
A Policy in Flux: New York State's Evolving Approach to Human Subjects Research Involving Individuals Who Lack Consent Capacity

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Despite existing federal and state law and regulation, new human subjects research (HSR) scandals involving “vulnerable” populations continue to surface.¹ Although existing oversight mechanisms were enacted to ensure voluntary informed consent for participants and institutional review board (IRB) oversight of HSR, these laws and regulations do not provide any special oversight mechanisms or protections to ensure the ethical and safe inclusion of cognitively impaired adults. The absence of rules to ensure consistently ethical conduct of research involving adults who lack consent capacity may either lead to exploitation of this vulnerable population or the dearth of important research into the broad range of diseases that impair cognition. In other words, while some institutions and investigators are conducting research with this group without guidance, others are taking an extremely conservative approach and are excluding these individuals from research. Without safeguards that are adequate and robust but not overly burdensome, conducting research involving this population is ethically and legally challenging.

In the state of New York, efforts have been made to regulate research involving individuals who lack consent capacity, particularly in response to the state's checkered history of ensuring the protection of this particular population.² In 1990, the New York State Office of Mental Health promulgated regulations to govern research that occurs at its facilities. However, these regulations were overturned because a New York

State court held that the agency did not have authority to make rules to oversee human subjects research. Eight years later, the New York State Department of Health – the agency with the authority to promulgate regulations governing HSR – commissioned a work group to develop regulations authorizing research involving individuals with decisional incapacity. However, for political and other reasons, these proposed regulations were never acted upon.

In January 2014, the New York State Task Force on Life and the Law released its *Report and Recommendations for Research with Human Subjects Who Lack Consent Capacity*, in an effort to ensure the ethical conduct of research involving cognitively impaired adults. The report is the result of a multi-year effort to respond to appeals for guidance from New York State IRBs, investigators, and research institutions on how to conduct ethical research involving adults who lack consent capacity. It represents the most recent step in a decades-long process across New York State agencies and courts to develop oversight mechanisms that are appropriately sensitive to the fine line between protecting a vulnerable population and impeding the advancement of research.

As a practical matter, the Task Force's report may have limited direct application. The report – and, for that matter, any New York State action – only applies to human subjects research conducted in the state that is *not* subject to federal oversight. The federal Common Rule governs human subjects research that is supported by federal funding, is conducted by the federal government, or is overseen by a federal agency – in other words, the vast majority of human subjects research conducted in the United States. New York State's Public Health Law only applies to research *not* covered by federal law.³ Thus, the Act applies to a

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minority of research activity in the state, because most research conducted in New York is either federally funded or otherwise subject to federal oversight.⁴

I. OMH Regulations and *T.D. v. N.Y. State Office of Mental Health*

To address the lack of oversight of research involving individuals who lack consent capacity in New York State, in 1990 the New York State Office of Mental Health (OMH), the state agency that supervises psychiatric facilities, promulgated regulations intended to allow residents of OMH facilities — both adults and minors — who lack consent capacity to participate in research protocols. The regulations' stated purpose was to "ensure the protection of patients who participate in research while simultaneously facilitating research into the very disorders from which they suffer and which underlie their impairment."⁵ Six patients who had been adjudicated mentally incapable of giving or withholding consent to participate in medical research brought an action against OMH challenging the regulations.⁶ The district court found that the regulations had been improperly promulgated by OMH because the New York State Department of Health had the exclusive responsibility of overseeing all human subjects research in New York.

