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Citation: 8 Yale J. Health Pol'y L. & Ethics 2008

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Proxy Consent to Research: The Legal Landscape

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I. INTRODUCTION

When an adult suffers from a disorder that impairs his or her capacity to consent, may another person enroll that individual in research? The answer, it appears, is not a simple "yes" or "no," but rather "it depends."

The lack of clear legal answers to this question has significant ramifications for the conduct of important research on disorders that affect many individuals. A growing population in our country suffers from illnesses that may affect decision-making, such as dementia, mental retardation, or, in certain instances, severe neuropsychiatric disorders. To illustrate this point, consider Alzheimer's disease ("AD"). As the most common cause of dementia, the current and projected impact of AD is immense. An estimated four to fifteen million people are expected to suffer from Alzheimer's disease by the year 2047.¹ Beyond the quantitative impact of AD, the personal and relational costs of the disease are staggering. Patients in later stages may not recognize family members and often lose many of their core human traits and abilities. Many patients face institutionalization because of the common, yet extremely challenging, behavioral and psychiatric expressions of the disease. The financial costs are also significant. Current annual costs, both direct and indirect, approach \$100 billion in the United States alone.² It is urgent that research on this disease be strongly encouraged and facilitated.

A person who may consent on behalf of another to participate in research is referred to as a "proxy" or "surrogate." Proxy consent for research on disorders such as AD has been called "a gray zone of law and ethics."³ Early bioethics documents such as the Nuremberg Opinion—not binding law but historically important—required consent from the subject himself,⁴ and thus proxy consent would never be allowable. However, later documents concerning scientific research, including the influential Belmont Report,⁵ did allow for proxy consent

I. Ronald Brookmeyer et al., Projections of Alzheimer's Disease in the United States and the Public Health Impact of Delaying Disease Onset, 88 AM. J. PUB. HEALTH 1337 (1998).

^{2.} Bernard S. Bloom et al., Cost of Illness of Alzheimer's Disease: How Useful Are Current Estimates? 43 GERONTOLOGIST 158 (2003); Glen T. Schumock, Economic Considerations in the Treatment and Management of Alzheimer's Disease, 55 AM. J. HEALTH-SYS. PHARMACY, S17 (1998).

^{3.} Paul S. Appelbaum, Involving Decisionally Impaired Subjects in Research: The Need for Legislation, 10 AM. J. GERIATRIC PSYCHIATRY 120 (2002).

^{4.} See United States v. Brandt, 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS 1 (1947).

^{5.} Nat'l Com'n for the Prot. of Human Subjects of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for Research Involving Human Subjects, 44 Fed. Reg. 23,192 (Apr. 18, 1979).

to research.⁶ Despite the promulgation of codes of ethics and statements by professional societies, clear guidelines are still lacking regarding the conditions under which proxy consent for research is acceptable.

Currently, federal regulations governing research allow proxy consent for research involving adults who lack decision-making capacity if a "Legally Authorized Representative" (LAR) gives permission.⁷ Under these regulations, however, an LAR is defined as "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research."⁸ The federal regulations presume that each state has law concerning research involving mentally impaired adults that will guide the decisions of researchers, institutional review boards (IRBs), and surrogates when they are called upon to make decisions. Unfortunately, the states' "applicable laws" regarding who can serve as an LAR (and under what conditions) are often unclear.⁹ While proxy decision-making is permissible in theory, in practice it may not be allowed because the states have not created clear laws governing its use.

States allow for different types of proxies, such as courts, guardians, people with Durable Powers of Attorney (DPAs) for health care, and family members. Of particular interest to researchers are states that allow families to be proxies in the research context. Allowing family members to be proxies for research may be the best solution to this problem because it allows both for autonomy of the patient—families are likely to know best what the patient would have wanted— and for much needed research to continue. Obtaining proxy consent from family members uses far fewer resources than going to court to seek a decision or appointment of a guardian. The latter method can be so taxing and time-consuming that researchers may simply stop trying to conduct research that involves incompetent patients.

There is no empirical data regarding the amount of research currently being conducted with decisionally impaired subjects, and therefore there is also no data showing how the lack of clear guidelines affects the supply of subjects. Despite the lack of statistics, there is anecdotal evidence that the research community has been burdened by the lack of clear regulations and that the absence of clarity has, at times, adversely affected the amount of research being performed. In 2002, for instance, the Executive Vice Chancellor of UCLA, concerned about the lack of

^{6.} See Bernard A. Fischer, IV, A Summary of Important Documents in the Field of Research Ethics, 32 SCHIZOPHRENIA BULL. 69 (2006); Scott Y.H. Kim et al., Proxy and Surrogate Consent in Geriatric Neuropsychiatric Research: Update and Recommendations, 161 AM. J. PSYCHIATRY 797 (2004).

^{7. 45} C.F.R. § 46.102(c) (2006).

^{8.} Id.

^{9.} See Kim et al., supra note 6, at 799-800.

clear regulatory guidance on how to handle the issue of surrogate consent for research involving people with diminished capacity, issued a university-wide moratorium on approval of human subjects research involving decisionally impaired participants unless the consent of a court-appointed conservator was obtained.¹⁰ After a divisive legislative session California's legislature passed A.B. 2328,¹¹ a law that took effect in January 2003 and allowed informal surrogates to consent on behalf of incompetent patients.¹² Data has not been collected to measure whether this law has encouraged research efforts involving decisionally impaired people with diseases such as AD. The topic of surrogate consent has also been highlighted by researchers who study the critically ill, who very often cannot provide their own informed consent.¹³ Further evidence that the research community considers these issues of consent to be timely can be found in the convening of a National Institutes for Health (NIH) group in Washington, DC, in July 2002 to discuss this type of proxy consent. The Office for Human Research Protections (OHRP), a federal agency, has also convened a committee to address this issue ¹⁴

This Article aims to enhance the clarity of existing guidelines and highlight the need for further regulation. In a more predictable legal environment we expect that research with decisionally impaired subjects will increase and improve. Not least, clarifying the legal landscape would encourage research by reducing researchers' fears of criminal and civil prosecution. Without reform, research on disorders that impair mental abilities likely will be encumbered. Because many states do not have "applicable laws" that guide LAR designation, the current state of the law may put research on disorders that impair decisional abilities at risk.¹⁵

We seek in this review to examine the legal landscape concerning LARs in the various states. After reviewing our methodology in Part II, we turn to the

^{10.} Memorandum from Daniel M. Neuman, Executive Vice Chancellor, Univ. of Cal., L.A., to the Faculty of Univ. of Cal., L.A., RE: Moratorium on IRB Approval of Surrogate or Proxy Informed Consent for Human Subjects Research (Sept. 30, 2002), *available at* http://www.oprs.ucla.edu/human/news/item?item_id=127481.

^{11. 2002} Cal. Legis. Serv. 489 (West) (codified at CAL. HEALTH & SAFETY CODE § 24178 (West 2006)).

^{12.} See John M. Luce, California's New Law Allowing Surrogate Consent for Clinical Research Involving Subjects with Impaired Decision-making Capacity, 29 INTENSIVE CARE MED. 1024 (2003).

^{13.} John M. Luce, Research Ethics and Consent in the Intensive Care Unit, 9 CURRENT OPINION CRITICAL CARE 540 (2003).

^{14.} For more information on the OHRP, see OHRP Fact Sheet, http://www.hhs.gov/ohrp/ about/ohrpfactsheet.htm (last visited Nov. 30, 2007).

^{15.} See, e.g., Scott Y.H. Kim et al., What Do People at Risk for Alzheimer Disease Think About Surrogate Consent for Research?, 65 NEUROLOGY 1395 (2005).

existing law in this area in Part III. Section A briefly reviews direct references to LARs in state statutes. Section B provides an overview of state laws directly relevant to inferring proxy consent in the research context. Section C examines the two most detailed statutes on proxy consent to research, passed in California and Virginia. Section D discusses formal letters issued between 2000 and 2006 by the Office of Human Research Protections (OHRP) which provide insight into federal interpretations of state laws. Section E reviews relevant case law on proxy consent to research and Section F reviews explicit limits placed on proxy decision-making in the research context. Appended to this Article are three tables that show our findings by state.16 Table 1 lists state statutes regarding proxy consent to treatment. Table 2 lists those statutes addressing family proxy consent to treatment. Table 3 classifies statutes by the powers that are given to substitute decision-makers.

After presenting our results, we discuss them in Part IV. In Section A—the "Positive Side"—we explore some meta-issues, such as the implications of using treatment proxies to define LARs in the research context. In Section B—the "Normative Side"—we discuss what the law *should* be in this area. As a matter of positive law, we believe that reasonable inferences from related statutes could support a finding that families may serve as proxies for research. As a normative matter, we believe that families often will be the best decision-makers and should therefore be authorized to make proxy research decisions, although some limits should be placed on when they may give proxy consent. Finally, in Part V, we note the limitations of our research and the need for further studies on various aspects of proxy consent issues.

II. METHODS

An important preliminary definitional issue must be addressed: the distinction between proxy consent to research and proxy consent to treatment. When applicable, we defer to the language of the state statutes. Statutes speaking of consent to "treatment" are classified as statutes regarding proxy consent to treatment. Where statutes speak of "research," or "experimental treatment," we classify them as concerning proxy consent to research.¹⁷

Federal regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."¹⁸ In contrast, treatment does not aim to lead to generalizable knowledge, but aims to ameliorate a specific patient's medical

^{16.} To view the tables online, please visit www.yale.edu/yjhple.

^{17.} We also are conservative about other locutions—e.g., "health care"—taking them to refer to treatment, though they could reasonably be interpreted to include both treatment and research.

^{18. 45} C.F.R. § 46.102(d) (2006).

condition. "Experimental treatment" may have both aims. It is "experimental" because it has not been established as part of the ordinary standard of care. In practice, this distinction can become blurry because something that is clearly "Human Subject Research" according to the definition in the regulations can offer subjects the prospect of direct benefit. The research is not individualized to the subject, so what he or she receives in the way of "treatment" is not individualized to his or her needs. Because the objective is to obtain generalizable knowledge, this intervention would be classified as research, even if it is helpful to the individual.

For the positive law sections and tables of this Article, we conducted an extensive search for statutes on proxy consent adopted by the legislatures of the fifty states.¹⁹ We did not research regulations promulgated by state agencies to effectuate statutes. We also conducted a thorough review of the case law created in judicial decisions interpreting statutes or addressing issues not encompassed in statutes.

In researching the statutes, we first located every direct reference to the term "Legally Authorized Representative." Second, we conducted a broad search in the fifty-state statutory databases of Lexis and Westlaw.²⁰ We also did more focused searches examining family consent in particular.²¹ We looked specifically for guardian and conservator consent through another search.²² We then searched for statutes on "durable powers of attorney" and related statutes.²³ Sinee many states do not have research proxy statutes, we designed our search to encompass laws concerning proxy consent in treatment-related contexts. Such statutes, while not directly on point, often allowed us to draw valuable inferences. For example, analyzing these statutes allowed us to review statutorily-imposed limits on proxy consent powers in the states.

We also reviewed letters issued by the Office of Human Research Protections during the years 2000-2006 that addressed proxy consent to research issues. This review provided insight into how the federal government office that

21. Search terms were: (health medic!) & consent & (spouse parent "next of").

^{19.} The ABA legislative update on the Commission on Law and Aging has tables with some information replicated in our three tables. Some of that information is dated; the tables do not address many of the items we address (e.g., the different routes for proxies in the research context or the standards by which proxies must make decisions). Our tables are organized in a way that aims to be helpful for making inferences about proxies in the research context. See Comm'n on Law & Aging, Am. Bar Assoc., Legislative Updates, http://www.abanet.org/aging/legislative updates/home.shtml (last visited Nov. 30, 2007).

^{20.} Search terms were: (health or medic!) & consent & (treatment research) & (surrogate or proxy or "durable power of attorney" or guardian or conservator).

^{22.} Search terms were: ((guardian conservator) /p consent) & (health! medic!).

^{23.} Search terms were: (DPA or "durable power of attorney") or surrogate or (substitute /2 decision /2 mak!).

oversees research conceptualizes this issue. We reviewed all letters issued by the OHRP for this time period and identified those relevant to proxy consent to research on adults. Finally, we did a thorough search of relevant case law to see if courts have addressed the interpretive difficulties that the statutes sometimes raise or if they have created their own guidelines on who qualifies as an LAR.

Of course these different approaches are not equally helpful in determining the extent to which individuals can give proxy consent to research. Methodologically, a statute which purports to define "Legally Authorized Representative" in the context of proxy consent to research is most on point. A statute which lists kinds of proxies who may consent to research (without mentioning the term LAR) is also extremely helpful. Beyond that, we are left to make more or less secure inferences from laws that concern other contexts and use these inferences to create a model. This issue is addressed further in Part IV.

III. RESULTS

A. Direct Mentions of "Legally Authorized Representative"

The term LAR occurs in state statutes approximately 295 times, not including multiple mentions of the term in the same section of a statute. The contexts in which LAR is mentioned include not only statutes about consent to treatment or research, but also whom medical information may be disclosed to and when agents of government officials may perform various activities. Indeed, the overwhelming majority of references (180) to the term concern the Legally Authorized Representative of state auditors examining the accounts of the books of various public agencies.²⁴

The statutes also sometimes use language qualifying the LAR language, giving some suggestion of what the term might mean. Examples are "the [LAR] or agent,"²⁵ "[LAR] or family,"²⁶ "a spouse or domestic partner of the individual absent other [LAR],"²⁷ "parent or [LAR],"²⁸ "next of kin or [LAR] or other legal representative,"²⁹ "conservator, guardian, or other [LAR],"³⁰ and "a guardian, conservator, or guardian ad litem authorized by the court, or other [LAR]."³¹

^{24.} See, e.g., IOWA CODE ANN. § 16.31(1) (West 2005); MISS. CODE ANN. § 43-33-747(1) (2007); N.J. STAT. ANN. § 12:11A-22(d) (West 1979); N.M. STAT. § 58-18-20(A) (1978).

^{25.} See, e.g., CONN. GEN. STAT. ANN. § 21a-8a(b) (West 2006).

^{26.} See, e.g., CAL. WELF. & INST. CODE § 4905(a) (West 1998).

^{27.} See, e.g., CAL. UNEMP. INS. CODE § 2705.1 (West 1986).

^{28.} See, e.g., KY. REV. STAT. ANN. § 214.468 (LexisNexis 2007).

^{29.} See, e.g., VA. CODE ANN. § 54.1-2961(E) (2005).

^{30.} See, e.g., CAL. WELF. & INST. CODE § 5622(b) (1998).

^{31.} See, e.g., MINN. STAT. ANN. § 245B.02(15) (West 2007).

In the specific context of consent to medical treatment or research, the term LAR is used twenty-nine times. The contexts include emergency treatment (California), treatment for developmental disability (California), HIV testing (Illinois, Michigan), predictive genetic tests (South Dakota), and treatment by telehealth (Nebraska).³² Texas statutes refer to the concept multiple times in numerous medical contexts: appropriate care settings,³³ mental retardation community placement,³⁴ information provided regarding long-term support,³⁵ consumer direction of services,³⁶ do not resuscitate orders,³⁷ and facilities and services for clients with mental retardation.³⁸

There are some thirty other references to LAR in the medical context that do not involve consent to treatment or research. These statutes discuss issues such as access to medical records or their disclosure to others,³⁹ and disclosure of results of tests for HIV.⁴⁰ In the research context in particular, there is a statute on the right to receive copies of signed consent forms and on the permissibility of disclosing a research record in individually identifiable form without the prior written consent of the person or his or her LAR.

