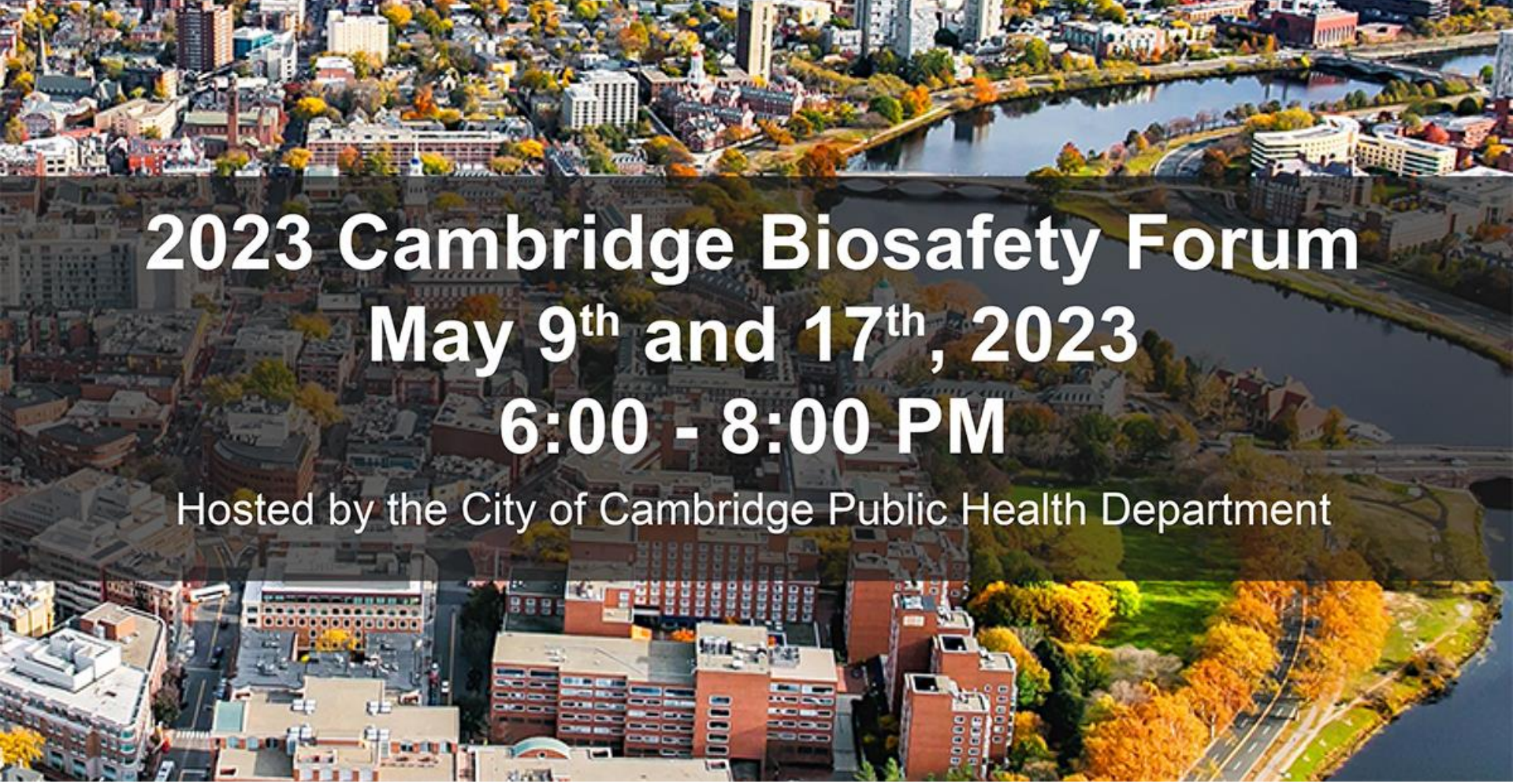


2023 Cambridge Biosafety Forum

May 9th and 17th, 2023

6:00 - 8:00 PM

Hosted by the City of Cambridge Public Health Department

Cambridge Public Health Department

CHA Cambridge Health Alliance

ENVIRONMENTAL HEALTH & ENGINEERING

SAFETY PARTNERS 1992–2017 Celebrating 25 Years

New England Biosafety Association

MASSACHUSETTS HEALTH OFFICERS ASSOCIATION MHOA

MEHA EST. 1948

MASSACHUSETTS ENVIRONMENTAL HEALTH ASSOCIATION

Thank You!