OMH appealed, and the appellate court upheld the district court's finding that OMH did not have authority to promulgate regulations governing human subjects research. The court went further, however, and held that the regulations violated the due process clauses of the New York State Constitution and the Fourteenth Amendment of the U.S. Constitution, as well as the state's common law rights to privacy and personal autonomy. This latter holding was based on the finding that the OMH regulations failed to provide for adequate notice and review procedures for individuals who were found to lack consent capacity and could be enrolled in research protocols. Moreover, the court found that by permitting research that involved more than minimal risk, the regulations struck an improper balance between the "interests of researchers and the rights of the subjects."⁷

One year later, the highest New York court held that the section of the appellate court's decision related to the constitutional and common law rights of individuals who lack consent capacity was an "inappropriate advisory opinion."⁸ Thus, only the court's reasoning that OMH was not authorized to oversee human subjects research in New York State is still good law. Nevertheless, many state agencies — even outside of New York — have been hesitant to provide guidance or regulations to include individuals who lack consent

capacity in research due to concern that courts assessing the validity of new regulations would impose similar requirements in the future.

II. New York State Advisory Work Group on Research Involving the Protected Classes

In response to the *T.D.* litigation, in 1998, the New York State Department of Health commissioned an advisory work group to develop regulations authorizing research involving individuals with decisional incapacity and to address the concept of surrogate consent to research. The work group released a draft report entitled *Recommendations on the Oversight of Human Subject Research Involving the Protected Classes* (the NYSAWG report).⁹ The report proposed specific and substantial regulatory language for the Department of Health, including investigator and IRB responsibilities, requirements for informed consent, procedures for assessing capacity of potential research subjects, surrogate authorization, use of research advance directives, special safeguards to protect the rights and well-being of research subjects, and reporting requirements. Specifically, it recommended allowing surrogate consent to certain kinds of research that offers no prospect of direct benefit presenting "minimal risk" or a "minor increase over minimal risk," and allowing participation in research that offers no prospect of direct benefit presenting "more than a minor increase over minimal risk" in special circumstances with additional safeguards in place.

The report was distributed to over 500 interested parties for comment. Although the Department of Health considered revisions to the report in response to comments and the final decision in *T.D.*, revised recommendations were never released. In 2000, the resignation of the former Commissioner of Health, Barbara Ann DeBuono, and appointment by Governor Pataki of a successor, Antonia C. Novello, "who would naturally require time to familiarize herself with the issues," led to a "delay" in taking next steps with the proposed regulations.¹⁰ Further, "sharp criticism from both advocates and researchers," including the state Medical Society ("a powerful lobbying group in Albany"¹¹), was credited for state inaction.¹² The Department of Health never acted on the report, nor did it promulgate any regulations regarding the conduct of human subjects research in New York State.

III. The Task Force on Life and the Law's Report and Recommendations for Research with Human Subjects Who Lack Consent Capacity

In the absence of rules at both the federal and state level to ensure consistently ethical conduct of research

involving adults lacking consent capacity, IRBs, investigators, research institutions, and other stakeholders appealed to the New York State Department of Health for guidance on how to conduct research involving this vulnerable population. The Department of Health, in turn, asked the New York State Task Force on Life and the Law (the Task Force) to analyze the legal and ethical dimensions of allowing adults who lack consent capacity in research protocols subject to New York State oversight. Established by Executive Order in 1985, the Task Force is composed of approximately 23

research includes individuals who lack consent capacity. Noting its advisory rather than controlling status, the Task Force focused on the court's emphasis on research subjects' autonomy and dignitary rights.

To address the significant inconsistency in the oversight and conduct of research involving individuals who lack consent capacity, the Task Force drafted a set of legal and ethical guidelines regarding the conduct of research in New York State involving this particular population.¹³ An underlying goal of the work was to ensure that research protocols are available to cogni-

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The Task Force began its endeavor in December 2007 by disseminating a survey to approximately 300 New York IRB chairs and members. The survey requested information about institutions' practices, if any, for conducting research involving the cognitively impaired, and views on the regulatory landscape. More than 100 responses provided a detailed and useful qualitative account of research practices in New York and indicated a need for guidelines to ensure consistently ethical research practices.

