATE HAS REASON TO BELIEVE THAT THE DECISIONALLY INCAPACITATED INDIVIDUAL WOULD HAVE AGREED TO PARTICIPATE IN THE RESEARCH IF THE DECISIONALLY INCAPACITATED INDIVIDUAL WERE ABLE TO GIVE INFORMED CONSENT.

(B) (1) THIS SUBSECTION APPLIES IF:

(I) A SURROGATE CAN NOT GIVE CONSENT UNDER SUBSECTION (A)(2) OF THIS SECTION; AND

(II) THE RESEARCH PRESENTS A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT.

(2) THE SURROGATE MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH IF THE SURROGATE CONCLUDES THAT PARTICIPATION IN THE RESEARCH IS IN THE MEDICAL BEST INTEREST OF THE DECISIONALLY INCAPACITATED INDIVIDUAL.

(C) IF SURROGATES WITH EQUAL DECISION MAKING PRIORITY UNDER THE HEALTH CARE DECISIONS ACT DISAGREE ABOUT PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN THE RESEARCH, THE DISAGREEMENT SHALL BE RESOLVED IN ACCORDANCE WITH § 5-605(B) OF THIS ARTICLE.

20-735.

(A) A PROXY DECISION MAKER DESIGNATED BY AN IRB UNDER § 20-717(B) OF THIS SUBTITLE MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH SPECIFIED IN § 20-731 OF THIS SUBTITLE IF:

(1) A RESEARCH AGENT, HEALTH CARE AGENT, OR SURROGATE IS NOT AVAILABLE; AND

(2) THE RESEARCH IS UNAMBIGUOUSLY INCLUDED IN AN ADVANCE DIRECTIVE OF THE DECISIONALLY INCAPACITATED INDIVIDUAL AND THE ADVANCE DIRECTIVE AUTHORIZES PARTICIPATION IN RESEARCH.

(B) (1) THIS SUBSECTION APPLIES IF:

(I) A PROXY DECISION MAKER CAN NOT GIVE CONSENT ON THE BASIS OF SUBSECTION (A)(2) OF THIS SECTION; AND

(II) THE RESEARCH PRESENTS A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT.

(2) A PROXY DECISION MAKER MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH IF THE PROXY DECISION MAKER CONCLUDES THAT PARTICIPATION IN THE RESEARCH IS IN THE MEDICAL BEST INTEREST OF THE DECISIONALLY INCAPACITATED INDIVIDUAL.

20-736. RESERVED.

20-737. RESERVED.

PART VII. CONSENT - RESEARCH INVOLVING NO DIRECT MEDICAL BENEFIT AND A MINOR INCREASE OVER MINIMAL RISK.

20-738.

THIS PART APPLIES TO RESEARCH CONDUCTED UNDER A RESEARCH PROTOCOL THAT, AS DETERMINED BY AN IRB:

(1) DOES NOT PRESENT A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO A DECISIONALLY INCAPACITATED INDIVIDUAL WHO IS A RESEARCH SUBJECT; AND

(2) PRESENTS A MINOR INCREASE OVER A MINIMAL RISK TO A DECISIONALLY INCAPACITATED INDIVIDUAL WHO IS A RESEARCH SUBJECT.

20-739.

A RESEARCH AGENT MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH SPECIFIED IN § 20-738 OF THIS SUBTITLE IF THE RESEARCH AGENT CONCLUDES, BASED ON AN ADVANCE DIRECTIVE AUTHORIZING PARTICIPATION IN RESEARCH AND OTHER PERTINENT INFORMATION, THAT THE DECISIONALLY INCAPACITATED INDIVIDUAL WOULD HAVE AGREED TO PARTICIPATE IN THE RESEARCH IF THE DECISIONALLY INCAPACITATED INDIVIDUAL WERE ABLE TO GIVE INFORMED CONSENT.

20-740.