- Cambridge Public Health Department
- Environmental Health & Engineering, Inc.
- Safety Partners, Inc.
- New England Biosafety Association (NEBSA)
- Massachusetts Environmental Health Association (MEHA)
- Massachusetts Health Officers Association (MHOA)
- Current and Future Institutional Biosafety Committee (IBC) Community Representatives
- Our Mock IBC Members: Jessica Healey, Dianna Olukotun, Mayomi Omebeyinje, Marissa Cardwell, Eddie Hall, Patrick MacDonald and my fellow presenters: Julien Farland, and Erin Bryant Hall
- Special thanks to Betsy Gilman Duane

Housekeeping

- All participants will be on mute.
- To ask a question, please use the Zoom **Q&A** button.
- We will take a limited number of questions as time allows.
- The session is being recorded and the link will be available at a later date on the Cambridge Public Health website.
- If you need CEUs or CMs, additional info will be available at a later date on the Cambridge Public Health website.
- Recordings, slides, IBC and biosafety materials, CEU info will be posted
- Anyone interested in serving as a Community Rep will be prompted to send their resume to Sam Lipson after the training sessions.

Cambridge Biosafety Forum 2023

Local Public Health and Biosafety in the Life Sciences sector

Sam Lipson, REHS

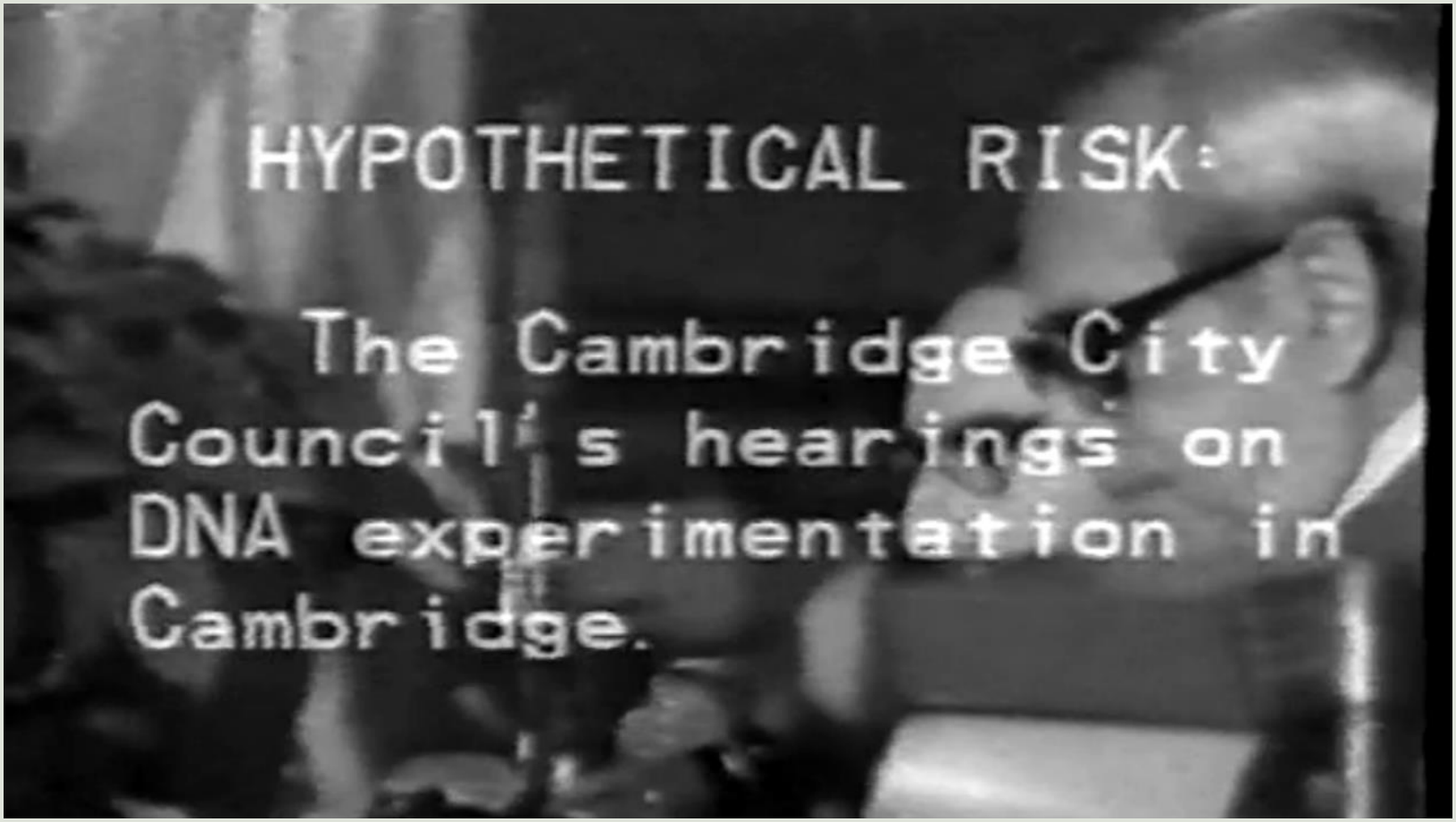
Sr Director of Environmental Health / Biosafety Committee Chair