Finally, the term LAR occurs specifically in the context of consent to participate in research in at least three jurisdictions: Guam, New York, and Virginia. Only a very small number of jurisdictions discuss or mention the meaning of LAR in a context that is relevant to this Article. Two statutes do not define LAR and simply refer to other state laws, at least on certain issues (Guam and Washington). The other two laws (Texas and Virginia) list people who may serve as LARs. Virginia does so explicitly in the context of consent to research, as discussed in detail in Subsection III.C.2.

Looking directly at the uses and definitions of LAR in statutes, then, is at most modestly useful. Most of these references concern matters other than research or treatment, and they do not provide helpful descriptions or definitions even when they are on point. Hence, we must survey related statutes and other legal materials to determine the answers to our questions about the permissibility of proxy consent.

^{32.} CAL. HEALTH & SAFETY CODE § 24177.5 (West 2006); MICH. COMP. LAWS ANN. § 333.5133 (West 2001); NEB. REV. STAT. § 71-8505 (2003); S.D. CODIFIED LAWS § 34-14-22 (2007).

^{33.} See TEX. GOV'T CODE ANN. § 531.0244 (Vernon 2004).

^{34.} See TEX. GOV'T CODE ANN. § 531.02442 (Vernon 2004).

^{35.} See TEX. GOV'T CODE ANN. § 531.042 (Vernon 2004).

^{36.} See TEX. GOV'T CODE ANN. § 531.051 (Vernon Supp. 2007).

^{37.} See Tex. Health & Safety Code Ann. § 166.081(6)(A) (Vernon 2001).

^{38.} See Tex. Health & Safety Code Ann. § 533.038 (Vernon 2003).

^{39.} See, e.g., 735 ILL. COMP. STAT. ANN. 5/8-2001 (West 2007).

^{40.} See, e.g., FLA. STAT. § 381.004(3)(e) (2007); 410 ILL. COMP. STAT. 305/9 (West 2007).

B. Inferring LAR Status by Examining State Laws Defining Proxies Per Se

We examined state statutes to see who is authorized to consent to research for someone who cannot consent for herself. The proxies appointed by statutes range from family members to guardians to courts. We are most interested in jurisdictions that explicitly allow families to consent in the research context. Many jurisdictions do not speak directly to this issue, and therefore we are forced to make inferences based on descriptions of the proxy's authority to provide consent for purposes other than research. For instance, what sorts of procedures are proxies permitted to decide upon in the treatment context? For which procedures are proxies precluded from giving consent, and how do these procedures compare with those used in various kinds of research? We cannot presume that absence of a statute necessarily means that proxy consent to research is not permitted.

Because analysis of the laws is not straightforward, we compiled our data about the statutes in three tables, appended to this Article and described below.

1. Statutes on Proxy Consent to Research

We turn now to when proxies may consent specifically to research participation. Table 1, Column 3 lists those states where family members are explicitly mentioned as individuals who can give proxy consent on behalf of their incompetent family members to participate in research. Nine jurisdictions have statutes that specifically allow this. Some of these jurisdictions restrict the use of proxy consent to certain populations, e.g., psychiatric patients (Montana), nursing home patients (Washington), developmentally disabled patients (D.C. and Montana), or terminally ill patients (Oklahoma). Others only allow its use in specific kinds of research, e.g., psychiatric (Delaware). Others impose certain limits on when such proxy consent is permissible, e.g., the research will assist the ward to develop or regain his abilities (Florida). But other statutes are fairly broad and general. Thus, practically speaking, even those researchers and Institutional Review Boards (IRBs) that are in states with these statutes must carefully consider the specific provisions of their state's laws.

Table 1, Column 4 lists those jurisdictions in which other persons are explicitly authorized to consent on behalf of an incapable subject without having been appointed by a court to do so. There are five statutes in this category. Listed here are those jurisdictions that allow a proxy to consent to research if there is an advance directive (North Carolina); or allow an agent with a health care DPA to consent to research (Missouri, Montana, and Oklahoma). Two of the three states that provide for DPAs' consent also allow consent to be obtained from others individuals, such as family members (Missouri and Oklahoma). One jurisdiction does not allow the DPA to consent to experimental mental health treatment, among other things, unless the DPA form provides otherwise (Wisconsin).

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Again, even when non-court-appointed surrogates are allowed, there are specific restrictions that make generalizations across states difficult.

Column 5 contains information about when legal guardians may consent to research on behalf of their incompetent wards. Fourteen jurisdictions explicitly mention guardian consent in the research context and do not require court authorization (e.g., Alaska, Missouri, and New Mexico). Some require court authorization only if there is no IRB approval for the research (e.g., Florida). Some jurisdictions put limits on when guardians can consent—e.g., only if the research is intended to preserve life or prevent serious injury, or only if it is intended to assist the ward to develop or regain abilities (e.g., Alaska and Connecticut). A number of them apply only to specific populations, such as developmentally disabled patients, psychiatric patients, or involuntarily committed patients (e.g., Colorado, Connecticut, D.C., Georgia, and New Mexico). And some refer to alternate routes for volunteering people for research (e.g., Connecticut and Missouri).

Column 6 has information about states where courts can consent to research on behalf of incompetent patients, where the courts' consent is required, and where courts may authorize a guardian to engage in proxy consent. In some cases, a requirement of court approval applies only to certain groups, e.g., psychiatric patients (D.C.) or developmentally disabled patients (e.g., Connecticut and North Dakota); in others, it applies to every incompetent subject. Certain jurisdictions put limits on when the courts can provide consent, e.g., only if the procedure is intended to preserve the life of the potential subject, or only if it is related to the specific goals of the patient's treatment program (e.g., Connecticut, Florida, Illinois, Nevada, New Jersey, and North Dakota).⁴¹

In total, nine states explicitly allow family members to give proxy consent to

^{41.} It should be noted that there are at least three states whose statutes raise interpretive difficulties. Florida seems both to allow guardians to decide, *see* FLA. STAT. ANN. § 394.4598 (West 2007); FLA. STAT. § 765.113 (1994), and to require court approval before guardians may consent, *see* FLA. STAT. § 744.3215(4)(b) (1994) (requiring court authorization for an "experimental biomedical or behavioral procedure"). Illinois seems to allow guardian or family consent without court approval, *see* 410 ILL. COMP. STAT. 50/3.1 (2005), but then requires court approval for "[u]nusual, hazardous, or experimental services or psychosurgery" if the patient "is under guardianship." 405 ILL. COMP. STAT. 5/2-110 (2005). These may be reconciled in that the latter is found in the chapter relating to rights of recipients of mental health and developmental disabilities services. North Dakota seems both to allow guardians to consent, *see* N.D. CENT. CODE § 25-03.1-40 (2002), and guardians to consent only with a court order. N.D. CENT. CODE § 25-03.1-40 (2002), and guardians to consent only with a court order. N.D. CENT. CODE § 25-01.2-11 (2002). These may be reconciled by the fact that the first only applies in the context of the "civil commitment of patients" while the second applies "to an institution or facility that provides residential care." In those cases where there seems to be a conflict, we have included the statutes in both columns of our table as they may need to be interpreted by case law.

research. Twenty-seven states⁴² have an explicit statute on proxy consent to research in general (e.g., guardian consent, DPA consent, etc.).

2. The Treatment Context

Even if a state does not have a specific law regulating proxy consent for research, it may have proxy laws for other contexts that shed light on, or have direct implications for, proxy consent for research in that state. For health care decisions, every jurisdiction has a guardianship statute that empowers the "courts to appoint guardians for decisionally incapacitated people."⁴³ Another survey found that, while far from uniform, all states have enacted some form of advanced health care directive that allows the declarant to specify treatment and to designate a health care proxy in the document.⁴⁴

Of most interest to us are states in which proxy consent by family members for treatment is explicitly allowed. Table 2 lists statutes that authorize family members to make proxy in the treatment context. Column 3 contains statutes regulating decisions by family proxies in the treatment context in general. Fifteen states have these types of statutes. Column 4 contains statutes regulating decisions by family proxies about life-sustaining treatment—whether to consent to or refuse it. Ten states, seven of which are not among the fifteen states listed in Column 3, have these types of statutes. Column 5 contains statutes regulating mental health, developmental disability or substance abuse treatment decisions, or decisions in the case of these kinds of patients. Fifteen states, six of which are not included in the first two columns, have these types of statutes. Column 6 contains statutes regulating other specific interventions as well as other miscellaneous proxies. Ten states, five of which are not listed in the other columns, have statutes that fall into this category. In total, thirty-four states fall into one (or more) of these categories.

3. General Standards for Proxy Decision-making

We now move to consider the statutory schemes that specify standards for proxy consent and set limits on proxy consent to certain interventions. This inquiry may be important in states where there is not an explicit authorization for

^{42.} There are twenty-seven states that have laws regarding which proxies may consent to research, i.e., states that have any item in any column. It should be noted that some jurisdictions are listed in more than one category.

^{43.} See, e.g., Marshall B. Kapp, Legal Basis of Guardianship, in GUARDIANSHIP OF THE ELDERLY: PSYCHIATRIC AND JUDICIAL ASPECTS 18 (George H. Zimny & George T. Grossberg eds., 1998).

^{44.} See Bretton J. Horttor, A Survey of Living Will and Advanced Health Care Directives, 74 N.D. L. REV. 233 (1998).

proxy consent to research or treatment, or for states that have a treatment statute but do not appear to allow it to serve as precedent for proxy consent to research.

There are three places to look for laws of this type: first, at statutes that generally describe the kinds of proxy decision-making that are allowable; second, at statutes that specify how the proxy decision shall be made; and third, at statutes that prohibit proxy decision-making in certain contexts.

Table 3, Column 3 describes in general terms the kinds of decisions proxies can make. For example, one statute describes the decision-maker's power to include "[a]ny medical decision the subject can make,"⁴⁵ while another covers "any decision a parent could make for her child."⁴⁶ One could argue that research decisions fall into any of these general categories. It should be noted, however, that we did not catalog the many jurisdictions that say, for example, that DPAs can make all "health care" decisions for their principal. The question, again, would be whether decisions to participate in research are "health care" decisions. A case can be made in either direction.

Column 4 describes the standard by which proxies are to decide—which may have implications for when proxy decisions are allowed. At least twentynine jurisdictions require a "substituted judgment" standard: what the patient would have decided if competent, provided his or her wishes are known. Seven other states require a "best interests" standard. Most states also say to use this standard if the patient's wishes are not known.

Another approach to answering questions about proxy consent is to consider what kinds of decisions DPAs and guardians are *not* permitted to make, at least without court approval. Column 5 catalogs these statutes. Five jurisdictions require court approval for proxy consent to abortion; nine require court approval for sterilization; six require court approval for electroconvulsive therapy; and seven require court approval for psychosurgery. Particularly relevant is that eight states require court approval for experimental treatment.

Although we do not review the case law that has been generated by court approval statutes in this Article, it is worth noting that there are also a number of state laws that require a judicial finding of incompetence before a person may lose his right to refuse psychotropic medication. These cases differ from the research context however, in that most commentators believe that a subject's dissent should serve as an absolute bar to research (despite a finding of incompetence and surrogate consent), whereas refusal of psychotropic medication for treatment purposes can be overridden.

^{45.} We cannot imagine any decision a proxy could make that a person himself could not make.

^{46.} For an example of a decision a parent cannot make for his or her child, imagine the situation where a parent is unable to give permission for an extremely risky procedure intended to primarily benefit another child, or, where a parent is unable to refuse a treatment necessary to save a child's life. *See* Table 3 for further information on these and related standards.

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In short, this approach to reviewing laws governing proxy consent to research looks at statutes which are permissive in the treatment context (statutes that, when read reasonably, seem to allow proxy consent for treatment) and at statutes which are limiting in this context (statutes that, when read reasonably, may prohibit proxy consent for treatment). Later we discuss how these statutes may or may not help to answer questions about the availability of proxy consent in the research context.

C. The Two Most Detailed State Laws

1. The California Law

In 2002, California passed a law, A.B. 2328, allowing proxy consent to be given for research.⁴⁷ There are several key features of this law. First, it allows proxy consent only to medical experiments that "relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants." Second, it applies only if subjects are "unable to consent" and, third, if they do not dissent. Fourth, the proxy must have "reasonable knowledge" of the research participant. Fifth, the proxy is required to exercise "substituted judgment" if possible, and use a "best interests" standard when it is not possible.⁴⁸

The possible proxies, in order of priority, are as follows: DPA, conservator, spouse, a domestic partner as defined by section 297 of the Family Code, adult son or daughter, custodial parent, adult sibling, adult grandchild, or an adult relative with the closest degree of kinship to the person. If there is more than one proxy in a given category-such as two siblings-then each member of the proxy group must consent to the proposed research. Note that both a DPA and a guardian come before family members. If there is no DPA or guardian, however, family members may consent. In practice, there will often be no DPA or guardian and the most frequent surrogates will be family members. An important aspect of the law is that it does not limit proxy consent to research that falls under some threshold risk/benefit ratio. Presumably, as long as the relevant IRB approves, research involving significant risk but without any potential to directly benefit the subject is possible in California. Another significant feature of the law is that it appears to be inapplicable to subjects who are involuntarily committed, voluntarily admitted, or admitted on a conservator-request to a psychiatric hospital.

^{47. 2002} Cal. Legis. Serv. 489 (West) (codified at CAL. HEALTH & SAFETY CODE § 24178 (West 2006).

^{48.} Id.

2. The Virginia Law

The Virginia law⁴⁹ appears to have been modeled after the federal regulations governing children's research⁵⁰ with some modifications for the adult surrogate consent context. The statute defines a LAR by listing the order of priority for proxy decision-makers: parents having custody of a minor; an agent appointed in an advance directive (provided the directive authorizes research decisions); a guardian; a spouse; an adult child; a parent when the subject is an adult; an adult brother or sister; and any other judicial or other body authorized by law. LAR status flows down from group to group—so if a person does not exist at the highest category, the power is then vested in a person (or persons) in the second highest category. The statute also says that an attorney-in-fact⁵¹ may serve as a proxy to the extent that the Durable Power of Attorney instrument grants the authority to make this decision. The law states that if there are two or more individuals in any given category at issue, then each member of the proxy group must consent for the subject to be enrolled.

The LAR may not consent if he knows or should know that a procedure is contrary to the religious beliefs or values of the prospective subject. The LAR also may not consent to research involving non-therapeutic sterilization, abortion, psychosurgery, or admission for research purposes to certain kinds of facilities or hospitals. And unlike the California law, the law stipulates a maximum level of risk that a LAR may consent to for non-therapeutic research.⁵² Furthermore, the risk must be deemed by the human subjects review committee to represent no more than a "minor increase over minimal risk."⁵³

D. Federal Law: The OHRP Letters

The federal government has weighed in on how to use state statutes about proxy consent in a general medical context to interpret the notion of an LAR in the research context. The OHRP is a federal regulatory body that oversees research with human subjects.⁵⁴ Issues of interest to the research community

^{49.} VA. CODE ANN. § 32.1-162.18 (2004).

^{50.} Compare VA. CODE ANN. § 32.1-162.18 (2004) with 45 C.F.R. § 46(D) (2006).

