RHODE ISLAND MEDICAL SOCIETY

Honorable Susan Donovan
Chair
House Health & Human Services Committee
Room 135
State House
Providence, RI 02903

Re: 24H-7301

SUPPORT (FOR)

February 29, 2024

Dear Chairman Donovan,

The Rhode Island Medical Society would like to thank Representative Ackerman for introducing H 7301, An Act Relating to Health and Safety – Licensing of Healthcare Facilities. This bill allows the 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.

This legislation will support the research opportunities at local institutions while ensuring patient consent and/or de-identification requirements are met through their Institutional Review Boards (IRBs). According to the Food and Drug Administration[i] an IRB is group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

We strongly encourage you and your committee members to act favorably on this important legislation.

Founded in 1812, the Rhode Island Medical Society (RIMS) is the eighth oldest medical society in the country. RIMS is the vehicle by which the medical community in Rhode Island meets the evolving challenges of medical practice and quality patient care.

Please let us know if we can provide any additional information or if you have any questions on our testimony. Thank you.

Sincerely,

Heather Smith, MD, MPH
President

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[i] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/institutional-review-boards-irbs-and-protection-human-subjects-clinical-trials