Cambridge Public Health Department

Wednesday, May 17th, 2023

Cambridge Public Health Department | CHA Cambridge Health Alliance | City of Cambridge

1976: Biological risk emerges as a topic of public concern

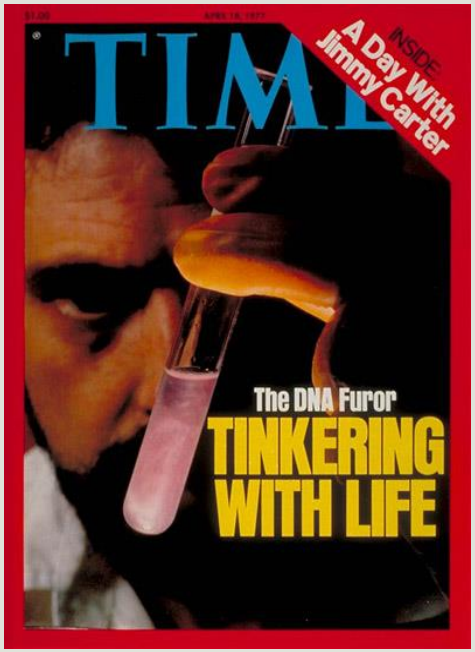


Biosafety Debate within Academia

- **General erosion of confidence in academia, military, government institutions**
- **1970s and the "Gene Scare"**
- **Scientific Review of risk (1973-75)**
  - Asilomar I (1973) – Oncogenic viruses (*SV40*)
  - Gordon (1973) – Nucleic acids & *EcoRI*
  - NAS (1974) – Caution, partial moratorium & guidelines
  - Asilomar II (1975) –rDNA risks; draft NIH Guidelines

  1) toxic gene products 2) increase virulence, AB-resistance, ecological range

  3) transfection to plant/animal cells modifying host
- **NIH promulgates biosafety standards (1976)**
- **IBCs established as mechanism for risk oversight (*community and worker risk provides rationale*)**



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Developing a Framework for Biosafety

- **NAS Committee Report (1974)**
  - A moratorium on certain experiments
  - Development of NIH guidelines for conduct and review of rDNA experiments,
- **Asilomar Summit – ("Asilomar II", 1975)**
  - **Premise:**
    - Scientists must take active responsibility for risks posed by their research activities
  - **Outcomes:**
    - Reaffirmation of the need for guidelines
    - Establishment of a new federal oversight committee (rDNA Advisory Committee – RAC)

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Lab Worker Safety & Community Risk

Factors driving occupational and public health risk

- Risk Group of agent (1-4)
- Infectivity (dose)
- Pathogen virulence
- Toxicants / Toxins
- Environmental stability
- Aerosolizing procedures
- Gene product function
- Pathogen host range
- Route/ease of transmission
- Vaccine availability & safety
- Availability/efficacy of Tx
- Latency of symptoms
- Disease surveillance systems
- Public Health infrastructure

Benefits of Local Regulations that adhere to the NIH Guidelines/BMBL

- **Increases internal commitment to worker safety, risk awareness**
  - Institutional Biosafety Committees (IBCs): safe lab practices, training, containment
- **Companies get more predictable regulatory oversight; public credibility**
  - MassBio grades communities based on their "readiness", e.g. local regulations based on NIH Guidelines

    https://www.massbio.org/initiatives/bioready-communities/
- **Public gains confidence through transparency and greater accountability**
- **Public participation on IBCs results in good will and credibility over time**
  - Recent controversies related to lab buildouts in Cambridge entirely focused on nuisance impacts and housing stock. Dramatic contrast with fear driving debates in outlying municipalities. Cambridge residents feel protected by the process.
- **Community involvement informs residents, demystifies sector**