^{51.} An attorney-in-fact is essentially a Durable Power of Attorney—someone appointed to make decisions for the person when he is incapable.

^{52.} Non-therapeutic research is essentially research that offers no prospect of direct benefit (today this research would be called no-direct-benefit research).

^{53.} For a discussion of what this means, see, for example, David Wendler & Ezekiel J. Emanuel, *What Is a "Minor" Increase over Minimal Risk?*, 147 J. PEDIATRICS 575 (2005), and David Wendler et al., *Quantifying the Federal Minimal Risk Standard: Implications for Pediatric Research Without a Prospect of Direct Benefit*, 294 JAMA 826 (2005).

^{54.} See OHRP Fact Sheet, supra note 14.

reach the OHRP, which issues opinion letters, in a variety of ways—e.g., investigators submit questions to them, whistle blowers contact them, or the OHRP itself uncovers them when "spot checking" different institutions.⁵⁵ We reviewed all letters from the OHRP written between 2000 and 2006, uncovering eighteen letters written during that time that discuss the concept of who may serve as an LAR in the (adult) research proxy context.⁵⁶ These letters addressed specific cases. Generally, what was at issue were studies involving incapacitated ICU patients whose participation in research seems to have been based on family consent. As we noted in the Introduction, the federal regulations defer to states on the issue of who is a proper LAR. Thus, the OHRP asks investigating institutions to explain the legal grounds on which they claim that family members are able to give proxy consent. The OHRP considers who has made the judgment, giving most authority to state Attorneys General but also looking, for instance, to hospital counsels' justifications. Sometimes the OHRP suggests that hospitals seek the advice of their state Attorney General's office.

A number of the OHRP letters seem to interpret the existence of a family proxy consent to treatment statute as also authorizing family proxy consent to research.⁵⁷ These letters may be interpreted in different ways:

(1) if a family member can give proxy consent to any reasonable treatment,

57. Letter from Office for Human Research Prot. to Richard M. Cagen, Adm'r, LDS Hosp. (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/ YR02/feb02e.pdf; Letter from Office for Human Research Prot. to Regis B. Kelly, Executive Vice Chancellor, Univ. of Cal., S.F. (Apr. 11, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/apr02p.pdf; Letter from Office for Human Research Prot. to Alvin W. Kwiram, Vice Provost for Research, Univ. of Wash. (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02g.pdf; Letter from Office for Human Research Prot. to Ralph Snyderman, President, Duke Univ. Health Sys. (Feb. 1, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02a.pdf; Letter from Office for Human Prot. to Fazwaz T. Ulaby, Vice President of Research, Univ. of Mich. (Feb. 11, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02a.pdf; Letter from Office for Human Research Prot. to Donald E. Wilson, Dean, Sch. of Med., Univ. of Md. (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02n.pdf; Letter from Office for Human Research Prot. to Donald E. Wilson, Dean, Sch. of Med., Univ. of Md. (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02n.pdf; Letter from Office for Human Research Prot. to Donald E. Wilson, Dean, Sch. of Med., Univ. of Md. (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02n.pdf; Letter from Office for Human Research Prot. to Donald E. Wilson, Dean, Sch. of Med., Univ. of Md. (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02 /feb02f.pdf.

^{55.} See Telephone Interview with Susan L. Rose, Executive Director, Office for the Protection of Research Subjects, University of Southern California, in L.A., Cal. (Oct. I, 2007).

^{56.} There are other letters from the OHRP about LARs in the context of proxy consent for children to participate in research. The scope of this Article is limited to adult subjects and thus we do not discuss the different set of issues that arise in the context of proxy consent for children. (While the regulations applicable to adults defer to the states, there are specific federal regulations regarding proxy consent in the case of children and thus these OHRP letters discuss issues irrelevant to our discussion.)

he can also give proxy consent to any reasonable research;

(2) if a family member can give proxy consent to treatment, he can also give proxy consent to this type of intervention in the research context;

(3) if a family member can give proxy consent to treatment, he can also give proxy consent to any research procedure which carries the same degree of risk;

(4) if a family member can give proxy consent to treatment by a particular, mentioned intervention (e.g., ventilation), he can also give proxy consent to this particular intervention in the research context (this is different from number (2), which analogizes research to whatever particular treatment is at issue, e.g., a medication, a particular surgery; while this interpretation compares research to the *particular treatment mentioned here*, e.g., ventilation); and

(5) if a family member can give proxy consent to treatment by a particular, mentioned intervention, he can also give proxy consent to any research with a degree of risk similar to that posed by the specified intervention.

It seems that all of these letters can be interpreted consistent with these five ways. The language of the letters, however, is, to us, most consonant with interpretation (2). This intuition is probably based on a literal reading of the relevant federal regulation, which refers to a "subject's participation in the *procedure(s)* involved in the research."⁵⁸ Although this is a reasonable parsing of the actual words of the regulations, it does create some tensions. If someone can give proxy consent to a spinal tap to discover whether the patient has a disease, can he also give proxy consent to a spinal tap in the research context, particularly when it is no-direct-benefit research? Clearly the risk/benefit ratio is different because of the absence of direct benefit to subjects in this example. Perhaps, then, the better position would be to allow proxy consent when the interventions in the different contexts (treatment versus research) have the same degree of risk compared to direct benefits.⁵⁹

The research teams mentioned in these letters sometimes could not rely on a general treatment-proxy statute, because they did not exist in their respective

^{58.} See 45 C.F.R. § 46.102(c) (2006).

^{59.} See Letter from Office for Human Research Prot. to Richard M. Cagen, *supra* note 57; Letter from Office for Human Research Prot. to Donald C. Harrison et al., Senior Vice President and Provost for Health Affairs, Univ. of Cincinnati (Dec. 20, 2001) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/dec01h.pdf.

states. Many of them instead cited laws permitting proxies in different contexts lifesaving treatment or treatment of the terminally ill,⁶⁰ interventions with people in persistent vegetative states (PVS),⁶¹ interventions in emergency situations,⁶² and autopsies and organ donation statutes.⁶³ In most cases, the OHRP did not allow such statutes to be used as precedents for proxy consent to research. They found that because the subjects are not in a PVS or are still living, autopsy and PVS cases are not analogous.

One letter does explicitly note that basing proxy consent to research on proxy consent to treatment is most apposite when the research is "therapeutic"— when there is direct benefit to participants.⁶⁴ The letter nevertheless suggests that more could conceivably be allowed if the intervention is in the subject's best interests, or even in the placebo context when the risk is small and the potential benefit great.

Another question is what happens if there is no family-proxy in the treatment or other relevant context? In one letter, a law provides for proxy consent by the guardian, DPA, or other "legal authority."⁶⁵ In two other letters, the investigators say—and the OHRP agrees—that Pennsylvania law permits a "legally responsible person" to give proxy consent, although this person is nowhere defined.⁶⁶ Conversely, in a letter to researchers at Vanderbilt, the OHRP

61. Letter from Office for Human Research Prot. to Gerald Litwack, Assoc. Dean for Scientific Affairs, Thomas Jefferson Univ., (Jan. 30, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jan02m.pdf.

62. Id.

63. Letter from Office for Human Research Prot. to Lee E. Limbird, Assoc. Vice Chancellor for Research, Vanderbilt Univ., (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02h.pdf.

64. Letter from Office for Human Research Prot. to Donald E. Wilson, supra note 57.

65. Letter from Office for Human Research Prot. to John R. Sladek, Jr., Vice Chancellor for Research, Univ. of Colo. (Jan. 31, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jan020.pdf.

66. Letter from Office for Human Research Prot. to Gerald Litwack, Thomas Jefferson Univ. (Jun. 10, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jun02a.pdf; Letter from Office for Human Research Prot. to Neal Nathanson, Vice Provost for Research, Univ. of Pa. (Jun. 10, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jun02b.pdf (referring to Letter from Office for Human Research Prot. to Gerald Litwack, *supra* note 61).

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^{60.} See Letter from Office for Human Research Prot. to Donald C. Harrison et al., supra note 59; Letter from Office for Human Research Prot. to Donald C. Harrison et al., Senior Vice President and Provost for Health Affairs, Univ. of Cincinnati (Feb. 5, 2002) (on file with author), available at http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02i.pdf; Letter from Office for Human Research Prot. to Floyd D. Loop, Executive Vice President and Chairman, Cleveland Clinic Found. (Feb. 7, 2002) (on file with author), available at http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02k.pdf.

concludes that there is no non-guardian, non-DPA authority to consent to treatment in Tennessee, and so the same is true of research as well.⁶⁷ Finally, in one correspondence, researchers cite statutes showing that a non-LAR may consent to research in their state and the OHRP explicitly disallows it.⁶⁸ This may be the only kind of case in which the OHRP does not defer to the states on the question of who is an allowable proxy.

In conclusion, the OHRP seems to allow general treatment proxy statutes that permit family consent to serve as authority establishing that family members can also serve as proxies for research. However, it generally does not consider more specific, treatment-focused proxy statutes to provide grounds for proxy consent to research. The interpretive difficulties noted above will need to be worked out to clarify exactly what it is that individuals should infer about proxy consent to research from the general, somewhat ambiguous statutes.

E. Relevant Case Law

Some of the interpretive issues regarding who should be deemed a proxy decision-maker in the research context could be answered by case law. In deciding cases about DPAs, courts may have interpreted the relevant federal and state statutes and articulated their own views about who should be allowed to provide proxy consent. A review of the case law, however, uncovered only two cases that deal explicitly with proxy decision-making in the research context, and only one of these cases involved adult subjects. In each, the court assumed that family may give proxy consent. The issue they addressed was whether family can consent to a particular kind of research. We address this issue both positively and normatively in our discussion Section below.

The first case, *T.D. v. N.Y. State Office of Mental Health*,⁶⁹ occurred in the mental health context. The plaintiffs included six involuntarily committed psychiatric patients who were deemed incapable of giving or withholding informed consent and were fearful that they would be entered into research protocols by proxies. The state regulations, discussed in two decisions by the appellate division, contained provisions regarding volunteering incapable subjects to participate in research, including "more than a minimal risk' nontherapeutic and possibly therapeutic experiments."⁷⁰ These studies involved

^{67.} Letter from Office for Human Research Prot. to Lee E. Limbard, Assoc. Vice Chancellor for Research, Vanderbilt Univ. (Jun. 26, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jun02e.pdf.

^{68.} Letter from Office for Human Research Prot. to John S. T. Gallagher, President, North Shore Univ. Hospital (Jan. 14, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jan02f.pdf.

^{69. 690} N.E.2d 1259, 1260 (N.Y. 1997).

^{70.} T.D. v. N.Y. State Office of Mental Health, 228 A.D.2d 95, 97 (N.Y. App. Div. 1996); see

approved and experimental antipsychotic and psychotropic drugs, "which are capable of causing permanent harmful or even fatal side effects and/or highly invasive painful testing procedures."⁷¹ Several involved a "medication-free or placebo phase in which subjects, who are being successfully treated with approved drugs, are taken off the medication for a period of time before the experimental medication is introduced, during which time they may relapse and suffer the adverse symptoms of their particular illnesses or disorders."⁷²

The decision of the state's highest court contains some ambiguities, but does say that that the regulations were promulgated beyond the authority of the Office of Mental Health because that authority was exclusively granted to another agency. The court went on to say that the regulations violated the state's constitutional and common law as well as the Federal Constitution.⁷³ The opinion is far-ranging and introduced concerns about the lack of notice and review of capacity decisions and surrogate decisions. It seemed to express concerns about the entire idea of this kind of research being decided by a proxy. And it plainly affirmed the court below.

The appellate division explicitly set forth a proxy consent standard. It held that:

When the proposed medical course does not involve an emergency and is not for the purpose of bettering the patient's condition, or ending suffering, it may be doubtful if a surrogate decisionmaker—a guardian, a committee, a healthcare proxy holder, a relative, or even a parent could properly give consent to permitting a ward to be used in experimental research with no prospect of direct therapeutic benefit to the patient himself.⁷⁴

The second case, *Grimes v. Kennedy Krieger Institute*, involved a lead abatement intervention study, with parents consenting on behalf of their children.⁷⁵ This case is outside the scope of our review because the holding was limited to children. However, it should be noted that, in deciding the case, the court cited the exact language used in the *T.D.* case.⁷⁶

Cases addressing proxy consent outside the research context mostly fall into two categories. The first category consists of cases involving life-sustaining or

also T.D. v. N.Y. State Office of Mental Health, 626 N.Y.S.2d 1015, 1020 (N.Y. App. Div. 1995).

^{71.} T.D., 228 A.D.2d at 97-98.

^{72.} Id. at 98.

^{73.} The Court of Appeals offered the view that the appellate court should not have gone beyond the holding about the regulatory body's authority, but dismissed the appeal because this argument was not actually made by the defendants. *See* T.D., 690 N.E.2d at 1260.

^{74.} T.D., 626 N.Y.S.2d at 1020.

^{75. 782} A.2d 807 (Md. 2001).

^{76.} Id. at 855-56.

life-saving treatment.⁷⁷ The second category consists of mental health cases, e.g., civil commitment, conditional release, refusal of medication, and refusal of electroconvulsive therapy.⁷⁸ There are also cases in the context of emergency care,⁷⁹ nursing homes,⁸⁰ kidney donation,⁸¹ sterilization,⁸² and abortion.⁸³ Other specific issues discussed in these cases are the standard of proof,⁸⁴ and whether a public agency can refuse to be appointed a guardian in certain cases.⁸⁵ None of these cases discuss whether it is legitimate to look at the existence of proxy consent in other contexts when attempting to make decisions about proxy consent in the rcsearch context.

Indeed, many of the interpretive questions regarding the statutes, such as

78. See, e.g., Myers v. Alaska Psychiatric Inst., 138 P.3d 238 (Alaska 2006); Von Luce v. Rankin, 588 S.W.2d 445 (Ark. 1979); In re L.H.R., 321 S.E.2d 716 (Ga. 1984); Harada v. Hatsuye T. (In re Hatsuye T.), 689 N.E.2d 248 (Ill. App. Ct. 1997); In re Boyle, 674 A.2d 912 (Me. 1996); Cohen v. Bolduc, 760 N.E.2d 714 (Mass. 2002); In re Foster, 547 N.W.2d 81 (Minn. 1996); In re Welch, 686 N.W.2d 54 (Minn. Ct. App. 2004); In re A.A., 885 A.2d 974 (N.J. Super. Ct. Ch. Div. 2005); Sanders v. N.M. Health & Env't Dep't (In re Sanders), 773 P.2d 1241 (N.M. Ct. App. 1989); In re S.A., 582 A.2d 137 (Vt. 1990).

79. See, e.g., Stafford v. La. State Univ., 448 So. 2d 852 (La. Ct. App. 1984); Miller v. R.I. Hosp., 625 A.2d 778 (R.I. 1993).

80. See, e.g., Rains v. Belshé, 38 Cal. Rptr. 2d 185 (App. 1995).

81. See, e.g., Hart v. Brown, 289 A.2d 386 (Conn. Super. Ct. 1972); Little v. Little, 576 S.W.2d 493 (Tex. Ct. App. 1979); Lausier v. Pescinski (*In re* Pescinski), 226 N.W.2d 180 (Wis. 1975).

82. See, e.g., Wirsing v. Mich. Prot. & Advocacy Serv. (In re Wirsing), 542 N.W.2d 594 (Mich. Ct. App. 1995); In re Grady, 405 A.2d 851(N.J. Super. Ct. Ch. Div. 1979).