A HEALTH CARE AGENT MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH SPECIFIED IN § 20-738 OF THIS SUBTITLE IF:

(1) A RESEARCH AGENT IS NOT AVAILABLE; AND

(2) BASED ON DIRECT AND EXPLICIT EVIDENCE OF THE WISH OF THE DECISIONALLY INCAPACITATED INDIVIDUAL TO PARTICIPATE IN THE RESEARCH AS DOCUMENTED IN ACCORDANCE WITH A STANDARD AND PROCEDURE DETERMINED BY AN IRB, THE HEALTH CARE AGENT CONCLUDES THAT THE DECISIONALLY INCAPACITATED INDIVIDUAL WOULD HAVE AGREED TO PARTICIPATE IN THE RESEARCH IF THE DECISIONALLY INCAPACITATED INDIVIDUAL WERE ABLE TO GIVE INFORMED CONSENT.

20-741.

ONLY A LEGALLY AUTHORIZED REPRESENTATIVE WHO IS A RESEARCH AGENT OR A HEALTH CARE AGENT MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH SPECIFIED IN § 20-738 OF THIS SUBTITLE.

20-742. RESERVED.

20-743. RESERVED.

PART VIII. CONSENT - RESEARCH INVOLVING NO DIRECT MEDICAL BENEFIT AND MORE THAN A MINOR INCREASE OVER MINIMAL RISK.

20-744.

THIS PART APPLIES TO RESEARCH CONDUCTED PURSUANT TO A RESEARCH PROTOCOL THAT, AS DETERMINED BY AN IRB:

(1) DOES NOT PRESENT A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO A DECISIONALLY INCAPACITATED INDIVIDUAL WHO IS A RESEARCH SUBJECT; AND

(2) PRESENTS MORE THAN A MINOR INCREASE OVER A MINIMAL RISK TO A DECISIONALLY INCAPACITATED INDIVIDUAL WHO IS A RESEARCH SUBJECT.

20-745.

(A) A RESEARCH AGENT MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH SPECIFIED IN § 20-744 OF THIS SUBTITLE IF:

(1) A MONITOR CONFIRMS THAT:

(I) THE RESEARCH IS UNAMBIGUOUSLY INCLUDED IN A RESEARCH ADVANCE DIRECTIVE OF THE DECISIONALLY INCAPACITATED INDIVIDUAL; AND

(II) THE RESEARCH AGENT UNDERSTANDS THE GOAL AND RISK OF THE RESEARCH; AND

(2) BASED ON THE RESEARCH ADVANCE DIRECTIVE AND OTHER PERTINENT INFORMATION, THE RESEARCH AGENT CONCLUDES THAT THE DECISIONALLY INCAPACITATED INDIVIDUAL WOULD HAVE AGREED TO PARTICIPATE IN THE RESEARCH IF THE DECISIONALLY INCAPACITATED INDIVIDUAL WERE ABLE TO GIVE INFORMED CONSENT.

(B) A MONITOR SHALL WITNESS THE PROCESS BY WHICH AN INVESTIGATOR PROVIDES THE RESEARCH AGENT WITH THE INFORMATION REQUIRED BY AN IRB FOR INFORMED CONSENT.

20-746.

ONLY A LEGALLY AUTHORIZED REPRESENTATIVE WHO IS A RESEARCH AGENT MAY CONSENT TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH SPECIFIED IN § 20-744 OF THIS SUBTITLE.

20-747. RESERVED.

20-748. RESERVED.

PART IX. PUBLIC INFORMATION AND ACCOUNTABILITY.

20-749.

(A) (1) FOR RESEARCH APPROVED BY AN IRB ON OR AFTER OCTOBER 1, 1999, INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL, THE IRB SHALL ASSURE THAT ANY MEMBER OF THE PUBLIC ON REQUEST MAY OBTAIN A COPY OF:

(I) THE RELEVANT PORTIONS OF THE MINUTES OF THE IRB;

(II) IF NOT INCLUDED IN THE MINUTES OF THE IRB, A SUMMARY OF THE RESEARCH PROTOCOL; AND

(III) A WRITTEN INFORMED CONSENT DOCUMENT APPROVED BY THE IRB.

