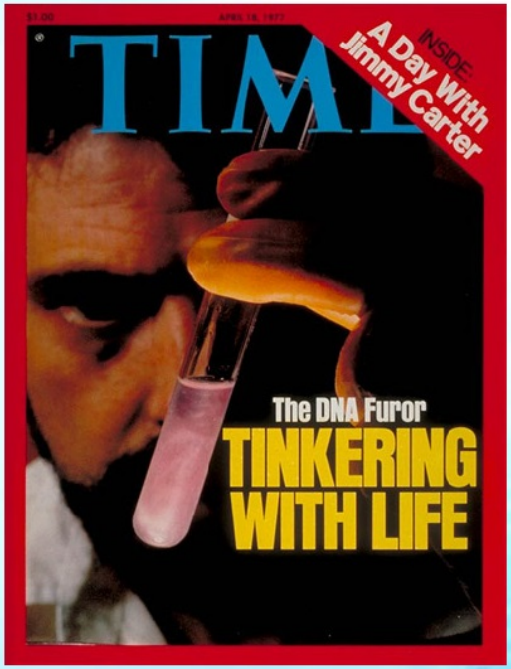
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

Samuel Varghese, Ph.D.

Director, IBC/IACUC

Mid-1970's

- Emergence of recombinant DNA technology (mid-1970's)
- Concerns among both scientific community and general public
  - Public health and safety
  - Environmental impact
  - Potential ethical and social implications



Establishment of IBC

- **Established specifically for the review of recombinant and synthetic nucleic acids.**
  - **1972: Creation of recombinant DNA (rDNA) molecules**
  - **1974: NIH created "Recombinant DNA Advisory Committee (RAC)"**
  - **1973 & 1975: Asilomar conferences considered the safety issues associated with rDNA**
  - **1976: NIH issued "Recombinant DNA Research Guidelines"**
  - **1980: First Gene Transfer studies in Europe**
  - **1889: First Gene Transfer studies in US**
- **IBC often reviews other research with biohazardous risks**
  - **Broader purview is a matter of institutional discretion**

Purview of UMMS IBC

- **Recombinant and Synthetic Nucleic Acids**
  - **NIH (OBA, RAC)**
- **Human and Primate Materials**
  - **OSHA**
- **Infectious Agents**
  - **CDC**
- **Biotoxins**
  - **NIH, CDC, OSHA**
- **Select Agents**
  - **CDC & USDA**
- **Dual Use Research of Concern (DURC)**
  - **NIH**

IBC (Composition and Responsibilities)

- 20 Committee Members (3 are community members)
  - Experts in different scientific disciplines, biological safety, public health issues and regulations
- IBC Charter and registers with NIH
- Meets once a month
- Responsible for:
  - Oversight of studies involving the use of all biological hazards
  - Establishing institutional policies and guidelines for biological safety
  - Reviewing and approving protocols
  - Assigning appropriate biocontainment for studies
  - Reviewing and approving Standard Operating Procedures (SOPs)
  - Reporting of adverse incidents to NIH and other agencies

2014 Statistics

- >310 active protocols
  - Protocols are active for 5 years, but require annual update
- ~200 Principal Investigators
- >1200 Personnel working with biological hazards at UMMS
- Median approval time: 31 days

Studies Applicable to CRPG
Gene Therapy

- Introduction of foreign nucleic acids into humans
  - Direct introduction synthetic or recombinant nucleic acids into human subjects
  - Introduction of cells modified with recombinant or synthetic nucleic acids into human subjects
- Each study requires a separate IBC protocol
- Requires IRB review
- May require RAC review
- IBC needs to review IRB protocol, Investigator's Brochure, Sponsor's Study Protocol, and Informed Consent
- Should receive IBC approval prior to patient enrolment

Studies Applicable to CRPG

Working with Human Samples

- Processing and storage of:
  - Blood
  - Other body fluids
  - Tissues
  - Organs
  - Cells
  - Established cell lines

Studies Applicable to CRPG

Working with Human Samples (cont'd)

