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Trey Sunderland, M.D.
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National Institute of Mental Health
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Building 10, Room #3D41
Bethesda, Maryland 20892

Dear Dr. Sunderland:

This letter has two purposes: to remind you that our working group on research involving cognitively impaired subjects will meet again on Tuesday, August 1, at 4:00 in the Superintendent's Conference Room at Spring Grove State Hospital; and to provide you with the promised background on a couple of issues — proxy consent to participation in research under the present Health Care Decisions Act, and the rulemaking authority of the Secretary of Health and Mental Hygiene as it might relate to research.

- *Proxy Consent*

The Health Care Decisions Act recognizes three possible decision-makers for an incapacitated patient: the patient herself, through an advance directive; a health care agent; or a surrogate.[1] Although these three differ in the source and scope of their authority, they have one thing in common. They all make "health care" decisions. Under §5-602(a) of the Health-General Article, a written advance directive concerns "the provision of health care ... or the withholding or withdrawal of health care ...." Under §5-602(b)(1), a health care agent may be appointed "to make health care decisions ...." Under §5-605(a)(2), a surrogate "may make decisions about health care ...."[2]

[1] For purposes of this discussion, I put to one side the authority of a court-appointed guardian of the person. Although the point is not free from doubt, I assume that a court could authorize a guardian to consent to the ward's participation in research. However, given the burden of litigation, frequent resort to guardianship would probably be impracticable. Hence, I focus on decision-makers who can act in the clinical setting without court involvement.

[2] A surrogate has no authority to authorize "[t]reatment for a mental disorder." §5-605(d)(2).

The term "health care" is not defined. However, other provisions in the Act make its meaning clear. It is synonymous with a procedure or course of treatment that relates to the disease state of the particular patient.

This intended scope of "health care" is reflected in the Act's itemization of factors related to substituted judgment. Health care agents and surrogates are to look exclusively at the ramifications if treatment were provided to, or forgone for, *that patient*. For example, in assessing whether the patient would wish to consent to a treatment were she able to, the agent or surrogate is to consider the patient's "[c]urrent diagnosis and prognosis with and without the treatment at issue ..." and any "[e]xpressed preferences regarding the provision of, or the withholding or withdrawal of, the specific treatment at issue or similar treatments." §5-605(c)(2)(i) and (ii).

This decisional framework, requiring a "health care" judgment framed in terms of the patient's assumed decision about a treatment, works well enough for therapeutic research. So long as there is an articulable link between the research and a possible improvement in the patient's condition, then a "health care" decision is possible, and the patient's hypothesized wishes would be the basis for it.

However, as I read it, the Act does not authorize an agent or surrogate to consent to a protocol that is expected to have no present or future therapeutic effect on the patient. Even an advance directive that generally consents to participation in future research cannot authorize an agent's or surrogate's decision that is unrelated to potential therapeutic effect on the patient. Altruism is noble, but it is not "health care."

Likewise, the Act's "best interest" test is entirely focussed on the impact of a treatment on the patient. A treatment is in the patient's best interest if "the benefits to the individual resulting from a treatment outweigh the burdens to the individual resulting from that treatment ...." §5-601(e). Under this formulation, participation in a clinical trial might be in the patient's best interest if, to use the language of the American College of Physicians, "the net additional risk caused by the participation is small, and there is scientific evidence that participation is reasonably likely to offer benefits over standard treatment or no treatment, if none exists." Even the risk that the patient might wind up in the placebo group of a double-blind, placebo-controlled study might be worth the potential benefit. Asked to consent to the patient's participation in such a research protocol, the proxy would consider the probability and nature of the benefit, the degree of risk, and the opportunity cost of forgone alternatives. If the proxy consented, the immunity provisions of the Act would apply to those who acted pursuant to the consent.

But suppose there is no scientific evidence that participation is reasonably likely to offer benefits to the patient. The Act's "best interest" calculus does not include potential benefits to society as a whole, or even to those who might suffer from the same disease in the future. Participation in research of that kind, even with minimal risk, is not a "health care" decision within the meaning of the Act.

If ultimately we think that health care agents or surrogates ought to have the authority to consent to nontherapeutic research under limited circumstances, and if researchers ought to enjoy immunity for acting upon such a consent, we should recommend a change in the law.

- DHMH Rulemaking

The Secretary of Health and Mental Hygiene has the authority to "adopt rules and regulations to carry out the provisions of law that are within the jurisdiction of the Secretary." §2-104(b)(1) of the Health-General Article. This grant of authority allows the Secretary to make policy choices (assuming that the Legislature itself has not done so) within the Secretary's areas of responsibility. But the Secretary has no power to make legally binding regulations outside of those areas.

For research conducted in DHMH facilities or by DHMH employees, the Secretary has broad discretion to regulate the informed consent process and other aspects of the research enterprise.[3] The Secretary may also manage grants involving federal or State funds in a manner that comports with existing law on research protocols. However, the Secretary does not have the authority to create legally binding standards for all clinical research conducted in Maryland, because no statute gives him that authority.

I hope that this information is helpful. I look forward to seeing you next Tuesday. If you've misplaced the directions that were enclosed with my prior letter, please call and we'll fax them to you.

Very truly yours,

Jack Schwartz
Chief Counsel
Opinions & Advice

[3] Research programs at the Maryland Psychiatric Research Center are the subject of special statutory procedures. *See* §§10-425 and 10-429(1) of the Health-General Article. The DHMH Secretary would not be authorized to substitute procedures inconsistent with those identified in the statute.