BIOETHICS.TECH
THE FOUNDATION FOR BIOETHICS IN TECHNOLOGY

STUDY GUIDE FOR LEGISLATORS

H7337 – Biotechnology Regulatory Sandbox Act

1. What This Bill Is Actually Authorizing

H7337 authorizes time-limited regulatory exemptions for biotechnology products and services under a "sandbox" framework. While framed as innovation policy, the bill enables experimentation involving biological systems, human subjects, and sensitive biological data.

This places H7337 within the domain of human-subject governance and biological pollution control, whether the bill names it or not.

2. A Sandbox Does Not Remove Risk — It Concentrates It

Regulatory sandboxes do not eliminate risk. They concentrate risk by:

- reducing oversight,
- accelerating deployment,
- and shifting uncertainty onto participants.

When biological systems or human bodies are involved, concentrated risk demands heightened protections, not relaxed ones.

3. Disclosure Is Not Informed Consent

H7337 relies on disclosure and acknowledgment requirements. These mechanisms are not equivalent to informed consent.

Informed consent requires:

- a meaningful ability to refuse participation,
- a clear right to withdraw without penalty,
- understanding of risks, data use, and downstream consequences,

- and protections against coercion or dependency.

Absent these elements, disclosure functions as a liability shield rather than an ethical safeguard.

4. Biotechnology Operates in a Pollution Context

Biotechnology experimentation does not occur in isolation. It occurs within biological, neurological, and environmental systems.

When experimentation involves:

- human biological material,
- genetic or biometric identifiers,
- neural or cognitive data,
- or experimental interventions,

it creates the potential for biological and informational pollution.

Pollution is defined by externalized impact, not intent.

Failing to name pollution does not prevent harm.
It prevents accountability.

5. Risk Asymmetry Is a Governance Choice

Under H7337:

- developers receive regulatory flexibility,
- the state accelerates experimentation,
- and participants bear uncertainty.

This asymmetry shifts risk away from innovators and onto individuals and communities. Even without bad intent, such structures predictably produce harm.

Ethical governance exists to correct this imbalance not to normalize it.

6. Oversight Cannot Be Promotional and Protective at the Same Time

H7337 places oversight authority within agencies tasked with fostering innovation. When development incentives and ethical enforcement share the same structure, a **structural conflict of interest** arises.

Ethical review must be:

- independent,
- explicit,
- enforceable,
- and insulated from commercial pressure.

Aspirational ethics language is not a substitute for statutory protection.

7. Why Data Limits Are Non-Negotiable

Biological, genetic, biometric, and neural data are **not consumer data**. Once collected, they are difficult or impossible to meaningfully revoke.

Without strict limits on:

- secondary use,
- retention,
- sale or transfer,

biological data becomes a permanent extraction rather than a controlled experiment.

.

8. The Question Before the Legislature

The question before Rhode Island is not whether innovation should proceed.
It is whether human beings are governed as rights-bearing participants or treated as test environments.

.

9. Core Principle

Innovation must not advance by externalizing biological risk onto the public.
Ethical governance must precede experimentation, not follow harm.

Once harm is normalized, it is no longer preventable, only litigated.

STAY HUMAN EVERYONE!

The Foundation for Bioethics in Technology is a non-political, non-profit 501(c)(3) organization proudly headquartered in Rhode Island.
Our mission is to ensure the next generation inherits not just convenience, but dignity and freedom.
Join us in shaping the future of technology ethically because innovation without ethics is catastrophe.

All gifts and donations are tax deductible. EIN 88-1132137