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Public Perception of Risk is Dynamic

- **Routine biotech work has been widely accepted - mostly BSL-1/ BSL-2**
  - Impacts beyond biological risk have replaced earlier concerns: **noise, light, parking**
  - More recently: social media including some disinformation has been a barrier to adoption of local zoning and ordinance changes to allow certain BSLs
- **Public still concerned about high-risk research, known threats**
  - Biological/Chemical/Radiological as agents of terror (CBRNE)
  - Biological weapons research and Dual-Use Research of Concern (DURC)
  - Both emerging pandemics and the Gain-of-Function studies needed to study them
  - BSL-3 & BSL-4 lab buildout across US (e.g. BU NEIDL), esp. when fully private
- **Public focus has also shifted to applications of rDNA tech**
  - GM foods / Patent control over seed stock
  - mRNA vaccines / Biopharmaceutical safety, efficacy, safety, access, and cost
  - Gene therapy / CRISPR-enabled bioengineering of human zygotes

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Pursuing a Culture of Accountability

- **IBC governance represents a compromise**
  - Self-governance by researchers with broader public accountability
- **Emphasis on biological risk assessment and discussion**
- **IBC authority – Wide discretion allowed, but rationale expected**
- **Biotech tools and source materials are constantly changing**
  - Risk-based judgement, experience and training are needed to manage new risks
  - Much more nuance involved than with chem, rad or materials hazards
- **Transparency, strong safety culture contribute to public assurance**
- **Emerging and related challenges:**
  - Laboratory incubator facilities and “science hotels”
  - Complex lab ecosystem (CROs, M&As, high staff turnover)
  - Biotech sector expanding into areas with limited local oversight or transparency
  - Animal care and use standards, oversight

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Developing local biosafety regulations

***Several questions/issues need to be addressed before proceeding*:**

- **Will oversight include health regulations or only special land-use requirements?**
  - e.g. BSL-3 zoning restrictions only
  - Emphasize safety practices and accountability vs. location-based risk
- **Will BSL-1 through BSL-3 be allowed? BSL-1 and BSL-2 only?**
- **Municipal/county biosafety committee**
  - Less public participation **may require fewer health department resources**
  - Less public participation **may limit public trust and familiarity with sector**
- **Determine whether regulations will include Animal Care Facilities**
  - Cambridge has laboratory animal permitting program (rare). Consulting model
- **Hybrid registration/permitting approach**
  - **BSL-1**: Registration / **BSL-2**: Standard permit / **BSL-3:** Permit with enhanced permit requirements and special land use requirements and restrictions
- **Local Public Health has been the anchor for oversight in MA**

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Permit holder responsibilities

- Comply with NIH Guidelines, BMBL and local requirements
- Establish an IBC per NIH Guidelines, incl. community members
- Appoint a Biosafety Officer (BSO) – primary compliance role
- Identify 2 Community Members (or local BOH) - orientation
- Provide IBC members training in content under review
- Establish med surveillance, post-exposure protocol, reporting reqs
- Report potentially infectious exposures (bites, punctures, cuts)
- Documentation: IBC minutes, protocols, rosters, Biosafety Manual
- Present to the Biosafety Committee or Health Department
- Some towns don't require presentation to BOH/Biosafety Cmtes

Applicant Presentations

- Purpose of Research - Mission
- Overview of rDNA procedures, vectors, agents
- Summary of biological agents by BSL, infectious agents
- Floor Plans: Lab areas by BSL, access, waste removal
- Medical surveillance provider or in-house capacity
- Summary of safety practices, training, lab policies
- Permit compliance (flammables, gases, rad, sewer, plumbing, chem)
- Service Contracts: biowaste, chem waste, pest control, air balance

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Laboratory Inspections

- Determine capacity and cadence for inspection/re-inspection
- General lab conditions, gowning, handwashing stations
- Storage and flow of consumable supplies
- Biological & chemical waste removal path, interim storage
- Wastewater treatment/pH neutralization
- Lab Signage (emergency info, biohazard, BSL, biological materials or agents present, special practices)
- Certification of air balance/BSCs/chem hoods
- General ergonomics, noise, and worker safety
- Governance (review IBC requirements, minutes, members)
- Virtual inspections for minor changes, expansions (photos)