83. See, e.g., In re Doe, 533 A.2d 523 (R.I. 1987).

84. See, e.g., Sabrosky v. Denver Dep't of Soc. Serv., 781 P.2d 106 (Colo. Ct. App. 1989).

85. See, e.g., In re D.A., 100 P.3d 650 (Mont. 2004).

^{77.} See, e.g., Rasmussen v. Fleming, 741 P.2d 674 (Ariz. 1987); Dep't of Insts., Grand Junction Reg'l Ctr. v. Carothers, 821 P.2d 891 (Colo. Ct. App. 1991); *In re* Tavel, 661 A.2d 1061 (Del. 1995); *In re* Gordy, 658 A.2d 613 (Del. Ch. 1994); *In re* Browning, 568 So. 2d 4 (Fla. 1990); *In re* L.H.R., 321 S.E.2d 716 (Ga. 1984); *In re* Lawrance, 579 N.E.2d 32 (Ind. 1991); Woods v. Commonwealth, 142 S.W.3d 24 (Ky. 2004); DeGrella v. Elston, 858 S.W.2d 698 (Ky. 1993); *In re* Doe, 583 N.E.2d 1263 (Mass. 1992); Rosebush v. Oakland County Prosecutor (*In re* Rosebush), 491 N.W.2d 633 (Mich. Ct. App. 1992); *In re* Torres, 357 N.W.2d 332 (Minn. 1984); Murphy v. Wheeler (*In re* Warren), 858 S.W.2d 263 (Mo. Ct. App. 1993); Jason S. v. Valley Hosp. Med. Ctr. (*In re* L.S.), 87 P.3d 521 (Nev. 2004); *In re* Conroy, 486 A.2d 1209 (N.J. 1985); *In re* AB, 768 N.Y.S.2d 256 (Sup. Ct. 2003); *In re* Univ. Hosp. of the State Univ. of N.Y. Upstate Med. Univ., 754 N.Y.S.2d 153 (Sup. Ct. 2002); *In re* Grant, 747 P.2d 445 (Wash. 1987); *In re* Hamlin, 689 P.2d 1372 (Wash. 1984); Belcher v. Charleston Area Med. Ctr., 422 S.E.2d 827 (W. Va. 1982); Lenz v. Phillips Career Dev. Ctr. (*In re* L.W.), 482 N.W.2d 60 (Wis. 1992).

whether those authorizing treatment proxies also authorize research proxies, are not resolved by court decisions. They simply do not address this question. In fact, the cases themselves ask these questions regarding the statutes. Hence, the force of treatment proxies as exemplars of proxies in the research context remains unclear in the cases no less than the statutes.⁸⁶

F. Limitations on Proxy Decision-making in the Research Context

We have discussed whether proxies are allowed and who may serve as proxies. Another important question remains: Are there any limits on proxy decision-making in the research context? We briefly noted limitations built into various statutes regarding research and we have identified some general limitations on proxy decision-making in Table 3. Our more extensive description of the California and Virginia laws showed different approaches to this question, and the *T.D.* case suggested a bar on proxy consent for no-direct-benefit research.

In this section we focus on statutory provisions that prescribe limits on what research proxies may decide. The only two family proxy statutes that put limits on proxy consent are California and Virginia.⁸⁷ Only seven other states (in eight different statutory sections) prescribe limits on guardian decision-making, court decision-making, or authorization of guardian decision-making.⁸⁸ A number of jurisdictions allow proxy consent only if, among other things, the intervention is intended to preserve the life of or prevent serious impairment or injury to the subject. There are additional requirements in these states too, as well as alternate ways to obtain consent. In Alaska, for example, the intervention must also not involve significant risk of physical or psychological harm.⁸⁹ In Connecticut, a guardian may consent if the intervention is intended to preserve the life of or prevent serious impairment to the ward (the statute also provides other routes, e.g., approval by an IRB); the ward's primary care physician approves; and the ward is developmentally disabled. For court approval in Connecticut for the developmentally disabled, the standard is not "preserving life, etc.," but the procedure must be "intended to assist the ward to regain the ward's abilities."90 In Florida and Nevada, a court may permit a guardian to consent if the intervention is "of direct benefit to, and intended to preserve the life of or prevent serious impairment to the physical or mental health of the ward; or it is intended

^{86.} We do not catalog the treatment proxy cases simply in the interests of space. In essence, the same arguments we make in the statutory context would apply in the case context. And since most states have some treatment proxy statute, those states also having cases on treatment proxies does not appreciably clarify our question.

^{87.} See Table I.

^{88.} Id.

^{89.} Id.

^{90.} Conn. Gen. Stat. § 45a-677 (Supp. 2007).

to assist the ward to develop or regain his abilities." In New Jersey, the experiment must be necessary and directly related to the goals of treatment. In North Dakota, no hazardous or intrusive experimental research is allowed unless it is directly related to specific goals of a person's treatment program.⁹¹

In short, the limitations imposed on proxy decision-makers encompass a number of requirements that are put together differently in the different jurisdictions. The three key standards are:

(1) intended to preserve the life of or prevent significant injury/impairment to the physical or mental health of the ward;

(2) intended to assist the ward to develop or regain his or her abilities; and

(3) directly related to the goals of treatment.

Additional requirements are imposed in some states. For instance, some states have rules stating that an intervention cannot be done if it involves significant risk of physical or psychological harm or that interventions must be of direct benefit to the participant. It is important to note, however, that most jurisdictions do not give a standard that applies uniquely to the research context.

Table 3 shows that there are other standards governing a substituted decision-maker's treatment decisions in different contexts; for example, a standard that permits a proxy to make any decision that a parent could make for his child. In this Article we do not explicitly draw inferences from these other laws for limitations on proxy consent to research. The kind of reasoning from treatment to research that we have applied to the question of who may consent may also be applied to limitations on consent.

IV. DISCUSSION

Because federal regulations have left the issue of proxy consent for research to the states, we planned for this review to be a comprehensive survey of state statutes bearing on that issue. After reviewing all state statutes that may have a bearing on the question of proxy consent for research, we found that there is relatively thin guidance from state statutes. Although nine states theoretically allow family consent for research, the scope and restrictions particular to each state make generalizations impossible, even among those states. Moreover, while there is considerably more state statutory guidance in the treatment context, it is far from clear how such statutes might be used to justify proxy consent for research. Considering that many states lack even de facto surrogate consent laws

^{91.} See Table 1.

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for treatment contexts, the issues become even murkier.

In considering how we might attempt to clarify this complex matter, at least three key questions arise: first, whether proxy consent for research is permitted at all; second, who may serve as proxies; and third, what kinds of research may they consent to—i.e., should there be limitations on what proxies may decide on behalf of another person? In this Part's first Section we interpret what is currently allowed as a matter of positive law, and in the second Section we discuss what type of regulation would be optimal.

A. The Positive Side of the Law

1. Is Proxy Research Permitted?

The first issue is to what extent proxy consent for research is currently allowed by the law. While the Nuremberg Opinion did not seem to allow proxy consent, it may be that the issue simply was not contemplated at the time it was written. The horrors of Nazi research were perpetrated on people who were decisionally capable. Later ethics documents allowed proxy consent. The federal regulations concerning research allow any Legally Authorized Representative to give proxy consent. This, of course, does not answer the question as to whether proxy consent is allowed in any given state. Instead, each state is expected to provide the answer for its particular jurisdiction.

Our survey of the states addresses whether the states allow proxy consent for research at all. Twenty-seven states explicitly allow at least some type of proxy consent for research. But what about the states that do not explicitly mention proxy decisions for research? A statute that is silent on this point could be read as not permitting proxies to agree to research, on the ground that being placed into a study is unlike any other medical decision made on a patient's behalf. On the other hand, instead of implicit prohibition, silence may mean that the legislature simply regarded research as analogous to other medical contexts, so proxies have the authority to consent, at least to research that does not involve major risks (most treatment decisions that proxies will be authorized to make will not involve major risks, or their benefits will offset their risks). It is worth remembering that OHRP allows analogizing from the treatment to the research context, and all states allow proxy consent for treatment. Still, because OHRP seems to require a positive reference to state or local law defining LAR, an absence of relevant laws (e.g., family surrogate treatment laws), from the federal perspective, may mean that that kind of surrogate-based research is not allowed in those states.

If a court wants to address this issue as a matter of state law, one place it should look for guidance is to prohibitions on proxy consent to treatment in a particular jurisdiction. For instance, some jurisdictions prohibit proxy consent for certain types of irreversible sterilization or psychosurgery. Such constraints make

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two kinds of argument possible. First, one could argue that it is also impermissible for proxies to consent to these particular interventions in the research context. Second, and more interestingly, one could argue that these limitations on proxy consent in the treatment context may support analogies to the research context. Is consent to research more like consent to sterilization or consent to another kind of surgery? Is a research protocol more like a mental health treatment to which a proxy may consent, or one such as psychosurgery, to which some proxies may not consent? Considered in these terms, one clearly relevant factor is the seriousness of the research intervention.

Another possible approach that jurisdictions that do not have relevant statutes could take is to ask whether research decisions fall into one of the general kinds of decisions proxies are empowered to make. For instance, does "any medical intervention" include research? Does "any decision a parent could make for his child" include research? Certainly, "any decisions the patient could have made for himself" would seem to include decisions authorizing participation in research. The point is that when a state gives a general categorization of kinds of decisions proxies may make, that implies that a proxy may make them. Indeed, giving the general categorization only makes sense on the theory that a proxy will decide, so these laws necessarily envision proxy consent. So, if a decision is in one of the general categories (e.g., "any medical decision the subject could make"), then a proxy decision-maker may be appointed to make that decision. Still, there is often no direct statement about who may serve as that proxy. Moreover, asking whether research is a "medical decision" simply repeats our initial question.

The examples listed in Table 3, Column 4 are even less helpful. Requiring decisions based on substituted judgment or best interests seems to countenance proxy decisions, but doing so does not determine who may serve as proxies or when proxies should be allowed to decide issues—e.g., can they consent to a particular course of research for a particular patient? That a proxy may make a decision, say, in your best interests, surely does not mean that he can decide for you *anything* that is in your best interests. For example, can one make her incompetent nephew travel to Timbuktu because she determines that it is in his best interests? Within a health care context, allowing or requiring decisions of certain kinds (e.g., "best interests," "substituted judgment") seems to countenance research that meets those standards. But a number of assumptions are necessary for these statutes to be understood as authorizing proxy consent, and the statutes are even less helpful in authorizing particular kinds of decisions made by proxy decision-makers.

Hence many state statutes seem to countenance proxy consent but sometimes do not state, first, whether specific types of research fall into the general categories within which proxies are authorized to make decisions, and, second, who is an allowable proxy. As we saw earlier, the "prohibiting" statutes may be clearer because they put specific limits on proxy consent to research.

Positively, then, it would seem that many places do allow consent to research by certain kinds of proxy. We also believe that—while non-appointed, non-court proxies are the most important—most jurisdictions, if push came to shove, would allow a court itself to make many proxy decisions, even if provision for this were not made explicitly in the statutes. Consider that proxy consent to research is sometimes in the best interests of a person; if the person cannot make the decision herself, it seems that *someone* must be authorized to decide. Of course, the federal regulations seem to contemplate that some entity has the power to decide—namely, whomever the states designate as LARs. Since courts are widely perceived as the optimal default decision-makers, it is hard to imagine that a court would not be allowed to make proxy decisions.

2. Who Can Serve as Proxies?

Our second question—targeted at those jurisdictions that allow proxy consent to research—involves what categories of individuals are allowed to be proxies for research decisions, and in what order of priority these categories of individuals stand. Again, we are most interested in informal proxies and, in particular, families. Many statutes are silent on this issue. As in the case of whether to allow proxies at all, one may read this silence in different ways: One may think the statutes forbid informal proxies to decide or that they allow any plausible proxy to decide. An intermediate position is to look again at other contexts, and to allow informal research proxies in some situations, but not others.

In any event, we should be clear that a statute mentioning one kind of proxy need not be read, at least in certain circumstances, as forbidding others that are not mentioned. Failure to mention family may not be decisive. A statute listing all the decisions a guardian may make does not necessarily imply that no one other than a guardian may make them (e.g., that a guardian may consent to antibiotics for her developmentally disabled ward does not mean that family members may not make this decision). Of course, if a statute says that *only* guardians may decide certain things; or if a fair reading of the guardianship statute is that guardians will be the exclusive decision-makers in a given context; or if a given statute purports to list *all* permissible research proxies, then such statutes may indeed exclude informal proxies. Determining the specific implications of each rule must be done on a state-by-state basis.

Also, we may draw inferences from proxy laws in contexts other than research. As a matter of positive law, it is of interest that all but sixteen states allow families to give proxy consent to treatment in general or to certain treatments in particular (although the latter may be too specific to be taken as precedents here). Again, the OHRP does rely on treatment proxies to argue for

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the permissibility of family research proxies. On the other hand, one may see the "glass-half-empty" here too: In at least sixteen states there is *no* basis for using a reference to family proxies in the treatment context to justify using them in the research context. There are also the "general categorizations" statutes that provide a basis for arguing in favor of family proxies, but again, though they may entitle us to countenance proxy decisions to research, these statutes explicitly limit the ability of the proxy to give consent.

Our principal question, however, is whether, as a result of statutory interpretation, we *should* take the existence of family proxies in the treatment context to mean that family proxies are also allowable in the research context. Again, there are arguments on both sides. Some arguments in favor of the broad interpretation are the following: First, many of the interventions in the research context are also found in routine medical care. If proxies are allowable in the latter context, then they should also be allowed in the former. At least in some cases, it seems unlikely that the interventions will be particularly dangerous. Second, if the research is potentially helpful, then it may be in the subject's best interests to enroll in the program. In this sense, a proxy research decision is very similar to a proxy treatment decision. Finally, proxies are allowed to decide upon treatments that are very risky, if the potential benefit compensates for the risk. Many research decisions are less risky than some of these decisions.

There are also considerations in favor of a more conservative approach. The fact that an intervention is allowed in the treatment context does not mean that it is or should be allowable in the research context. For instance, as we noted, the risk/benefit ratio for a procedure like a spinal tap is very different in the treatment than the no-direct-benefit research context. Second, one might argue that research should not be conceived as being in individual subjects' best interests in the way that clinical treatment aims to be. Research is not primarily designed to meet an individual patient's needs, whereas treatment is. To conceive of the research as a treatment designed for a particular patient would be a "therapeutic misconception."⁹² Finally, the rare treatment decisions that are extremely risky may justify only some research decisions at best; in addition, in really rare high-risk cases, it already is often the case that some formal decision-maker is called upon to review the proxy decision.

Perhaps the answer is to suggest again that family proxy consent to research be allowed in the case of some research—e.g., research that is most like treatment—and be prohibited in others. That is, we need not say either that

^{92.} See generally Paul S. Appelbaum et al., False Hopes and Best Data: Consent to Research and the Therapeutic Misconception, 17 HASTINGS CENTER REP. 20 (1987); Paul S. Appelbaum et al., The Therapeutic Misconception: Informed Consent in Psychiatric Research, 5 INT'L J.L. & PSYCHIATRY 319 (1982); Charles W. Lidz & Paul S. Appelbaum, The Therapeutic Misconception: Problems and Solutions, 40 MED. CARE V55 (2002).