(2) DISCLOSURE OF A DOCUMENT SPECIFIED IN PARAGRAPH (1) OF THIS SUBSECTION 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) A DISCLOSURE REQUIRED BY SUBSECTION (A) OF THIS SECTION IS IN ADDITION TO ANY DISCLOSURE OF INFORMATION OR DOCUMENT RELATED TO RESEARCH THAT IS REQUIRED OR AUTHORIZED BY:

(1) A STATUTE, REGULATION, OR POLICY OF THE FEDERAL GOVERNMENT OR OF THIS STATE; OR

(2) A POLICY OF AN IRB, A SPONSOR OF RESEARCH, AN INSTITUTION WITH WHICH THE IRB IS AFFILIATED, OR AN INSTITUTION AT WHICH RESEARCH OCCURS.

20-750.

NOT LATER THAN FEBRUARY 15 OF EACH YEAR BEGINNING IN 2000, AN IRB THAT, DURING THE PRECEDING CALENDAR YEAR, APPROVED RESEARCH IN WHICH A DECISIONALLY INCAPACITATED INDIVIDUAL WAS INTENDED TO BE A SUBJECT OF RESEARCH SHALL REPORT TO THE SECRETARY AND TO THE ATTORNEY GENERAL:

(1) THE TITLE OF EACH RESEARCH PROTOCOL APPROVED BY THE IRB;

(2) THE NUMBER OF DECISIONALLY INCAPACITATED INDIVIDUALS WHO WERE AUTHORIZED TO BECOME RESEARCH SUBJECTS IN EACH PROTOCOL;

(3) THE DETERMINATION BY THE IRB WHETHER EACH APPROVED PROTOCOL PRESENTED A REASONABLE PROSPECT OF DIRECT MEDICAL BENEFIT TO THE DECISIONALLY INCAPACITATED INDIVIDUALS;

(4) THE LEVEL OF RISK DETERMINED BY THE IRB FOR EACH APPROVED PROTOCOL; AND

(5) THE PROTOCOLS IN WHICH INVESTIGATORS REPORTED UNEXPECTED SERIOUS HARM TO A DECISIONALLY INCAPACITATED INDIVIDUAL.

20-751. RESERVED.

20-752. RESERVED.

PART X. AUTHORITY OF SECRETARY.

20-753.

THE SECRETARY MAY ADOPT ANY REGULATION TO:

(1) DESIGNATE THE LEVEL OF RISK ORDINARILY PRESENTED BY A PARTICULAR TYPE OF RESEARCH;

(2) REQUIRE AN ADDITIONAL DISCLOSURE TO A LEGALLY AUTHORIZED REPRESENTATIVE OR TO THE PUBLIC; AND

(3) CLARIFY ANY OTHER ASPECT OF THIS SUBTITLE.

20-754.

THE SECRETARY MAY ORDER THE IMMEDIATE SUSPENSION OR TERMINATION OF ANY RESEARCH INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL WHICH, IN THE JUDGMENT OF THE SECRETARY, ENDANGERS THE HEALTH OR SAFETY OF THAT DECISIONALLY INCAPACITATED INDIVIDUAL.

20-755.

(A) TO THE EXTENT FEASIBLE AND IN COOPERATION WITH THE OFFICE OF THE ATTORNEY GENERAL, THE SECRETARY PERIODICALLY SHALL STUDY THE EFFECT OF THIS SUBTITLE ON THE PROTECTION OF DECISIONALLY INCAPACITATED INDIVIDUALS AND THE CONDUCT OF RESEARCH INVOLVING DECISIONALLY INCAPACITATED INDIVIDUALS.

(B) A STUDY SHALL INCLUDE AN ASSESSMENT OF:

(1) THE PERFORMANCE OF AN IRB IN DESIGNATING THE LEVEL OF RISK OF RESEARCH; AND

(2) THE EFFECTIVENESS OF THE SAFEGUARDS SPECIFIED IN THIS SUBTITLE FOR PROTECTING A DECISIONALLY INCAPACITATED INDIVIDUAL AGAINST HARM.

(C) THE SECRETARY SHALL MAKE AVAILABLE TO THE PUBLIC THE RESULTS OF ANY STUDY CONDUCTED UNDER THIS SECTION.

20-756. RESERVED.

20-757. RESERVED.

PART XI. IMMUNITY AND LIABILITY.

20-758.