In its examination of the issues associated with research involving cognitively impaired adults, the Task Force reviewed medical and policy literature on human subjects research, informed consent, surrogate consent, capacity assessment, risk-benefit analysis, research protections, adverse events, and related topics. It conducted extensive legal research of federal and state regulatory standards, including New York's, and case studies pertaining to human subjects research involving the cognitively impaired. The Task Force analyzed previously-released reports, recommendations, and draft regulations on human subjects research by the Department of Health and the public comments to these efforts, including the NYSAWG report. It also took into account the controversial advisory opinion in *T.D.*, in which the court addressed the need for special protections where

tively impaired individuals so that they may reap the benefits of research and share its risks and burdens like their non-cognitively impaired peers, while also ensuring the appropriate level of protections.

Unlike the NYSAWG report, which proposed the promulgation of specific regulations pursuant to New York State law,¹⁴ the Task Force's report proposed guidance — recommendations for IRBs, investigators, institutions, and legally authorized representatives (LARs) for the ethical conduct of research involving individuals who lack consent capacity. The Task Force encouraged voluntary adherence to these recommendations for all human subjects research involving adults lacking full consent capacity conducted in New York State. Moreover, in developing its guidance, the Task Force considered and declined to recommend legislation governing research involving individuals who lack consent capacity. It concluded that because existing law permits research involving this population, no statutory change was needed.

In its report, the Task Force made a number of important and, in some cases, unique recommendations regarding adults who lack consent capacity in human subjects research. For one, in the past, surrogate consent to research in New York State was limited because of uncertainty about who could provide surrogate consent to participation. The Task Force's report relied on the 2010 passage of the Family Health

Care Decisions Act (FHCDA), which changed the legal landscape by permitting surrogate consent to health care. The surrogate hierarchy contained in the statute thus opened up the field of research requiring surrogate consent in New York State.¹⁵

In addition, and probably most importantly, the Task Force recommended that, in rare circumstances, adults who lack consent capacity may be enrolled in research that presents more than a minor increase over minimal risk that offers no prospect of direct benefit, provided that a number of significant safeguards and protections are in place.¹⁶ In such cases, for research with a minor increase over minimal risk and no prospect of direct benefit to the participant, the Task Force recommended that IRBs may approve such studies only if the research is vitally important to further the understanding of the etiology, prevention, diagnosis, pathophysiology, or alleviation or treatment of a condition or disorder that affects the research population, and if the risks are reasonable in relation to the research's "vital importance." Furthermore, IRBs may approve such studies only if they require mandatory rigorous procedures and oversight for enrollment and monitoring of participants through the use of safeguards, including an independent consent monitor (ICM) and a medically responsible clinician (MRC). For research with more than a minor increase over minimal risk and no prospect of direct benefit to the participant, IRBs may approve such studies in only two circumscribed circumstances: where the potential participants have a previously executed research advance directive *or* in special situations with notification to the Department of Health and use of a special review panel.

The latter circumstance would require an alternative approval process consisting of several steps: (1) IRB review, (2) Department of Health notification by the IRB and possible referral by the Department of Health to a special review panel, and (3) an IRB decision to approve or reject the research protocol. For a protocol to be considered under this alternative process, the IRB must first examine whether the research is of vital importance. In addition, although this type of research protocol must be labeled as offering no prospect of direct benefit, for some research participants, a remote possibility exists that they may benefit from the research or from the knowledge gained. In such cases, the IRB must consider whether this remote possibility of benefit exists for potential participants and weigh it against the potential risks of the protocol. Furthermore, the IRB should ensure that the study requires rigorous procedures and oversight for enrollment and monitoring of participants through the use of safeguards, including an ICM and MRC.

Under step two of the process, the IRB should notify the Department of Health. At its discretion, the Department may: (1) reject the study (and thus the research could not be approved by the IRB), (2) approve the study (whereby the research could be approved by the IRB), or (3) convene a special review panel of experts who will examine the study and issue recommendations to the IRB on whether the study should be approved.¹⁷ If the Department of Health decides that a special review panel must examine the protocol, after the special panel has made its recommendations, the Department should refer the protocol back to the IRB for review, and the IRB will make the final determination based on the panel's recommendations.