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family proxy consent to research is allowed or that it is not allowed depending solely on whether there is a proxy treatment statute. Other considerations may be important, such as whether the research is like treatment in some significant way. Again, though, it may make sense to be more expansive than this: One may read silence as a complicit way of allowing inferences to be drawn from statutes allowing treatment proxies to the research proxy context.

3. What Are the Limits on Proxy Consent?

The third question in our positive discussion concerns when a proxy is authorized to consent.⁹³ That is, if a proxy is authorized to decide, can he decide "yes" to *this particular* piece of research? Only nine states speak directly to this question in their research statutes and only one court has addressed this issue directly. Earlier, we noted the different positions that the states took. When a state does not speak to the issue of when proxy consent can be given in its research statutes, then one can reach a variety of different conclusions about which standard governs the proxy's decision-making ability: One could assume that the broadest standard in such cases applies—the substituted judgment of the patient, or, if that is not known, her best interests; one could infer that the general standard used in the treatment context also applies in the research context (e.g., that one may decide as a parent may decide for his or her child); or one could look at specific, analogous treatment contexts and argue that the standard from those situations should apply to the current one.

There are a number of considerations, of course, that will feed into a decision about the appropriateness of proxy consent to different kinds of research. These include the risks of the research intervention, the degree of the patient's incapacity, the ability to ascertain the patient's competent wishes, the likely benefit to the patient, the absence of other promising non-research interventions that will offer similar benefits, as well as other considerations. Below we address the normative question of whether we should limit proxy choices, and, if so, how.

It will be clear that our three questions interact in a variety of ways. To say that proxy consent should be allowed does not say when it should and should not be allowed. And empowering proxies to make decisions does not say which proxies should be making decisions, or when they should have this power. We may want more protective proxy policies under certain circumstances, e.g., when the risks inherent in a research program are high. However, it is only by thinking about each of these three questions that one can arrive at a comprehensive statute.

^{93.} See Diane E. Hoffman & Jack Schwartz, Proxy Consents to Participation of the Decisionally Impaired in Medical Research-Maryland's Policy Initiative, 1 J. HEALTH CARE L. & POL'Y 123 (1998).

B. The Normative Side of the Law

Thus far this Article has looked at the positive law that exists addressing questions related to the permissibility of proxy consent to research. We have examined explicit laws regarding proxy consent to research and we have asked whether we may infer a legal position on its legality based on how states have dealt with proxy consent issues in other contexts.

We now turn to the normative dimension of our three questions. Specifically, we look at the following: First, should proxy consent to research be allowed? Second, who should be designated to serve as proxies and in what order? Third, under what conditions should proxies decide "yes" to proposed research?⁹⁴

One important note before we begin: Our positive law interpretation and normative discussion interact in important ways. Our answers to the normative questions may provide reasons to interpret positive law in particular ways. If it is right or better that X, then perhaps we should interpret a law to mean X when such an interpretation is plausible. It is also the case that the inferences can go in reverse: if there is a lot of positive law that X, then there may be a societal consensus that X is right or good.⁹⁵

1. Should Proxy Research Be Permitted?

The first normative question is whether we should allow proxy consent for research at all. We think the answer is a clear "yes." More than half of the states explicitly allow proxy consent to research of some kind and all states have some kind of treatment proxies. The widespread existence of proxy consent—both as a

^{94.} For discussion of the normative issues, see Jessica Wilen Berg, Legal and Ethical Complexities of Consent with Cognitively Impaired Research Subjects: Proposed Guidelines, 24 J. L. MED. & ETHICS 18 (2001); Richard J. Bonnie, Research with Cognitively Impaired Subjects: Unfinished Business in the Regulation of Human Research, 54 ARCHIVES GEN. PSYCHIATRY 105 (1997); Dallas M. High, Advancing Research with Alzheimer Disease Subjects: Investigators' Perceptions and Ethical Issues, 7 ALZHEIMER DISEASE & ASSOCIATED DISORDERS 165 (1993); Dallas M. High et al., Guidelines for Addressing Ethical and Legal Issues in Alzheimer Disease Research: A Position Paper, 8 ALZHEIMER DISEASE & ASSOCIATED DISORDERS 66 (1994); Kim et al., supra note 15; Henry J. Silverman et al., Protecting Subjects with Decisional Impairment in Research: The Need for a Multifaceted Approach, 169 AM. J. RESPIRATORY & CRITICAL CARE MED. 10 (2004); Dave Wendler et al., Views of Potential Subjects Toward Proposed Regulations for Clinical Research with Adults Unable to Consent, 159 AM. J. PSYCHIATRY 585 (2002).

^{95.} An example of the latter type of reasoning occurs in the "cruel and unusual punishment" context, which turns on prevailing norms of decency. For example, the Supreme Court took there to be a consensus that executing people with mental retardation was wrong because most states had passed statutes forbidding it. *See* Atkins v. Virginia, 536 U.S. 304, 313-16 (2002).

matter of law and of practice—may be evidence that there is a societal consensus that proxy consent is a permissible and desirable phenomenon.

This position can also be justified normatively. While forbidding research on the decisionally incapable would ensure that we would not exploit vulnerable persons, such a prohibition would have unfortunate consequences. Most importantly, in cases where the only way to learn about an illness that affects the decisionally impaired is to study decisionally impaired people, a ban against such research would mean that we could never learn about the illness. For example, studying severe dementia requires researchers to enroll the severely demented a group who are inherently a class of decisionally impaired people. Or consider people with particular kinds of late-stage cancer who are necessarily decisionally impaired (e.g., patients suffering from late-stage brain cancer); we can only study their condition by enrolling decisionally impaired people in research.

Certainly there are limits to this kind of consequentialist argument. Some studies may provide too little potential benefit to subjects while placing them at significant risk; these studies should not be done even if they are the only feasible way to research a condition. But to forbid *all* research with decisionally impaired people would sweep so broadly that it could cripple research into certain illnesses.

In addition, one can imagine many cases of research with decisionally impaired people that would not be controversial to most people. Take the case, for example, of a person giving an advance directive consenting to a particular research study, prior to becoming decisionally impaired. Assume that the study involves known procedures and risks that have not changed over time and that the subject clearly understood when giving the advance consent. Or take the case of a study with substantial potential benefit and very limited risk. If we forbid all research consented to by proxies, we prevent studies that most people would think are perfectly acceptable. Finally, there are justice concerns in the sense that we deprive the group of decisionally impaired patients of the possible benefits of research, which they may be unable to get in any other way.

There are three possible answers to the question of whether we should allow proxy consent for research at all. The first is to forbid it altogether. The second is to allow it potentially in all research decisions. And the third is to acknowledge limits on proxy decision-making by only allowing it in some cases. We will begin by discussing the first of these options, leaving our discussion of the second and third options to the following section on proxy decision-making.

There are contexts in which we flat-out forbid proxy consent. For example, we do not let guardians volunteer their wards to be married. On the other hand, the rationale in these cases is probably that the decision is too personal for someone else to make, ought to involve understanding on the ward's part, and is not essential. For example, a guardian's belief that a marriage would be in someone's interest should certainly not trump what the person *wants*, no matter

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whether the person is competent. Even if the guardian and the person agree about the marriage, we may require a competent choice by the person himself to enter into a marriage. Additionally, a marriage decision is also clearly optional in a way that some medical decisions are not.

There are other examples of this kind of flat-out ban on someone else deciding something for her ward. For instance, a guardian or other proxy cannot write a will for a person, nor can he volunteer his incompetent ward to engage in a boxing contest. Rules with parents are even stricter—e.g., a parent cannot volunteer his child to work when the child is underage. Each example has its own complexities, but each shows that there are some things guardians and proxies are simply forbidden to decide.

Research choices, however, are more like medical choices and less like choices to marry. Research choices are less personal, and they involve the *kind* of decisions that proxies already make all the time in the medical arena. In addition, the subject's competency is not crucial in research—you need to understand what you are doing when you get married for the marriage to have meaning, but such understanding is not necessary when a doctor gives you medicine or performs surgery. Finally, some research decisions are not optional, so to speak: for example, a research study that is a subject's only hope for treatment may be one where we want *someone* to make the decision. That is, the decision is not optional in the same way a decision to marry is, and not deciding in this situation becomes a de facto decision to exclude the person from the study.

Normatively, then, the answer to the question of whether we should have proxy consent to research at all seems to be yes. Entirely eliminating proxy research appears to be quite an undesirable option. If all research involving people who are incompetent to decide for themselves is disallowed, then we exclude a whole population from the advantages of research and research participation, and we severely curtail research advances for their conditions. Moreover, such a ban would preclude people from altruistically consenting to research. Finally, such a rule would frustrate the desires of individuals who may have wanted to participate in this research, and who might have even expressed this clearly in an advance directive.

2. Who Should Serve as Proxies?

Our second normative question is who should be allowed to serve as proxies and in what order we should designate potential proxies. As with the question of whether there should be proxy consent to research at all, the existence of family proxy statutes, together with the widespread practice of family consent in the treatment context, suggests that there is a broad, societally sanctioned consensus that proxy consent is permissible and appropriate for the research context as well as for treatment. As a normative matter, then, we argue that family proxies should be allowed in the research context. A guardian or court need not be involved. Families generally know their family members best and care about them most. And, unlike in the context, say, of psychiatric treatment for unwilling patients—where we might not want to pit family member against family member—in the research context the patient must agree to the intervention. Hence, we believe that families should be considered LARs for purposes of the law in this arena.

Indeed, family proxies in the research context may be less problematic at times than those in the treatment context. In the research context there will *always* be a thorough committee review of the decision, unlike in the treatment context where the proxy's will gets implemented without further review. Further, in the research context an IRB exists to ensure that the risk/benefit ratio of the research is favorable, that the investigators have considered every possible safeguard for subjects, and that other requirements have been fulfilled.

When there is more than one person available to serve as a proxy, (e.g., a named person who has a DPA for research decision-making, a DPA for treatment, and a family member), then who should serve as the proxy? If there is a DPA for research, this is a relatively easy case: if a person, while competent, chooses a particular person to make decisions for her, and if that selection included decisions in the research context, there is good reason to accept that proxy's decisions. In these cases, the potential subject herself has selected a particular person and asked us to respect that proxy's judgment in the research context. Each potential subject should know best whom to trust with these decisions. If a DPA for research has been selected, that proxy's judgment should have first priority.

A DPA for treatment should be recognized next. Again, the potential subject has personally pre-authorized a trusted person to look after her medical needs. Some research implicates the medical interests of its subjects. Even when it offers no prospect of direct benefit, it may have the same degree of consequentiality as certain medical decisions. Finally, the subject has endorsed the DPA as someone who can be trusted to best discern her wishes and interests.

Whether a guardian or an informal family proxy should be next in line is a vexing question. One solution is that family proxies should come first. They are likely the most available, know the potential subject better, and care deeply about him or her. On the other hand, what should we make of the fact that family members, if there is a guardian available, are not the guardians themselves? One might think that if they truly cared about the potential subject, they would have volunteered or been chosen to be a guardian. There are arguments on the other side, however. First, if the guardian is a guardian of the estate, family members may have declined to participate because they were not competent to make financial decisions. Indeed, it seems like we might prefer family proxies to guardians of the estate whenever the latter have been chosen for their financial

expertise, as that base of knowledge is not inherently salient to research decisions. Second, even if the guardian is a guardian of the person, family members may not have volunteered because of the time-intensive nature of looking after that person. But this does not mean that these family members do not still care for the potential subject, and they may still want to be consulted about important decisions.

Even if we accept that a person's refusal to volunteer to be a guardian does not rule that person out as a proxy, we still must ask who is the most likely to be the best decision-maker in the research context. Guardians have a fiduciary duty to make the best choice for their wards. But in certain circumstances, family proxies may also bear a similar duty, even if it is not as plain as in the case of a guardian.⁹⁶ Guardians may be more impartial, as a non-guardian family member's own interests may be more involved in the ward's outcome. For instance, family members are likely to benefit more if the research helps the subject. Or, more pessimistically, a family member may be concerned about receiving the potential subject's inheritance. It is not difficult to imagine a case where an adult child of a person with Alzheimer's disease might not be very concerned about his parent's well-being, but may be concerned about the depletion of his inheritance due to the costs of care for his parent. On the other hand, it seems wrong to presume that family members will not try to make the very best decision for the ward; as much as their own interests are implicated in treatment decisions, they probably care about the ward more than a non-family guardian. Finally, regarding "knowledge of the ward," it would seem that family members typically have the upper hand over a fiduciary guardian who is not bound by familial ties. But, then again, because they lack intimate knowledge of the ward, a non-family guardian may make more efforts-do more "due diligence"-to find out what the ward would have wanted and what would be best for him.

Given all of these considerations, we believe the following would be the best protocol. If a family member is the guardian, the researcher should go to him or her (assuming no DPA exists). If not, we should look at the treatment proxy laws to determine who should come next. If most treatment proxy statutes put guardians before families, for example, we would follow this, but would allow one exception: when the guardian is very hard to find—if it will take

^{96.} See, e.g., 37 C.J.S. Fraud § 6 (2007) (stating that a fiduciary is "a person, having a duty ... to act primarily for another's benefit," and that "the primary question" in determining whether a fiduciary relationship exists in a family "is whether one family member has dominion over the other family member in regard to the transaction involved"); Tamar Frankel, *Fiduciary Law*, 71 CAL. L. REV. 795, 808 (1983) (stating that when a parent "substitutes for a child who is unable to take care of himself," this substitution "fall[s] into a status category but is not automatically fiduciary"); Elizabeth S. Scott & Robert E. Scott, *Parents as Fiduciaries*, 81 VA. L. REV. 2401, 2401-03 (1995) (characterizing parents as fiduciaries of their children, but acknowledging that the parent-child relationship differs from most traditional fiduciary relationships).

considerable effort to find and consult her—family members should be permitted to serve as proxies.

Our main point is that family should be allowed to serve as proxies. In what order they should be consulted is a difficult question. We believe that DPAs should come first, but that whether family or guardians should come next remains open to debate. It also seems important to collect empirical evidence about what is actually happening—e.g., the frequency of each kind of proxy actually being consulted in the context of research projects. This could help give a sense of what the societal consensus is about who may serve as proxies and in what order.

3. What Should Be the Limits on Proxy Consent?

The third normative question concerns when proxies should be able to consent. There are two general positions one can take on this issue. First, IRBs now struggle with the task of making sure that research with decisionally incapable people (indeed, all research) has a favorable risk/benefit ratio—that the risks are justified by the potential benefit. In weighing these factors, IRBs may take into account the potential benefits to society that the research may provide. Once an IRB has made an initial positive determination, a proxy may volunteer his ward for the research provided it meets some general standard that applies to all proxy decisions—e.g., that the intervention is what the person would have wanted if competent, or is in the person's best interests (not necessarily best medical interests), or some combination thereof.

The second position would be to argue that IRBs and proxies must apply a standard above and beyond the substituted judgment and best interests standards. That is, the first position is that IRBs and proxies are given no standard in addition to a general risk/benefit inquiry and best interests/substituted judgment standard in order to decide; and the second position is that their decision must meet some further specified standard.

