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February 15, 2024

Susan R. Donovan, Chair
House Committee on Health and Human Services
State House
82 Smith St.
Providence, RI 02903

RE: H 7301 -- An Act Relating to Health and Safety -- Licensing of Healthcare Facilities

Dear Chair Donovan:

Please accept this letter regarding H 7301, legislation that would allow a healthcare facility to conduct human-subject research on patients subject to 21 C.F.R. Pt 50 and/or 45 C.F.R. Pt 46 (relating to the informed consent of human subjects). The Rhode Island Department of Health (RIDOH) applauds the intent of the bill, which is focused on protecting the rights of patients, RIDOH offers the following amendments on page 2, line 21 for consideration. RIDOH's suggested amendments are in green font.

(ii) No facility shall be required to inform prospectively the patient of the proposal and the patient's right to refuse to participate when: (A) The facility's human-subjects research involves the investigation of potentially lifesaving devices, medications, and/or treatments and the patient is unable to grant consent due to a life-threatening situation and consent is not available from the agent pursuant to chapter 4.10 of this title or the patient's decision maker if an agent has not been designated or an applicable advanced directive has not been executed by the patient; ~~and~~ ~~or~~ and (B) ~~The facility's~~ An institutional review board approves the human-subjects research pursuant to the patient consent and/or de-identification requirements of 21 C.F.R. Pt. 50 and/or 45 C.F.R. Pt. 46 (relating to the informed consent of human subjects). Any healthcare facility engaging in research pursuant to the requirements of this paragraph (10)(ii) shall file a copy of the relevant research protocol with the department of health, which filing shall be publicly available.

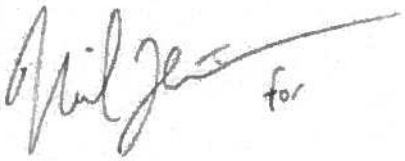
RIDOH believes that in situations where the patient cannot provide consent (i.e., patients with cognitive disability and/or those who are unconscious), the "and" (not "or") should remain to connect the inability to provide informed consent with Institutional Review Board (IRB) approval. Research performed on patients who cannot provide consent requires oversight, which would no longer be required by this statute if the "and" was changed to "or". If the intent of H 7301 is to allow research without consent in other settings allowed by federal law (i.e., situations with a

minimal patient risk where the research cannot be done without waiving consent), then a potential solution would be to delete clause (A) and just require IRB oversight under federal IRB rules. If clause (A) is not deleted, then RIDOH strongly suggests not changing "and" to "or".

RIDOH supports the other proposed changes on page 2, line 21 as well as the proposed changes on page 2, lines 22 and 23. The current statutory wording unnecessarily limits the ability of smaller institutions to participate in research and is inconsistent with a 2018 federal regulation requiring a single IRB for multi-site research projects. The updated language addresses those issues.

I thank you for the opportunity to comment on the proposed legislation and would be happy to work with the sponsor(s) and members of the Committee to work on proposed amendments.

Sincerely,



Utpala Bandy, MD, MPH
Interim Director

CC: The Honorable Members of the House Committee on Health and Human Services
The Honorable Mia A. Ackerman
Nicole McCarty, Chief Legal Counsel
Lynne Urbani, Director of House Policy