(A) THIS SECTION MAY NOT APPLY TO AN INDIVIDUAL WHO, BY A PREPONDERANCE OF THE EVIDENCE, FAILS TO COMPLY IN GOOD FAITH WITH THIS SUBTITLE.

(B) (1) THIS SUBSECTION MAY NOT AFFECT THE LIABILITY OF AN INVESTIGATOR FOR ANY ACTION OF THE INVESTIGATOR, EXCEPT FOR AN ACTION OF AN INVESTIGATOR IN CONDUCTING RESEARCH WITHOUT THE INFORMED CONSENT OF AN INDIVIDUAL WHO IS A RESEARCH SUBJECT AS AUTHORIZED UNDER THIS SUBTITLE.

(2) IF RESEARCH INVOLVING A DECISIONALLY INCAPACITATED INDIVIDUAL IS AUTHORIZED UNDER THIS SUBTITLE, AN INVESTIGATOR IS NOT SUBJECT TO CRIMINAL PROSECUTION OR CIVIL LIABILITY OR DEEMED TO HAVE ENGAGED IN UNPROFESSIONAL CONDUCT SOLELY AS A RESULT OF CONDUCTING THE RESEARCH WITHOUT THE INFORMED CONSENT OF THE DECISIONALLY INCAPACITATED INDIVIDUAL.

(C) A LEGALLY AUTHORIZED REPRESENTATIVE WHO, AS AUTHORIZED UNDER THIS SUBTITLE, CONSENTS TO PARTICIPATION BY A DECISIONALLY INCAPACITATED INDIVIDUAL IN RESEARCH IS NOT SUBJECT TO:

(1) CRIMINAL PROSECUTION OR CIVIL LIABILITY FOR GIVING THAT CONSENT; OR

(2) LIABILITY FOR ANY COST ASSOCIATED WITH THE PARTICIPATION IN RESEARCH BASED SOLELY ON THE CONSENT OF THE LEGALLY AUTHORIZED REPRESENTATIVE.

(D) A MEMBER OF AN IRB, A MONITOR, OR A MEDICALLY RESPONSIBLE CLINICIAN IS NOT SUBJECT TO CRIMINAL PROSECUTION OR CIVIL LIABILITY OR DEEMED TO HAVE ENGAGED IN UNPROFESSIONAL CONDUCT AS A RESULT OF AN ACTION PERFORMED BY THE MEMBER OF THE IRB, A MONITOR, OR A MEDICALLY RESPONSIBLE CLINICIAN IN ACCORDANCE WITH THIS SUBTITLE.

20-759.

(A) NOTWITHSTANDING ANY OTHER PROVISION OF THIS PART, AN INVESTIGATOR WHO KNOWINGLY INVOLVES A DECISIONALLY INCAPACITATED

INDIVIDUAL IN RESEARCH IN VIOLATION OF THIS SUBTITLE IS SUBJECT TO CRIMINAL PROSECUTION OR CIVIL LIABILITY AS OTHERWISE PROVIDED BY LAW.

(B) 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.

(C) AN INVESTIGATOR WHO KNOWINGLY AND WILLFULLY CONDUCTS RESEARCH THAT HAS BEEN SUSPENDED OR TERMINATED BY AN IRB OR BY THE SECRETARY IS GUILTY OF A MISDEMEANOR AND ON CONVICTION IS SUBJECT TO A FINE NOT EXCEEDING $10,000 OR IMPRISONMENT NOT EXCEEDING 12 MONTHS OR BOTH.

20-760. RESERVED.

20-761. RESERVED.

PART XII. MISCELLANEOUS.

20-762.

A RESEARCH ADVANCE DIRECTIVE MADE BEFORE OCTOBER 1, 1999, SHALL BE GIVEN EFFECT AS PROVIDED IN THIS SUBTITLE.

20-763.

THE ATTORNEY GENERAL SHALL PREPARE AND DISSEMINATE TO THE PUBLIC A SUMMARY OF THE PROVISIONS OF THIS SUBTITLE.

20-764.

THIS SUBTITLE MAY BE CITED AS "THE DECISIONALLY INCAPACITATED RESEARCH SUBJECT PROTECTION ACT."

20-765. RESERVED.

20-766. RESERVED.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 1999.