It is important to note one complication that exists with any standard that is used—proxies generally do not seem to know how to apply them. For instance, proxies—even when given a substituted-judgment-if-known standard—appear to use a combined standard of substituted judgment and best interests.⁹⁷ Laws specifying *how* proxies *should* make decisions may be pointless because there is no way to ensure that this is what is happening and it seems idealized, based on the fairly limited evidence we have on how proxies make decisions. On the other

^{97.} See, e.g., Jason H.T. Karlawish et al., How Do AD Patients and Their Caregivers Decide Whether To Enroll in a Clinical Trial?, 56 NEUROLOGY 789 (2001); Greg A. Sachs et al., Ethical Aspects of Dementia Research: Informed Consent and Proxy Consent, 42 CLINICAL RES. 403 (1994).

hand, a similar point in an analogous situation has not led us to abandon our legal standards. We do not use the fact that juries seem often to make insanity determinations based on how deranged the person seemed, rather than whether he met the criteria for the insanity defenses to recommend that we jettison the criteria for insanity.⁹⁸ It may be that the standard binds discretion in some ways. And we do not want people to think that they should feel free to ignore the interests protected by the legal standard and to make arbitrary decisions concerning their wards. Indeed, perhaps the combined standard that people seem to use in this context is a result of proxies *trying* to apply the legal standard. If they just decided however they wished, we might get worse quality decisions than we currently have. In short, there may be good reasons to articulate a proxy decision-making standard even if it does not seem as though proxy decision-makers are conscientiously applying it.

Again, the second possibility is to propose a standard for what research should be allowed. We discussed a number of suggestions regarding potential standards earlier. The three key standards mentioned were: intended to preserve life or prevent significant injury/impairment to the physical or mental health of the ward; intended to assist the ward to develop or regain his or her abilities; and directly related to the goals of treatment. Additional requirements have been imposed in some states. For instance, a ban on interventions that involve significant risk of physical or psychological harm, or a requirement that the research be of direct benefit to the participant.

We suggest that, even if we do not follow the first tack, the second should allow more room for research that is not necessarily intended to benefit the subject. We would propose considering a kind of risk/benefit calculation which would allow some no-direct-benefit research. This is in contrast to some of the standards above, which require the possibility of some benefit. In the end, we focus on the hardest case, suggesting that the only risk/benefit ratio that might conceivably be forbidden out of hand—or be presumed to be forbidden—should be very high risk, no-direct-benefit research. If we allow proxy consent in the hardest of cases, it will also obviously be permissible in easier cases when the risk is lower and/or the prospect of benefit greater.

Let us first consider the kinds of interventions with decisionally impaired people that we might want to forbid. Three historical cases serve as examples.⁹⁹

^{98.} For discussion of the literature on how juries make insanity judgments, including original research, see, for example, Norman J. Finkel & Sharon F. Handel, *How Jurors Construe* "Insanity," 13 LAW & HUM. BEHAV. 41 (1989); Jennifer L. Skeem & Stephen L. Golding, Describing Jurors' Personal Conceptions of Insanity and Their Relationship to Case Judgments, 7 PSYCHOL., PUB. POL'Y & L. 561 (2001).

^{99.} These are not exactly on point in that one involves children, the second involves coercion and not capacity, and the third involves kidney donation and not research. Still, they are all

The first is the Willowbrook study.¹⁰⁰ Developmentally disabled patients in a hospital for the mentally retarded were infected with hepatitis to study its natural course in an institutional setting. These were institutionalized people who did not have the capacity to consent to the intervention. They were, then, doubly incapacitated: because of their mental state and because of the coercive nature of institutionalization.

In this case, the experimenters solicited the proxy consent of the patient's parents or family members. However their family members' consent was invalid, as the proxies were under undue influence because their consent was a precondition to admission. This form of coerced consent is uniformly considered to be invalid. It is true that this disease is more of a problem for the institutionalized than it is for people in non-institutionalized communities, so studying the disease course perhaps required having institutionalized participants. However, the developmentally disabled people included in the Willowbrook study were arguably not necessary to the experiment, as other institutionalized individuals would obviously have had a greater capacity to consider the risks and benefits of being a part of the study, and provided their own personal consent. Yet without knowing the details of the study we cannot know if there was something special about the disease that merited a specific focus on people with developmental disabilities. But, even if studying them were "necessary," we may not want such studies done, or at least not in situations where coercive means are used upon proxy decision-makers. In short, this appears to be a case of exploiting vulnerable people. Whether family proxies could consent if given proper understanding and a real choice is at least questionable. In the end, the study has been viewed as a model of mistreatment of the vulnerable in the research context.101

The second example occurs in the *Kaimowitz* case,¹⁰² which concerns experimental psychosurgery on a prisoner who was informed that he was unlikely to be able to leave the institution without the psychosurgery, but that he might be able to leave if it was performed. The court considered the inmate's diminished capacity, as well as the extreme paucity of knowledge about the risks of the procedure. It focused mostly, though, on the coercive nature of the

examples of cases where we might—or perhaps should not be allowed to—subject the ward to the intervention on the basis of a proxy decision.

^{100.} David J. Rothman, Were Tuskegee & Willowbrook 'Studies in Nature'?, 12 Hastings Center Rep. 5, 5-7 (1982).

^{101.} See Chez Josephine v. Columbia Univ., No. 101362-2002, 2004 NY Slip Op 51006U at *8 (N.Y. App. Div. June 29, 2004) (describing the legislative reaction in New York to the Willowbrook experiment); see also ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 70-71 (2d ed. 1988); Rothman, *supra* note 100.

^{102.} Kaimowitz v. Dep't of Mental Health, 13 Crim. L. Rep. (BNA) 2455 (Mich. 1973); see also Alexander D. Brooks, Law, Psychiatry and the Mental Health System 902-24 (1974).

inmate's situation. Most interesting for us, the court held that "although guardian or parental consent may be adequate when arising out of traditional circumstances, it is legally ineffective in the psychosurgery situation. The guardian or parent cannot do that which the patient, absent a guardian, would be legally unable to do."¹⁰³ It is not made clear why proxies may consent when their ward is legally unable to consent in other circumstances—e.g., when they are incompetent to consent to a hernia operation—but may not provide consent here. Still, the bottom line is that there could be no proxy consent to the psychosurgery. The court adverted to the extreme risk and very low possibility of benefit of the psychosurgery as one of the factors in its decision. The fact that this case has more to do with coercion than capacity is unimportant; the important thing is that the court has placed limits on proxies even when the subject him or herself, for whatever reason, could not consent.

The third example does not concern a research study, but is similar in that a medical procedure was done for the benefit of someone else and not for the medical interests of the person undergoing the procedure. In this case, In re Pescinski,¹⁰⁴ a long-institutionalized man with schizophrenia was volunteered by his guardian-sister to be a kidney donor for his other sister. Here, as in no-directbenefit research, the man would be acting in the interests of his sister, as the medical intervention would not advance his interests at all. Of interest in the case is that there were several other family members who, from a medical point of view, were potentially eligible donors. Each of the potential donors, however, had a reason to say no-one was too old, one was too young, one was a farmer with many children, etc. The court decided that the guardian-sister could not volunteer her incompetent brother for the surgery. The case seemed too much like it was a case of "harvesting" the organs of a person who could not consent. While in one sense the risk of the procedure was relatively low-major surgery always carries risks, but complications in kidney donations are uncommon-in another sense the risk was high: if the incompetent brother should have an accident and need another kidney, he could potentially lose his life.

We should also note that in this case, the potential patient did not belong to a class of individuals that would eventually benefit, in a medical sense, from the procedure. The case is most relevant when we think of the possible situations in which proxy consent could be provided for procedures that would harm the patient, but aid third parties. Particularly in the case of kidney donation, the "necessity" requirement is implicated, as many potential kidney donors exist.

These three cases raise the question of the permissibility of proxy consent to research. We should arguably never allow proxy consent to research with these kinds of risk/benefit ratios. In each case the subjects could not consent

^{103.} BROOKS, supra note 102, at 914.

^{104. 226} N.W.2d 180 (Wis. 1975).

themselves. In each case a proxy decision seemed problematic, whether because of the risk/benefit ratio or the exploitation of incompetent people when others could have participated equally as easily. We have already given cases where most people find proxy consent to be acceptable and a few hard cases should not convince us to ban proxy consent altogether. But the argument here is different certain kinds of proxy consent are so problematic that perhaps we should characterize them in a particular way and wholly rule them out.¹⁰⁵

Let us focus, then, on the hardest case—medical research that is high risk and offers no prospect of direct benefit to its subjects. While the psychosurgery case could conceivably have had direct benefit for the subject, it is still true that the risks were exceedingly high. The developmentally disabled patients in the Willowbrook case, on the other hand, would not have benefited themselves from the study as it focused on the impact the disease has as it goes untreated. The kidney donation case also provides a good example of this type of situation as it involved risks for the patient and provided no potential direct medical benefit.

What should we do in these hard cases? One possibility is to say that in any case that falls in the category of high risk and no direct benefit, proxy consent should be forbidden. We believe this is problematic for two reasons. First, we think the most important issue in deciding on research for an incompetent person is what he would have wanted if competent. If such a patient, while competent, had signed an advance directive that he wanted to participate in high risk, no-direct-benefit research—indeed, the case becomes even stronger if he identified a particular research project, whose risks and benefits he fully understood—then his enrollment in the study would be appropriate. We might even say that if there is clear evidence that the person would have wanted this research—through letters, public statements, etc.—then we should permit such research on a substituted judgment basis as well. While it is highly unlikely that this kind of evidence will be available in most cases,¹⁰⁶ in those cases where it does exist, proxies should be permitted to consent to high risk, no direct benefit research.

The second point is that some interventions of this kind are justified even when they are not in the medical interests of the ward. As a counterpoint to the *Pescinski* case there is the case of *Hart v. Brown.*¹⁰⁷ In this case the court

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^{105.} If we wish to put it in risk/benefit terms, we believe that most people would overwhelmingly agree that minimum risk research is perfectly acceptable, as is a minor increase over minimum risk but with potential benefit. Perhaps more controversial—but still acceptable—would be research with more than a minor increase over minimum risk if there is a prospect of direct benefit, or with a minor increase over minimum risk even if there is no direct benefit. The latter two may be more controversial, and the ability to apply these standards of "minimum risk," "minor increase over minimum risk," and is extremely problematic.

^{106.} See Wendler et al., supra note 94, at 590.

^{107. 289} A.2d 386 (Conn. Super. Ct. 1972).

approved the donation of a kidney by a seven-year-old for the sake of her twin sister. The court required that the parents' reasoning, as well as the state of the child, be evaluated. It also noted that, quite apart from her medical interests, it was in the general best interests of the healthy twin to save her sister, whom she loved and wanted to help. In other words, the court countenances that the girl's gratification at being altruistic and her interest in saving her sister were enough to justify this procedure. It will be noted that the necessity requirement is arguably not met here—other kidneys might be available—yet we still may want to grant the twin the right to donate her kidney to her sister.

The point is that if we have an inflexible, bright-line rule, the healthy sister in *Hart* would not have been allowed to save her twin. Of course high risk/nodirect-benefit research can also be like this. A person may want to participate in such research because he recognizes that future generations of his family may benefit; because being a self-sacrificing, altruistic person gives the person great utility; because her caregivers may benefit and be better caregivers (on nonmedical measures) to the person; because the person is dying and wants his life and illness to serve a higher purpose or have meaning, in the way the individual constructs that meaning. In other words, if, in the best interests scenario, we focus only on medical benefit, we prevent decisions to participate in research that are, broadly speaking, in the interests of the person as she perceives them.

If we do not want to simply rule out proxy consent to these types of research, there remain two possibilities. First, given that there is always a full ethics committee review by an IRB, we could simply let the proxy decide using a substituted judgment or best interests standard without further direction. Or, second, we could raise a presumption that "high risk, no-direct-benefit research" is impermissible, but allow the presumption to be rebutted if the IRB or proxy can establish that other factors support going ahead with the research. Essentially, there are two issues here: whether there should be a presumption against such research and, if one does exist, what agent should be able to decide if the presumption has been overcome—the IRB and/or the proxy?

As for whether a presumptive standard should be used, there are a number of considerations. Consider a different context: imposing medication on an incompetent patient. Some jurisdictions allow the guardian to require medication if the guardian finds that it is either what the patient would have wanted if competent or that it is in the patient's best interests. Other jurisdictions allow involuntary medication only if it will help the patient recover from a significant illness in a much shorter time than if other interventions are used. Clearly the former gives the proxy greater discretion in deciding. But the latter may prevent decisions from being made that many people would not want to prevent.

In other words, a standard guides discretion and this may useful so long as the standard is good and if it covers most cases that will occur. It is undesirable if there are often cases where we want decisions that depart from the ex ante rule, and it is hard to rebut the presumption. It is also undesirable if the standard is too hard to apply. A standard that bases decision-making authority in terms of degrees of risk, for instance, has been shown to be difficult to apply.¹⁰⁸ The same is likely true of standards that discuss different degrees of benefit to the patient.

In short, the choice between no rule and a presumptive rule probably turns on, and should turn on, how much we want to guide the discretion of the decision-maker.

Which brings us to the next issue: if we do use a presumptive rule, both the IRB and the proxy must apply it, albeit in different ways. The IRB will *always* make the initial decision in reviewing the protocol. They will ask whether there are circumstances in which the presumption against this research could conceivably be rebutted. IRBs are important to involve, as they will have more experience than individual investigators. And giving them a central decision-making role will also be likely to lead to greater consistency, as boards' compositions tend to be stable over time.

On the other hand, individual proxies are more likely to be able to spend time on specific issues, with a more finely grained understanding of the complexities presented by particular situations. Once an IRB has decided to approve a research project, it remains for the proxy to look at the individual for whom she is making the proxy decision and decide whether this person would have wanted to be involved in the research and whether it is in her best interest. In short, we could have regulatory language that sets a presumption against involving decisionally impaired individuals in certain types of research, but allow IRB and proxy decision-making to possibly rebut this presumption.

In the end, given all the considerations we have discussed, we believe that the best approach is to maintain current IRB functions and allow proxies to consent to any research which they think the subject would have wanted, or, if this is not sufficiently known, to any research that would be in his best interests (as conceived in a broad sense). That is, we would not lay out a presumption against certain research which the IRB and the proxy would have to rebut. The presumptive rules themselves only give illusory guidance because applying them is fraught with difficulty. And giving proxies the highest level of authority to decide for their loved ones what they think best is probably the best way to protect subjects.

In concluding, we note that we would impose three further requirements on

^{108.} See, e.g., Seema Shah et al., How Do Institutional Review Boards Apply the Federal Risk and Benefit Standards for Pediatric Research?, 291 JAMA 476 (2004); Helen M. Sharp & Robert D. Orr, When "Minimal Risk" Research Yields Clinically-Significant Data, Maybe the Risks Aren't So Minimal, 4 AM. J. BIOETHICS W32 (2004); Henry Silverman et al., Variability Among Institutional Review Boards' Decisions Within the Context of a Multicenter Trial, 29 CRITICAL CARE MED. 235 (2001).

research with the decisionally impaired. First, the participation of decisionally impaired individuals should, generally, be necessary—fulfilling the so-called "necessity requirement" as discussed in the kidney donation case.¹⁰⁹ Second. their dissent from any research participation should always be honored. Finally, we should require a heightened degree of proxy understanding before we accept their consent. If the first requirement is not met-if non-decisionally impaired people are available to do the study-then we have no good reason to volunteer the decisionally impaired in the study. We would have a caveat even to this, though. If the research is potentially very beneficial to the subject and the subject could not get such benefit unless he participates, then his participation perhaps should be allowed. As to the second requirement, we believe that forbidding dissenting people to be volunteered makes sense even if the research is potentially beneficial. Being studied primarily for the benefit of other people should not be something a person is forced to do even if she is considered incapable of effectively refusing. Finally, given the risks inherent to research, and the fact that the proxy decision-maker herself is not assuming the risk, we should make sure she truly understands the risks and benefits of the research. Dispelling any "therapeutic misconception" is particularly important here. Indeed, for research that poses the very highest risk with no benefit we may want to assure ourselves that the proxy understands and is considering the appropriate factors in making her decision. This is a question that deserves greater study.