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Further notes on BSL-3 Laboratories

- BSL-3 facilities/practices are designed to manage higher biological risk (virulence, ability to treat, respiratory pathways)
- Much more likely to contain infectious pathogens that remain "replication competent" (capable of infecting a person)
- Engineering standards in US for BSL-3 labs are very high, but validation that completed lab includes required air controls and other safety features requires detailed 3rd-party commissioning
- Emphasis on safety trainings and protocols in reviewing risks
- Additional costs to retain safety consultants for application review and lab inspections should be funded by permit fees
- Fire Department orientation to facility, drills, intro to biorisk
- Even without a complete biosafety permitting program Bay Area counties should adopt uniform BSL-3 land-use rules and permits

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Summary of recommendations

- Local BOHs should consider staff capacity, allowable BSLs, and animal research requirements before promulgating regs
- Life Sciences labs mostly use non-infectious agents (BSL-1/BSL-2), some live agent work . Very low community risk
- Local biosafety regulations reduce risk, improve incentives for good practice, engender public trust. Public Biosafety Committees may be appropriate in some communities
- Labs using funds from most federal agencies are required to meet NIH regs and reporting standards (not private labs)
- Community Members on IBCs bring accountability and trust
- Making IBCs transparent and accountable to BOHs works to bring predictability (applicant) and credibility (residents)

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YouTube Videos: Early debates over biosafety and the newly emerging biotech sector

From Controversy to Cure - Inside the Cambridge Biotech Boom
MIT Video Productions
https://youtu.be/L2SbS0tNTXQ

Asilomar '75: The Beginning of the Future
NIH Office of Science Policy
https://youtu.be/g23oM-VqT_M

Cambridge Public Health Department

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Department

Sam Lipson, REHS

Sr. Director of Environmental Health

Chair, Cambridge Biosafety Committee (1998-present)

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www.cambridgepublichealth.org/laboratory-biosafety

Questions

1) How much training is needed for a BOH staff person to properly review biosafety applications and compliance documents (protocol summaries, biosafety manuals, IBC minutes)?

2) Can you describe how you conduct inspections? Are they announced? Do you use a checklist? What do you look for?

3) What improvements or quality checks do you recommend to institutions when evaluating IBC minutes? Are there best practices for IBC minutes they should keep in mind?

4) What kinds of laboratory exposures and incidents are reportable to the BOH? Is this specified in the local regulations?

5) How does a BOH retain the potentially sensitive information from the applicant (presentation slides, protocol summaries, IBC minutes)? See MA Public Records law (see Chapter 66, MGLA for exemptions from public records requests)

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Local Oversight of Laboratory Animal Use

Erin Bryant Hall, DVM, DACLAM, MPH
Commissioner of Laboratory Animals
City of Cambridge, MA

Wednesday, May 17th, 2023

Cambridge Public Health Department | CHA Cambridge Health Alliance | City of Cambridge

ebryanthall@cambridgepublichealth.org
https://www.cambridgepublichealth.org

Existing regulations governing animal use

		Funding Status: Private	All Vertebrate Species	Applicable notes
1	Animal Welfare Act/Regulations (USDA)	✓	X	• Covers all "warm-blooded" animals except for mice and rats of certain genera and birds bred for research, and farm animals used for agriculture research • Applies to all research institutions with covered species
2	PHS Policy/HREA/ *Guide for the Care and Use of Laboratory Animals*/NIH/OLAW	X	✓	• Covers rats, mice, birds, and fish • Only applicable to research receiving federal funds

Possible exceptions:

- Institutional AAALAC accreditation status (voluntary)
- Journals requiring institutions to comply with the Guide for manuscript publication (e.g. Science)

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Cambridge Ordinance and History

- Ordinance passed in 1989; first and only of its type in the country
  - Directs the CLA to oversee the care and use of laboratory animals in the city
  - “All experiments on all animals within the City shall be undertaken in conformity with all federal . . . regulations concerning the welfare of animals including the Guide for the Care and Use of Animals of the National Institutes of Health, the "Animal Welfare Act" (7 U.S.C. sections 2131, et seq.), the Health Research Extension Act of 1985, the "Public Health Service Policy on Humane Care and Use of Laboratory Animals"

Other nearby local regulations

- e.g. Everett, Revere

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Questions

1) What are the existing regulations applicable to using animals in biomedical research?

2) What are potential options for developing local regulations governing animal research at the municipal level?

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