- One blanket protocol can cover several clinical trials
- IBC application should list:
  - All procedures
  - All personnel
  - All locations
- All personnel must complete appropriate training
- Should maintain a Biosafety Manual in the Laboratory

Questionnaire to determine if IBC registration and approval is required for a project involving human subjects

1. Does the protocol involve administration of any of the following to human subjects?
   a) Recombinant or synthetic nucleic acids (e.g. recombinant viral vectors for gene therapy, DNA immunization)
   b) Cells, tissues or other biological products that were previously modified by recombinant or synthetic nucleic acids (e.g. harvested stem cells modified with recombinant viral vectors)

☐ YES ☐ NO

If the response is "YES", then a separate IBC registration for the protocol is required.

2. Does the protocol involve processing/manipulation and/or storage of human samples (blood, saliva, tissues, etc.) in a research laboratory covered by a blanket (lab-wide) IBC approval?

Examples of clinical research laboratories with blanket IBC approval:

- Clinical Research Center Lab; AC1-044, AC1-037 and AC1-039
- Department of Anesthesiology Clinical Research Labs; S2-746 and S2-718

☐ YES ☐ NO

If the response is "YES", then please provide the following information to the IRB:

   a) The laboratory name and locations
   b) The IBC docket number that documents approval for processing/manipulation and/or storage of human samples for clinical protocols at this laboratory location

If no IBC registration (docket number) already exists for the research laboratory location to be used, then a new IBC registration for the laboratory must be submitted.

Note: A single IBC registration for a research lab may cover any number of clinical protocols that ONLY involve processing/manipulation and/or storage of human samples at that particular laboratory location. It is not necessary to submit an IBC registration for each new clinical protocol as long as an approved clinical research lab location is being used.

An IBC registration is NOT required if:

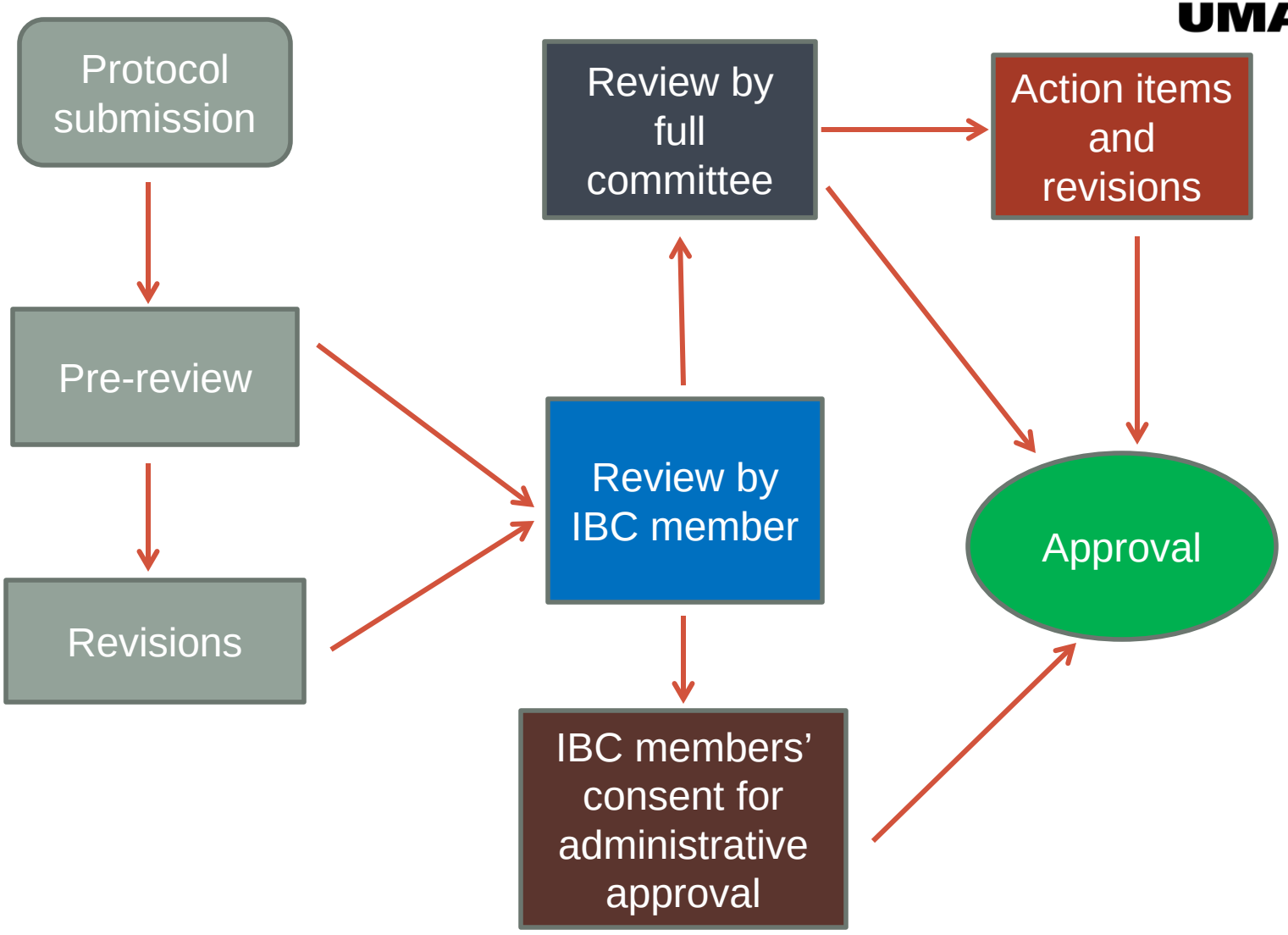
- The protocol ONLY involves sending human samples to the UMMHC clinical laboratories.
- The protocol ONLY involves packaging human samples to be sent to a central laboratory.