Further, acknowledging the appellate court's opinion in *T.D.*, the Task Force recognized that a potential research participant should be notified and allowed the opportunity for review of all decisions to involve him or her in research, including assessments of capacity. The Task Force emphasized the importance of procedures for providing notice to the potential research participant and, if necessary, the LAR, regarding the capacity assessment and opportunities for objection and review. Researchers should provide notice to the potential participant and/or LAR that an assessment will be conducted and the consequences (if any) of a determination of incapacity. Providing notice promotes transparency by alleviating any concerns that an individual might be involved in research without the knowledge of the participant or LAR. It also demonstrates respect for the prospective participant by presenting an opportunity for the individual or his/her LAR to object to either the capacity assessment or the results of the evaluation. When capacity assessments are contested, the most ethical alternative may be to decline to enroll the individual in the research protocol. However, in some cases, alternatives short of non-enrollment could appropriately deal with any objection, such as a second capacity assessment. Readily available review procedures allow individuals an opportunity to request further information or a second opinion where they or their LARs see fit. Furthermore, steps should be taken during the notification process to ensure that the results of the capacity assessment remain confidential and that the privacy of the individual is respected.

Conclusions

Although existing New York State law governs human subjects research for a subset of research conducted in the state by providing mechanisms for ensuring voluntary informed consent for participants and IRB review of research protocols, it does not provide any

special oversight mechanisms for research involving adults who lack consent capacity. Despite calls to do so, federal law also does not provide safeguards or special protections for research involving “mentally disabled persons.”¹⁸ The absence of such guidelines or regulations may lead to unethical or unsafe research protocols or the dearth of important research into the broad range of diseases that impair cognition. Despite the continued absence of rules at both the federal and state level to ensure consistently ethical conduct of research involving adults lacking consent capacity, such research continues “in the shadow of the law.”¹⁹ While some institutions and investigators are conducting research with this population without oversight or guidance, others are taking an extremely conservative approach and are excluding these individuals from research, citing concerns about vulnerability and exploitation. Without appropriately protective but not overly burdensome safeguards, this will remain a challenge to the conduct of ethical research.

Guidance like the Task Force’s report is becoming increasingly necessary. In its survey of New York IRB chairs and members, the Task Force found that, in the absence of clear guidance, institutions either abstained entirely from research that required surrogate consent or engaged in such research despite the lack of clear authority. Beyond New York, research involving individuals who lack consent capacity occurs, even without legal or regulatory oversight. Laws that explicitly authorize research with incapacitated individuals are isolated exceptions; in the vast majority of states, research with individuals who lack consent capacity continues without any noticeable oversight, including regarding *who* may consent to research on behalf of the incapacitated participant. As of 2008, nine states had statutes that specifically allow family members to give proxy consent on behalf of their incompetent family members to participate in research, although some of these jurisdictions restrict the use of proxy consent to certain populations or certain types of research.²⁰

Various commentators have opined on the “unsuccessful” proposals of the federal, New York, and Maryland commissions that, in the late 1990s, made recommendations for the inclusion of cognitively impaired individuals in research.²¹ Like the Task Force’s current recommendations, all three past reports “agreed that no-direct-benefit studies involving more than

minimal risks should be permissible under some circumstances.”²² To the extent that the Task Force’s recommendations deviate from past reports and the “inappropriate advisory opinion” in *T.D.*, they seek to offset concerns with proposals for significant additional safeguards and oversight mechanisms.