In considering the various laws examined here, we believe that the California law comes closest to setting a reasonable example. We believe that the law is a little narrow—e.g., we might want to allow proxy consent to research for diseases that are not "serious or life-threatening" but nevertheless substantially affect the lives of those affected. On the other hand, it does not use standards in terms of risks that are hard to understand and apply. Moreover, it explicitly does allow family proxies, thereby reassuring investigators.

V. LIMITATIONS OF OUR RESEARCH AND DIRECTIONS FOR FUTURE RESEARCH

The biggest limitation regarding the positive part of our study is our focus on state statutes and six years of OHRP letters, and not on other sources of law. State statutes are typically the most important source for this kind of study because they have the full force of law and, at times, directly set forth the legal standards that govern an issue. Some states, however, have regulations and letters from their Attorney General—sources of law that were not discussed in this Article—that bear on our question. While we did look at relevant case law, we found little guidance in court opinions regarding the appropriate answers to our questions. Thus, this study looks primarily at just a few pieces of a much larger

^{109.} See Hart, 289 A.2d at 386.

puzzle. Future research into these other sources of law would be helpful.

The normative part of our study is a first step in a bigger project of justifying normatively a proxy consent protocol in the research context. We need further analysis of these issues and more research into what researchers, subjects, and citizens think about this issue. For example, empirical studies are needed that look at how proxies are actually used in the research context in different jurisdictions—and how adequate proxies are at meeting statutorily-imposed standards. Do most jurisdictions use informal family proxies in the research context, despite the fact that doing so lacks clear state law authorization?¹¹⁰ Is there a consensus among stakeholders of all kinds about who should serve as proxies and in what order? Is there also a consensus among stakeholders about which sorts of research? While there are some empirical studies of such issues, more would be worthwhile.¹¹¹

Other evidence should be gathered on whether the current system works in the case of decisionally vulnerable populations—are IRBs making the normatively correct judgments? Is there evidence on whether decision-makers consistently understand different levels of risk and benefit? Is there a difference in decisions which use a presumptive rule and those which do not?

VI. CONCLUSION

In conclusion, we have surveyed the current state of the law on the question of who may serve as a proxy in different research contexts. This is an important question because there is anecdotal evidence that an unclear answer has hindered important research and left investigators and IRBs to seek guidance from state and federal agencies.

Our results show that nine states specifically allow family members to serve as proxies in the research context, at least in some cases, and that twenty-seven states allow some kind of proxy decision-making in the research context. In the treatment context, there are seventeen states that explicitly allow family proxy decision-making for general treatment decisions. We also looked at general proxy decision-making standards. The two most detailed laws on proxies in the research context do allow families to make decisions on behalf of a decisionally impaired individual. And the OHRP appears to allow general treatment proxy statutes to authorize family proxies in the research context. There are also

^{110.} See, e.g., Jason H.T. Karlawish et al., Informed Consent for Alzheimer's Disease Clinical Trials: A Survey of Clinical Investigators, 24 IRB: ETHICS & HUMAN RES. 1, 3-5 (2002).

^{111.} See Scott Y.H. Kim et al., Impaired Decision-Making Ability in Subjects with Alzheimer's Disease and Willingness to Participate in Research, 159 AM. J. PSYCHIATRY 797 (2002); see also Kim et al., supra note 15, at 1395-1400.

statutes that place limitations on when proxies may make these types of decisions (e.g., only if the intervention is intended to preserve the life of or prevent serious injury to the subject).

In addition to discussing how to interpret unclear or ambiguous laws, we also looked at the three central normative questions in this arena: whether proxies should be allowed; who should serve as proxies; and what limits should exist on the types of things to which proxies can consent?

Conclusively answering all the questions we have raised would be impossible in a brief paper. Developing a model statute is arguably desirable, given the amount of multi-site research being done on these issues. In addition, the factors playing a role in deciding a number of issues—e.g., whether family proxies should be allowable—would not seem to differ depending on the patient's home state. However, it may also be the case that we prefer that different states experiment with such issues.

Whether or not a model statute is desirable at this point, however, it is certainly desirable that states adopt clear, well thought out statutes that specify who may serve as a Legally Authorized Representative. We suggest that laws similar to California's be adopted. In any event, such statutes should address our three main questions—whether proxies may consent to research, and, if so, which individuals should serve as proxies, and for which sorts of research they can provide consent. Finally, future research is needed on a variety of issues. Rules on proxy consent are necessary to allow important research to be done in an ethically appropriate manner.

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						rdian, only with court order approval, for tion, sterilization, psychosurgery, or removal otily organs			catry in guardian column. 76	rt must approve of pharmaceutical research	2017(c)(2) crian in the case of the mentally ill only if the ris expressly set forth in the order of initment or after subsequent hearing and order e court
	Gaardiau		§ 13.26.150(e)(4) Only if intended to preserve life or prevent serious impairment	§ 47.30.830 Not if it involves significant risk of physical or psychological harm (limit applies to all proprimtal procedures, not just guardian- made decisione)		Out abor of b		§ 27-10.5-114 For developmentally disabled ("DD") persons	For the mertually retarded, a guardian may not concart to corperimental bromedical or behavioral procecharse or participation in any biomedical or behavioral experiment, unless it (A) is intended to preserve life, (B) is intended to assist in regaining abilities and has been approved by a recognic (C) has been (i) approved by a recognic (C) has been (i) approved by a recognic of the Department of Mernal Retardation, and (iii) approved for the ward by such ward's primary care physician. \$\$ 1121, 1122	Guardian or representative may consent if Cou patient adjudicated incompetent	§ 7-1305.09 For DD, pairch's consent or consent of parent Ous or guardian is required before involvement in pow experimental research of the
	Non-Guardian Surrogate										
	Family as Legally Authorized Representative						Detailed law discussed in text, <i>supra</i> Subsection III.C.1		\$\$ 1122, 5176	Rights de volve to next of kin, guardian, or pharasetativir to internal health Cousent may be waived if in patient's best interst, and there is prior written approval of guardian, or if toone, of next of kin, and court approves on affidavit	§ 7-1305.09 Consent of mentally retarded or of guardian or parent
•	Cite		ALASKA STAT. §§ 13.26.150, 47.30.830 (2006)			АКК. СОРЕ АЛИ. § 28-65-302 (1987)	CAL. HEALTH& SAFETY CODE § 24178 (West 2006)	COLO. REV. STAT. § 27-10.5-114 (2002)	CONN. GEN. STAT. § 438-677(e)(6) (2007) (2007) (2007) DEL. CODE ANN. HI.	16, §§ 1121, 1122, 5176 (2003)	D.C. CODE §§ 7- 1305.09, 21- 2047(c)(2) (Supp. 2007)
	State	Mabama	Alaska		Arizona	Arkansas	California	Colorndo	Connectleut		District of Columbia

TABLE 1: STATE STATUTES ADDRESSING PROXY CONSENT & RESEARCH Discussed in lext supra 111.8.1

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Florida	Fla. Stat. §§ 394.4598, 744.3215(6)(e), 765.113 (2006)			§§ 394, 4598, 744, 3215(6)(e), 765.113 Guardian advocate cannot consent to research without IRB approval or without court order	§§ 394.4598, 765.113 Guardian consent is acceptable for research that lacks IRB approval so long as court approval exists
					§744.3215(4)(b) Court may permit guardian to consent if "[j]t is of direct benefit to, and is intended to preserve the life of or prevent serious impairment to the mental or physical health of the ward; or it is intended to assist the ward to develop or regain his or her abilities"
Georgia	GA. CODE ANN. § 37-3-162 (2006)			If a treatment is not a standard psychiatric treatment, patient or guardian must consent	If not standard psychiatric treatment and consent is given by someone other than the patient or guardian, court must approve
Hawali					
Idaho					
Blinols	405 ILL COMP. STAT. 5/2-110 (2005); 410 ILL. COMP. STAT. 50/3.1 (2005)	50/3.1 Looks to prior consent of the patient, but if that is unavailable, then to guardian, spouse, pareur or authorized agent			5/2-110 In case of mental health, if minor or under guardianship, a parent or guardian can provide consent only with a count order of approval and if treatment is in best interest of ward
Iudiana					
Iowa					
Kansas	KAN. STAT. ANN. § 59-29b78 (2006)				For people with alcohol or substance abuse problems, consent is required from a legal guardian who has obtained authority to consent from a court
Kentucky					
Lonisiana					
Maine					
Maryland					
Massachusett					
Michtgan	MICH. COMP. LAWS § 330.1629 (1999)				Guardian-provided consent, but only with a court order of approval for extraordinary procedures
Minnesota	MIXN. STAT. § 524.5-313 (Supp. 2007)				Guardian-provided consent, but only with a court order of approval
Mississippi					
Missourt	Mo. Rev. STAT. §§ 431.064, 630.115 (Supp. 2007)	Consent to experimental treatment by attorney-trefact, legal guardian, or family noder of priority given; patient may dissent Limitations when patient has expressly withheld consent	Durable power of attorney	Ouardians may consent as well as others	

PROXY CONSENT TO RESEARCH

		Gurardian shall are coursen to experiment undess specifically empowered by the court, which shall authorize it cany if it is of direct benefit to the patient and intended to preserve the life or to prevent actions impairment to the mental or physical health of the ward or casist in developing or regaining abilities	Guzzdian-provided consert, but only with a court order of approval	For patients an institutions governed by the State Department, if patient is incompetent, court determines if the coperiment is necessary. Requires direct relationship between goals of treatment and goals of experiment			
Gtærdian may consent					Petition for guardian for civilly commuted patient if he is incapable of conseming to research		
Non-guardian surrogate							Durable power of attorney/advance directive
No research without informed correct of the resident or putent, or the resident/patient is pacents or parentins or a responsible person appointed by the court after consultation with specialists; Consent must be buddined by the patient if competent and the guardina or parents or responsible person or "friend"; Statutes apply to people with "developmental discbilities" or "serious methal illness.						PCB. HEALTH LAV § 4.12 PCB. HEALTH LAV § 4.12 If shiped is incompable, consent to research vabulb be subscribed to in writing by surpo uther person as may be legally empowered to act on behalf of the human subject". Language vagne, bur may include family For instance, a net in MEDT HYTG. Law § 80.01 states that the legislature wishes to "strengthen the surrogate decision-maching "strengthen the surrogate decision-maching	role of parents and other tamuly memoers
Movr. Code Avs. §§ 53-20-147, 53- 21-147 (2007)		NEV. REV. STAT. § 159.0805 (2003)	N.H. REV. STAT. ANN. § 464-A:25 (2006)	N.J. STAT. ANN. §§ 30:4-24.2(d)(2), 30:4-27.11d (West 1997)	N.M. STAT. § 43-1- 15 (2003)	N.Y. MENTAL HVG. (AW 8001 (AW 8001) N.Y. Pus. HEALTH LAW \$242 (McKinney 2002)	N.C. GEN. STAT. { 122C-57 (2005)
Moutana	Nebraska	Nevada	New Hampshire	New Jersey	New Mexico	New York	North Carolina

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North Dakata	N.D. CEN. CODE §§ 25.01.2-09(4), 23.01.1-00(12) (2002); N.D. CEN. CODE § 301-28-12 (Supp. 2007)			§ 25-03.1 :4-0(1.2) Right not to be subjected to experimental research without informed consent of painent or grandian (note than this appears under section regarding commitment procedures; may apply to painents adjudicetted and found not incepateitated)	§30.1-28-12 Guardian-provided consent, but enly with a court order of topprovial (for guardians of incapacitated persons) § 2501.2-99(4) Å institutions for the DD, no medical behavioral At institutions for the DD, no medical behavioral activity and the provise experimental research to behavioral artitutions or intrusive experimental research
					unless directly related to specific goals of person's treatment program
Ohio					
Oklatomo	OKLA STAT. 111. 63, § 3102(a) (2007)	For IKB -approved experimental treatment, test or drug in the case of a terminally ill or persistently unconssions patient: may obtain informed consent of legal guardian, machie power of atorney, or family mamber in order of priority, tests paties control consent over a patient's objection	Durnble power of attorncy may give consent	Guardian may give consent	
Oregon					
Pennsylvan a	20 Pa. Cons. Stat. Ann. § 5521 (West 2005)			Guardiar-provided conseru, but (d) requires a court order of approval for experimental biomedical or behavioral medical procedurs or participation in biomedical or behavioral experiment	See entry in guadian column
Rhode Island					
South Carolina					
South Dakota					
Tennessee					
Texas					
Utab					
Vermont					
Virginia	VA. CODE ANN. § 32.1-162.18 (2005)	Detailed law discussed in text, supra Subsection III.C.2			
Washington	WASH, REV. CODE § 74.42.040 (2001)			In case of residents in nursing homes, residents and guardians, if any, have a right to give informed, written conscurb before participating in experimental research	
West Virginia					

PROXY CONSENT TO RESEARCH

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	Val 11 a Val

State	Cite	Treatment	Life-Sustaining Treatment	Mental Health/Developmental	Other
Alabama	ALA. CODE § 22-8A-11 (2006)		If a patient has not executed a do not resuscitate order and he or she is	Disabilities Treatment	
			incompetent, physician may execute one together with guardian or durable power of attorney or family, taking into consideration what the patient would have wanted and where there		
			is no hope that patient will regain ability to make decisions		
Alaska					
Arizoua	ARIZ. REV. STAT. ANN § 36- 3231 (2003)	If no guardian or durable power of attorney, family in order of priority			
\rkansas					
alifornia	CAL. HEALTH & SAFELY CODE § 121020 (West 2006)				
olorado	COLO. REV. STAT. §§ 15-14- 401. 27-10-114 (2002)				
onnecticut	Conv. GEN. STAT. §§ 17a-238, 19a-582 (2007)			§ 17a-238(f)(3) For mental patients	
lelaware	DEL CODE ANN. tit. 31, § 3908 (2003)				
district of columbia					
lorida	FLA. STAT. §§ 415.105, 415.1051 (2006)				
Georgia	Ga. Code Anv. §§ 31-9-2, 31- 36A-6, 37-4-21 (2006)	§ 31-36A-6 Also must consent speeifically to admission, transfer and discharge	§§ 31-9-2, 31-36A-6 Families may consent to do not resuscitate order		
Iawali	HAW. REV. STAT. § 327E-5 (2004)	If surrogate is not designated or unavailable, go to other family members			
dabo					
linois	755 ILL. COMP. STAT. 5/11a-17, 40/20 (2007)		Including do not resuscitate order, but not for mental health		
ndlago					

PROXY CONSENT TO RESEARCH

TABLE 2: STATE STATUTES ADDRESSING FAMILY PROXY CONSENT & TREATMENT Discussed in lext supra III.B.2