IBC Registration Form

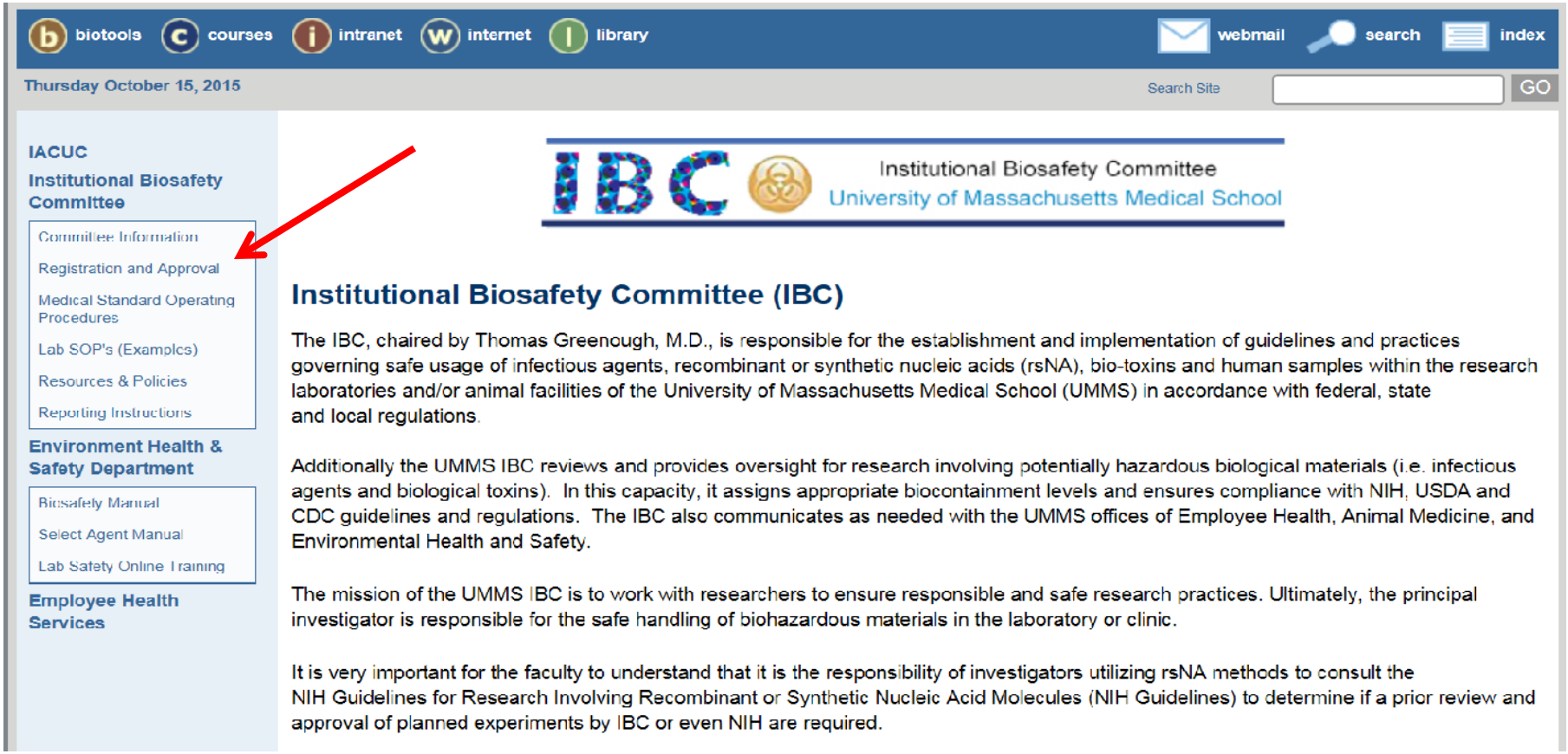
Applicable sections for Human Materials

- Face page
- Section A: Project Summary
- Section D: Material of Human Origin
- Section H: Management of Biohazards
- Section I: Plans for Accidental Exposures
- Section J: Biocontainment and Biosafety Precautions
- Section H: List of personnel

IBC Review Process



IBC Website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Committee Information
Registration and Approval
Medical Standard Operating Procedures
Lab SOP's (Examples)
Resources & Policies
Reporting Instructions
Environment Health & Safety Department
Biosafety Manual
Select Agent Manual
Lab Safety Online Training
Employee Health Services
IBC
Institutional Biosafety Committee
University of Massachusetts Medical School
Institutional Biosafety Committee (IBC)
The IBC, chaired by Thomas Greenough, M.D., is responsible for the establishment and implementation of guidelines and practices governing safe usage of infectious agents, recombinant or synthetic nucleic acids (rsNA), bio-toxins and human samples within the research laboratories and/or animal facilities of the University of Massachusetts Medical School (UMMS) in accordance with federal, state and local regulations.
Additionally the UMMS IBC reviews and provides oversight for research involving potentially hazardous biological materials (i.e. infectious agents and biological toxins). In this capacity, it assigns appropriate biocontainment levels and ensures compliance with NIH, USDA and CDC guidelines and regulations. The IBC also communicates as needed with the UMMS offices of Employee Health, Animal Medicine, and Environmental Health and Safety.
The mission of the UMMS IBC is to work with researchers to ensure responsible and safe research practices. Ultimately, the principal investigator is responsible for the safe handling of biohazardous materials in the laboratory or clinic.
It is very important for the faculty to understand that it is the responsibility of investigators utilizing rsNA methods to consult the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) to determine if a prior review and approval of planned experiments by IBC or even NIH are required.

IBC Resources

Biosafety Training

- Coordinated by Environmental Health and Safety (EH&S) Department
  - Contact Megan Lachowski and JoAnne Ranslow
  - IBC gives EH&S the names of personnel and they follow up with training
  - EH&S uses an outside vendor “Litmos system” for training
  - Personnel will receive notifications from Litmos for training

Requirements for BSL-2

Contact BSO (Colleen Driskill) for biosafety questions

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink required
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: Limited access Biohazard warning signs "Sharps" precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers = Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPEs: laboratory coats; gloves; face protection as needed	BSL-1 plus: Autoclave available

Questions?