The Task Force’s report may be better received than past recommendations for two reasons. First, since the state’s previous efforts to regulate research involving the cognitively impaired, a few other states have

Thus, for entities that previously did not pursue research with adults lacking consent capacity, the report endeavors to provide the foundation that will enable them to pursue research protocols that will lead to a better understanding of conditions that impair cognition. For those who already enroll adults who lack consent capacity in research protocols, the report will help them ensure that consistent and appropriate safeguards are in place to protect the welfare of these vulnerable individuals.

passed laws authorizing research with incapacitated persons.²³ A handful of states have passed laws specifically authorizing research with incapacitated persons, including California, New Jersey, Virginia, Oklahoma, and Wyoming.²⁴ Nevertheless, most current laws only authorize surrogate consent to research without enumerating any significant safeguards. Second, although regulatory oversight mechanisms may be more effective in ensuring consistent and uniform protections of individuals who lack consent capacity in research, the framing of the report as guidance, rather than mandatory rules, may make the recommendations more palatable — at least initially — to investigators, research institutions, IRBs, and other stakeholders. Policy makers may eventually seek to enact mandatory regulatory oversight mechanisms, based on observations of the success (or lack thereof) of the guidelines.

The Task Force’s recommendations may also serve as a model for research policy in other states and at the federal level. Importantly, they are more comprehensive and propose more significant safeguards for research involving individuals who lack consent capacity than existing federal and state oversight mechanisms. Thus, for entities that previously did not pursue research with adults lacking consent capacity, the report endeavors to provide the foundation that