0 ;	IOWA CODE § 144A.7 (2005)		If parient has not executed a do not		
			incompetent, physician may execute one together with guardian or durable		
			fores of mouses of tantity		
2					
2	LA. REV. STAT. ANN. § 28:223 (2007); LA. REV. STAT. ANN. §§ 40:1299.53, 40:1299.58 (2001)	§ 40:1299.53 List of individuals able to consent		§§ 28:223, 40:1299.58 For mentally retarded persons	
	ME. REV. STAT. ANN: UI. 18-A, § 5-806 (1998), ME. REV. STAT. ANN: UI. 18-A, § 5-805 (Supp. 2006)		If a patient has not executed a do not resuscitant oxder and is incompleten; physiciant may execute one logether with guardian or durable power of atterney or finanily; surrogate may withdraw life-saving treatment if guardian has not been appointed or is pot available		
2					
busetts	Mass. GEN. LAWS CD. 201D, §§ 5, 16 (2004)	§ 16 If no proxy appointed, may rely on informed consent of responsible parties to the extent permitted by the law extent permitted by the law	§ 5 Agent's authority subject to limitations on proxy		
4					
đ	XID:St. STAT. § 144.651(10)(b) (2003); MID:St. STAT. § 253B.03(6) (Supp. 2007)	§ 144.051(10)(0) When a patient is admitted and is unconscious, connuise or unable to communicette, family may unless it is known than patient does not want treatment.		§ 253B.03(6) For civily committed patients, if they are incompetent and have no guardian, then their mearest relative holds the power to constant; if a guardian exists, then the guardian coultois consent	
İdd	NESS. CODE ANN. 55 41-30-21, 41-41-211 (1972)	\$ 41-41-211 By surrogates, i.e., agents other than guardians, including family		§ 41-30-21 Request for discharge from voltndary inputient treatment recognized if the patient is incompetent and the request is made by parami, legal guardian or other representative	
-	макт. Сорв Аки. § 50-5-1201 (2007)				For safety devices, patient or legally appointed representative may consent
e					

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Nevada	NEV. REV. STAT. §§ 449.613, 449.624, 449.626 (2005)		If a patient has not executed a do not returstingt order and to or sho is incompetent, physician may execute one together with guardian or durable power of attorney or family		
New Hampshire					
New Jersey					
New Mexico					
New York	N.Y. MENTAL HYG. LAW §§ 80.01-13 (McKimiey 2006)			State establishes state-wide quasi- judicial surrogate decision-making process which aims to strengthen the process which aims of other family members	
North Carolina	N.C. GEN. STAT. § 90-21.13(a)	No informed consent action			
	(2005)	where certain conditions are met if proxy does not get consent from patient, or			
		spouse, parent, guardian or nearest relative			
North Dakota	N.D. CEAT. CODE § 23-12-13 (2007)	Family may give informed consent for incapable person; excludes consent for sterilization, abortion, prycholbrargy but does not mention research			
	OTTO BELL CODE ANN SE		£ 3133.08B	5 51 73 8K	
Ohio	0HIO KEV. CODE ANN. 98 2133.08B, 5123.86 (LexisNexis 2007)		s 2 122.000 If a patient has not executed a do not resuscitate order and he or she is	g 2122.00 For major procedures, if patient is incapable due to mental illness, a	
			incompetent, physician may execute one together with guardian or durable	natural or court-appointed guardian may give informed consent; in case	
			power of attorney or family	of an emergency decision-making ability flows in order of priority; for	
				therapy, consent can come from	
_				testociii e guaruani, spouse, next ot kin	
Oklahoma	OKLA. STAT. tit. 36, § 6804 (1999)	If a patient is incapable, then their representative decides		Mental health patients, before major operation, must inform family	
Oregon	OR. REV. STAT. §§ 127.540,		If a patient has not executed a do not		
	127.635 (2005)		resuscitate order and he or she is incapable; physician may execute one together with guardian or durable power of attorney or family		
Pennsylvania					
Rhode Island	R.I. GEN. LAWS § 40.1-26-3 (2006)			For mental patients and the DD, any medical decision; if incompetent, guardian or relative nust consent to	
				invasive treatment or surgery	

PROXY CONSENT TO RESEARCH

						9. 8. 2. 3. 4. 3. 4. 4. 4. 4. 4. 4. 4. 4. 4. 4. 1. incapable woman may be given an abortion only if consent is provided by a parent, guarding, other person standing in loco parentis, or a committee diminities of the second standing in loco parentis, or a second standing in loca parentis, or a second standing in loca parentis, or a second standing in loca parentis, or a second standing standard
Admission of DD on request of the DD, if competent, or family, among others		For DD and mental health parients: surrogate, including family, may decide on dental, psychological or routine medical or psychiatric treatment	§ 597.041 For DD: list of family members who may consent to treament on their behalf		In merital health cases, consent of putient, attorney, guardian, or next of kin is required for any form of surgery	5.4.1.2570. For a metaral health or retardusion patient in a fucility or recursing case without informed consent permitted, if no legally authorized guardian or committee, reasonable efforts are made to advise parent on reast of kin of need for action, and no reasonable and two physicians have cause to believe patient unable to consent \$70.96A.110(1) believe patient unable to consent \$70.96A.110(3) syno.96A.120(6) \$70.96A.120(6) \$70.96A.120(6) of need of head of annity or neess of kin of patient's attainist addiction
			§ 313.004 Family consent to treatment including life-saving treatment			
			§ 313.004 Treatment decisions, including those conserming life eaving treatments, made by people in order of listed priority, including family			§ 5.4.1-2086 (f a patient is incompetent, doctors may provide or withdraw treatment including life probonging treatment, based on the consent of listed people, including family, in order of statutorily created priority of a priority, including family family
S.C. CODE AXN. § 44-20-440 (2002)		ТЕХК. СОDE A.N. § 33-3-219 (2001)	TEX. HEALTH.& SAFETY CODE ANN: 55 313.004; 462.009; 597.041 (Yermon 2001)		VT. STAT. ANN. ili. 18, § 7708 (2002).	VA. CODE ANN. §5 18.2.76(Å), 54.1-2970, 54.1-2986 (2005). Wash. Rev. Cope § 7.70.065 (2007): Wash. Rev. Cope § 7.0095.4.110(1), 70.96A.120(6) (2002)
South Carolina	South Dakota	Tennessee	Texas	Litah	Vermont	Virginia Washington

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§ 16-3C-4(e) Consent for HIV testing of incapacitated putters may be provided by other individuals, in order of statutority created priority list		§ 33-20-105 Solf, cargerst, conservator, guardian, parardian ad litem on families may request protective services: an provided without patient consent, or -if patient licks capacity—that of the above persons.
§§ 16. 30-3, 16-30-8 If adult sarrogate resconably wealthe and villing to make health care, then can consent on behalf of the priven; if on correction of the more provey selected by mere privation statue fists prevent, iocluding fists prevent, iocluding fists prevent, iocluding physician may select	Lists the order of priority, including family, by which provies can consorn to the admission of incepactined people to facilitics, though provies do nargosted as mentally provies do nargosted as mentally ill, DD, or adjudicated incompetent, provies may do nado health care decisions to the same extent es a guardian	§ 35-22-006 In absence of designation or life a designes is not reasonably available, consent flows to family in statuorily- defined order of priority
W. V.A. Conz §§ 16-3C-4(a), 16-30-3, 16-30-8 (2006)	Wis. STAT. ANN. § 50.06 (West 2006)	WYO. STAT. ANN. §§ 35-20- 105, 35-22-406 (2007)
West Virginia	Wisconsin	Wyoming

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LIMITATIONS ON POWERS	
JBSTITUTE DECISION-MAKERS	
S ADDRESSING POWERS OF SU	
TABLE 3: STATE STATUTES	Discussed in toxi supra III.B.3

r

State	Cite	Description of Substitute Decision-Maker ("SDM")	Standard for Substitute Decision	Explicit Court Approval Necessary:
		Power: A) SDM may decide anything subject could decide if comment. withhest to limitation simposed by subject	Makers: A) Substituted Judgment (if wishes	A) Abortion B) Sterilization
		B) SDM may take actions that are expressly	kaowu)	C) Experimental Treatment
		cutuorused by power of autoruey C) SDM has same rights as parent with respect to	C) Not noted	E) Contaction of the second seco
		child D) SDM may take actions not limited by power of		
		attorney E) None noted		
Alabama	ALA. CODE § 22-8A-6 (2006)	A (limited by specific instructions of the individual, if any	c	Ŀ
Alaska	ALASKA STAT. §§ 13.26.116, 13.26.150c (2006)	§ 13.26.150 C (when guardian is SDM)	Q	ц.
Artzona	ARIZ. REV. STAT. ANN. § 14-5312 (2005)	§ 14-5312(A) C (for guardian may be modified by guardianship order) § 14-5312(13) A (for neural health)	§ 14-5312(13) A	Ĩ4.
Arkaosas	ARK. CODE ANN. § 20-9-602 (1987)	A Note: "to any surgical or medical treatment or procedure"	c	24
California	CAL PROB. CODE § 45A-656 (West 2007); CAL. PROB. CODE § 2355 (West 2002)	§45A-656 A: C (for guardian)	§ 2355 A (guardian)	5
Catorndo	COLO. REV. STAT. § 15-14-314(1) (2002)	Y	А	64.
Connecticut	CONN. GEN. STAT. §§ 45a-656 (West Supp. 2007)	Е	C	124
Delaware	DEL CODE ANN. th. 12, § 3922 (2001)	A; C (for guardian, but may be modified by guardianship order)	А	Ľ4,
District of Columbia	D.C. CODE § 21-2047 (2001); D.C. CODE § 21-2047 (Supp. 2007)	§ 21-2047(b)(4) (2001) A Note: "Consent to medical examination and medical or Other professional treatment"	§ 21-2047(s)(6) (Supp. 2007) Å	6.
Florida	FLA STAT. §§ 394.4598, 765.401 (2006)	§ 394.4598(6) A; B (guardian advocates are subject to the same restrictions as provice)	§ 765.401 A	§ 394.4598(6) A; Β; C; D; Ε
Georgia	GA. CODE ANN. § 29-4-23 (2006)	A	c	14
Hawall	HAW. REV. STAT. § 327E-6 (2004)	V	J	ц
Idaho	IDAHO CODE ANN. §§ 15-5-312, 66-606 (2001)	§ 15-5-312 A; C (for guardian)	§ 66-606 B	d
Ditnois	755 ILL. COMP. STAT. 5/1 In-17 (2007)	A (for mental health treatment); B (guardian abilities limited by the Health Care Surrogate Act)	A (guardian)	4
Indiana	IND. CODE § 16-36-1-7 (1993); IND. CODE § 29-3-8-2 (2000).	§ 29-3-8-2(b) C	§ 16-36-1-7(h)(1) B	Ľ.
lowa	IOWA CODE § 144B.6 (2005); IOWA CODE § 633.635 (2003)	\$§ 148.6, 633.635 A	\$ 144B.6 A	§ 633.635(2)(b) P

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			5 60 30766 3631	ſ
Kansas	(2002) 2/ 05-92 \$ 20-50 (2002)	s 25-26/05 B (guardian's abilities subject to the control and direction of the court for all things)	(a) Automatic (a) (a) (a) (a) (b) (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c	
Kentucky	KY. REV. STAT. ANN. § 387.065 (1999)	c	c	F
Louislana	LA. REV. STAT. ANN. § 28:227 (2007)	A	A	F
Maine	ME. REV. STAT. ANN. tit. 18-A, §§ 5- 312 5-RD6 (1008)	\$ 5-312 C (for sundian, excent as modified by court)	§§ 5-312, 5-806 A (guardian)	4
Maryland	MD. CODE ANN. EST. & TRUSTS § 13- 708 (LexisNexis Supp. 2006)	B (guardian's powers limited to those approved by court)	υ	64
Massachusetts	MASS. GEN. LAWS ch. 201D, § 5 (2004)	Y	A	F
Michigae	MICH. COMP. LAWS § 330.1602 (West 1999)	V	A	A; B; C
Minnesota				
Mississippi	MISS. CODE ANN. § 41-41-211 (1972)	Α	B	14
Missouri	Mo. REV. STAT. §§ 431.064, 475.120(2) (2007)	Е	§ 475.120(2) B	§ 431.064 A; D; E
Montana	MONT. CODE ANN. § 72-5-321 (2007)	В	U	Ľ.
Nebraska	NEB. REV. STAT. § 30-2628 (Supp. 2006)	c	A	Ł
Nevada	NEV. REV. STAT. §§ 159.079, 159.0805 (2003)	§ 159.079(1) A	c	§ 159.0805 B; C
New Hampshire	N.H. REV. STAT. ANN. §§ 137-J:2, 464- A:25 (2006)	\$ 137-J:2 A	§§ 137-J-2, 464-A:25 B	§ 464-A:25 B; C; D; E
New Jersey	N.J. STAT. ANN. §§ 3B:12-57, 30:4- 24.2 (2007)	ä	§ 3B: 12-57 A	§ 30:4-24.2 B; C; D; E
New Mexico	N.M. STAT. § 45-5-312 (2007)	c	×	6
New York	N.Y. MENTAL HYG. LAW § 81.22 (McKinney 2006)	۷	A	F
North Carolina	N.C. GEN. STAT. §§ 35A-1241, 35A- 1245 (2005)	§ 35A-1241 A	B	§ 35A-1245 B
North Dakota	N.D. CENT. CODE §§ 23-12-13(3), 23- 12-13(4) (2002)	§ 23-12-13(3) A	A	§ 23-12-13(4) A: B; C; E
Ohio	OHIO REV. CODE ANN. §§ 2111.13, 5123.86 (LexisNexis 2007)	§2111.13 E	§2111.13 C	§ 5123.86 D
Oklahoma	OKLA STAT. tit. 30, § 3-118 (West 1991)	V	A	Н
Oregon	OR. REV. STAT. §§ 125.320, 127.535 (2005)	\$ 127.535 A	\$ 127.535 A	§ 125.320 A
Pennsylvania	20 P.A. CONS. STAT. ANN. § 5521 (West 2005)	B	А	A; B; C; D; E
Rhode Island	R.I. GEN. LAWS § 40.1-26-3 (2002)	Е	A	64
South Carolina	S.C. CODE ANN. § 62-5-312 (2002)	C	U	E .
South Dakota	S.D. CODFTED LAWS § 29A-5-402 (2004)	A	A	н
Tennessee	TENN. CODE ANN. § 3-219 (2002)	A	A	(L
Texas	TEX. PROB. CODE ANN. § 767 (Vernon 2001)	Α	A	64
Utah				

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Vermoat	VT. STAT. ANN. III. 14, § 3069 (Supp. 2007), VT. STAT. ANN. III. 14, § 3071 (2002), VT. STAT. ANN. III. 18, § 8708 (2000)	§§ 3069, 3071 A	§§ 3069, 3071 A	§ 8708 B
Virgiaia				
Washington	WASH, REV. CODE, ANN. §§ 11,88,010,	§ 11.88.010	§ 7.70.065	§ 11.52.043 (5)
_	11.92.043(5) (West 2006); WASH, REV. CODE, ANN, § 7,770.065 (West 2007)	ţ	V	14
West Virginia	W. VA. CODE § 44A-3-1 (2006)	V	A	F
Wisconsin	WIS, STAT. ANN. §§ 54.20, 54.25 (West Supp. 2006)	§ 54.20 D	§ 54.20 A	§ 54.25 B; C
Wjoming	WYO. STAT. ANN. §§ 3-2-201, 3-2-202 (2007)	§ 3-2-201 A	§3-2-201 A	§ 3-2002 B; D; E

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