

Amend or Reject S-2394A/H-7301B, Relating to Non-Consensual Patient Research

The Office of the Mental Health Advocate and the ACLU of Rhode Island strongly urge you to amend, or else reject, 24-S 2394A and H-7301B when they come to the floor for a vote. A last-minute amendment that has been included in the Sub A/B versions of these bills raises troubling issues of accountability and transparency from our perspective.

These bills would allow healthcare facilities to conduct certain human-subject research without following the standard protocols requiring informed patient consent and confidentiality. While any such research would need to be approved by an institutional review board and be in accordance with federal regulations governing these special circumstances, the newest version of the bills goes one step further by eliminating current language in the law [Page 2, lines 24-26] that requires healthcare facilities engaged in this type of human research **to file a public copy of their research protocol with DOH**. This requirement strikes us as a logical and important transparency safeguard for research exempting itself from the usual informed consent standards for medical research. We are deeply concerned that these bills now seek to eliminate that safeguard and could disproportionately leave in the dark both vulnerable patients who are unable to advocate for themselves and the advocates representing their interests.

There has been no testimony explaining the origin of, or rationale for, this last-minute deletion. We urge the Senate to reinstate the stricken language on Page 2, lines 24-26 before approving the bill, or else to vote it down. There are too many examples of scientific human research conducted in secret that have not only had enormous adverse ramifications for vulnerable populations, but have also had the unfortunate by-product of generating skepticism in medical research with deleterious consequences for all.

Thank you for considering this.

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