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- H.K. Beecher, "Ethics and Clinical Research," *New England Journal of Medicine* 274, no. 24 (1966): 1354-1360.
- N.Y. Pub. Health Law Art. 24-A.
- Where research is both federally and state funded, only the federal rules apply.
- T.D. v. N.Y. State Office of Mental Health*, 228 A.2d 95 (1st Dept. 1996) (citing 4 N.Y.C.R.R. § 527.10(b)).
- Id.*
- T.D. v. N.Y. State Office of Mental Health*, 650 N.Y.S.2d 175, 177 (App. Div. 1996).
- T.D. v. N.Y. State Office of Mental Health*, 690 N.E.2d 1259 (Ct. App. N.Y. 1997).
- See Department of Health Advisory Work Group on Human Subject Research Involving Protected Classes, *Recommendations on the Oversight of Human Subject Research Involving Protected Classes* (1998): at 16, available at <<http://www.nysl.nysed.gov/scandoclinks/ocm49377072.htm>> (last visited July 30, 2014).
- D. E. Hoffmann, J. Schwartz, and E. G. DeRenzo, "Regulating Research with Decisionally Impaired Individuals: Are We Making Progress?" *DePaul Journal of Health Care Law* 3, no. 3-4 (2000): 547-608, at 591.
- G. Birnbaum, "Hospitals Fight for Freedom to Experiment," *N.Y. Post*, March 21, 1999: at 20.
- See Hoffmann et al., *supra* note 10 (citing a "series of articles that appeared in the *New York Post* on the ... recommendations in early 1999."). "According to one article, John Cardinal O'Connor, 'evoking Nazi Germany, warned ... that the recommendations were dangerous' and '[a]dvocates for the mentally ill vowed to go to court if necessary to block them.' A subsequent article stated that 'hundreds of advocates for the mentally ill protested at the Capitol' against what they viewed as recommendations supporting 'state-sponsored drug experiments using vulnerable people as 'human guinea pigs.' The article further recounted that Cardinal O'Connor, prior to a meeting on this issue with Governor Pataki, said that 'to allow experiments with some risk - and no benefit to the subject - on adults who are too ill to consent on their own ... could be a potentially horrifying thing.'" *Id.* See G. Birnbaum, "O'Connor Boosts Drug-Test Protesters," *N.Y. Post*, March 10, 1999: at 12 (stating that "[t]he department has not yet acted on the recommendations ... and is still analyzing the complex proposals after seeking public comment on them."); G. Birnbaum, "Hospitals Fight for Freedom to Experiment," *N.Y. Post*, March 21, 1999: at 20. See also R. Dresser, "Dementia Research: Ethics and Policy for the Twenty-First Century," *Georgia Law Review* 35, no. 2 (2001): 661-90, at 689 ("politics and the bureaucracy have kept the ... New York recommendations from being enacted into policy.").
- The New York State Task Force on Life and the Law, *Report and Recommendations for Research with Human Subjects Who Lack Consent Capacity* (2014), available at <http://www.health.ny.gov/regulations/task_force/reports_publications/> (last visited July 30, 2014). See also V. G. Koch and S. A. Han, "Of Vital Importance' The New York State Task Force on Life and the Law's Report and Recommendations for Research with Human Subjects Who Lack Consent Capacity," *New York State Bar Association Health Law Journal* 19, no. 1 (2014): 27-37.
- Pursuant to Public Health Law 24-A, the Department of Health may promulgate rules and regulations only for protocols that are not federally funded or otherwise federally regulated.
- B. Roxland and C. Zoubul, "The Family Health Care Decisions Act and Human Subjects Research in New York State," *New York State Bar Association Health Law Journal* 16, no. 1 (2011): 84-89.
- The Task Force recognized that for research that is categorized as offering no prospect of direct benefit, it may nevertheless be unclear whether the study has more than a negligible prospect of direct benefit or, if more than negligible, how much more; clarity (or its absence) often depends on the current state of available scientific knowledge. In order to clarify this statement, the Task Force offers the example of deep brain stimulation: prospectively, the desired (and achieved) benefit in cases where deep brain stimulation has been administered to patients who have experienced traumatic brain injury and are in minimally conscious states is uncertain. Although the surgical procedure involves more than a minor increase over minimal risk, there are no other known clinical or research interventions that may improve the condition of these patients. Because deep brain stimulation is an innovative and risky procedure, with little data available, it would be arguably improper to suggest that the study holds out a prospect of direct benefit. However, in the few instances in which the procedure has been performed, remarkable progress has been shown and such knowledge may be invaluable for future studies.
- This special review panel is based on the Common Rule's section 407 Review Children's Panels, which examines research protocols involving children that are otherwise not approvable because of their risk level.
- 45 C.F.R. § 46.111.
- C. H. Coleman, "Research with Decisionally Incapacitated Human Subjects: An Argument for a Systemic Approach to Risk-Benefit Assessment," *Indiana Law Journal* 83, no. 3 (2008): 743-89, at 765.
- E. R. Saks et al., "Proxy Consent to Research: The Legal Landscape," *Yale Journal of Health Policy, Law, & Ethics* 8, no. 1 (2008): 37-92, at 46. Twenty-seven had an explicit statute on proxy consent to research in general. And federal law defers to the states to establish who may serve as an LAR, looking to their formulations of LAR to determine who may consent to research conducted in that state. Thus, states with an explicit health care/treatment surrogate hierarchy may rely on that list to appoint an LAR to research.
- See Hoffmann et al., *supra* note 10, at 591; Coleman, *supra* note 19, at 745.
- Id.*, at 764.
- Id.*, at 765 (citing Cal. Health & Safety Code § 24178(2007); Kan. Stat. Ann. § 65-4974 (2006); N.J. Stat. § 26:14-1 (2008); Va. Code Ann. § 32.1-162.18(B) (2008), 12 Va. Admin. Code § 5-20-40 (2007); Okla. Stat. Ann. tit. 63, § 3102A (2007); Wyo. Stat. Ann. § 25-5-132(d)(iii) (2007)). Some states have statutes authorizing surrogate consent to "experimental treatment" for certain incapacitated patients. See, e.g., Fla. Stat. Ann. § 393.13(4)(c)(6) (2007). However, these statutes would probably exclude studies that do not offer a prospect of direct medical benefit, as such studies could not plausibly be considered a form of treatment.
- See Saks et al., *supra* note 20.