NEW YORK STATE BAR ASSOCIATION
One Elk Street, Albany, New York 12207 • PH 518.463.3200 • www.nysba.org

Health Memo #1 May 17, 2021

Greetings,

The Health Law Section of the New York State Bar Association (the "NYSBA Health Law Section") supports robust protections for research subjects and careful oversight over research involving human subjects and has worked with policymakers and providers to help build a detailed and consistent regulatory structure to protect the rights of patients involved in human subject research. Informed consent is an essential component of this structure, and to the extent that the goal of bill S.1172/A.4954 is to ensure patients are fully informed of their existing rights, we support it. However, we write to express our concerns that, in its efforts to reach that laudable goal, the language of the bill inadvertently creates new rights that are inconsistent with and potentially harmful to the existing structure of patient protections.

The bill would require New York general hospitals add the following to the statement of patient rights required under Public Health Law ("PHL") Section 2803(1)(g):

"A right to be informed of any human research and to voluntarily provide written informed consent to participate"

We are concerned that this proposed insertion does not capture the current legal rights of a patient with respect to the informed consent process but rather expands and adds new rights. Such new rights would add an unnecessary, additional burden to research institutions in the State, slowing down research in the State of New York.

Federal and State law sufficiently define the requirements of informed consent, the review of the informed consent by an institutional body tasked with protection of human subjects, and the monitoring of such process. Therefore, the NYSBA Health Law Section does not believe the additional language cited above is needed. More specific points follow:

1) ***The bill should be harmonized with the requirements of federal human protections regulation***s. The current language of the bill would seem to require "written informed consent" in all instances of "human research." Under federal law, however, Institutional Review Boards can approve oral consent or waive written consent requirements in certain situations:

a. An institutional review board might reasonably decide to waive the requirement that informed consent be obtained, for instance, when research presents minimal risks and does not involve procedures for which consent would be required in a clinical setting (see *45 CFR* § 46.117(c)).
b. An institutional review board overseeing research may, if regulatory requirements are met, determine that research is exempt from generally applicable requirements, including an informed consent, such as when the research consists of benign behavioral interventions (e.g., playing an online game). (see *45 CFR.* § 46.104); or
c. Informed consent may be appropriately provided orally, in some circumstances and only when regulatory requirements are met and approved by the institutional review board, rather than in writing (see *45 CFR* § 46.116(a)).

2) ***The bill should be limited to patients whose healthcare will be modified by taking part in a clinical trial.*** The current language of the bill may be interpreted to require that all patients at a hospital be told of all research involving humans in which that hospital is participating, even if they would not be eligible to participate or their medical practitioner does not think it would be best for such patient. Therefore, this language might significantly impair the doctor-patient relationship, by requiring substantial unnecessary disclosures irrelevant to the patient. We suggest that the mandate be limited to communicating to the patient about human research that would modify health care procedures or treatments such patient would receive.

3) ***The bill should be harmonized with Public Health Law Section 2445.*** In 2019 the Legislature amended PHL Section 2445 to allow institutions conducting research in the State to attest that they comply with the regulations promulgated by agencies of the federal government for the protection of human subjects (regardless of source of funding). That attestation permits research institutions to comply solely with such federal laws, removing their human research activities from the applicability of PHL Article 24A, which governs human subject research. This provision helps NYS research institutions avoid the complication, confusion and ambiguities that arise when such institutions must comply with overlapping federal and state laws for the protection of human subjects. Federal and State law already adequately protect human subjects of research. Requiring written informed consent, without taking into account the reasonable exceptions found in federal law, could impose substantial burdens on hospitals in New York, severely slowing down research in the State without adding significant new protections to patients. Such additional burdens would not be applicable to researchers in other states, placing NYS research at a disadvantage without a significant increase in patient protections. Moreover, the bill would apply these new requirements to only one sector of the New York State research community (i.e., general hospitals). Imposing this requirement would also leave New York patients unable to participate in research that falls under those categories where oral or no informed consent are otherwise permissible.

As recently as 2019, New York State has wisely determined that the significant and potentially life-saving human research occurring within its borders should not be slowed or stopped by State laws that overlap with or go beyond the substantial and carefully calibrated existing requirements of federal law. We write to respectfully express our concern that the bill could have a significant

negative impact on research occurring in New York. We ask that the Legislature either not insert such new requirement into the patient bill of rights, or, alternatively, amend the language to better capture the current rights of patients regarding informed consents for research, as follows:

"A right to be informed of any human research that directs or alters a health care procedure or treatment to be received by the patient and to provide voluntary written informed consent to participate in that research as a human subject, except as may otherwise be approved by a committee responsible for safeguarding the rights and welfare of the research participants at the hospital in accordance with applicable law."

We thank you for your consideration and would be pleased to discuss these issues with you further if you believe it may prove helpful.

Karen L. I. Gallinari, Esq
NYSBA Health Law Section Chair
Adjunct Professor, Elisabeth Haub School of Law, Pace University