The IBC is:

The Institutional Biosafety Committee

National Institutes of Health has official authority over IBCs

The Changing Landscape

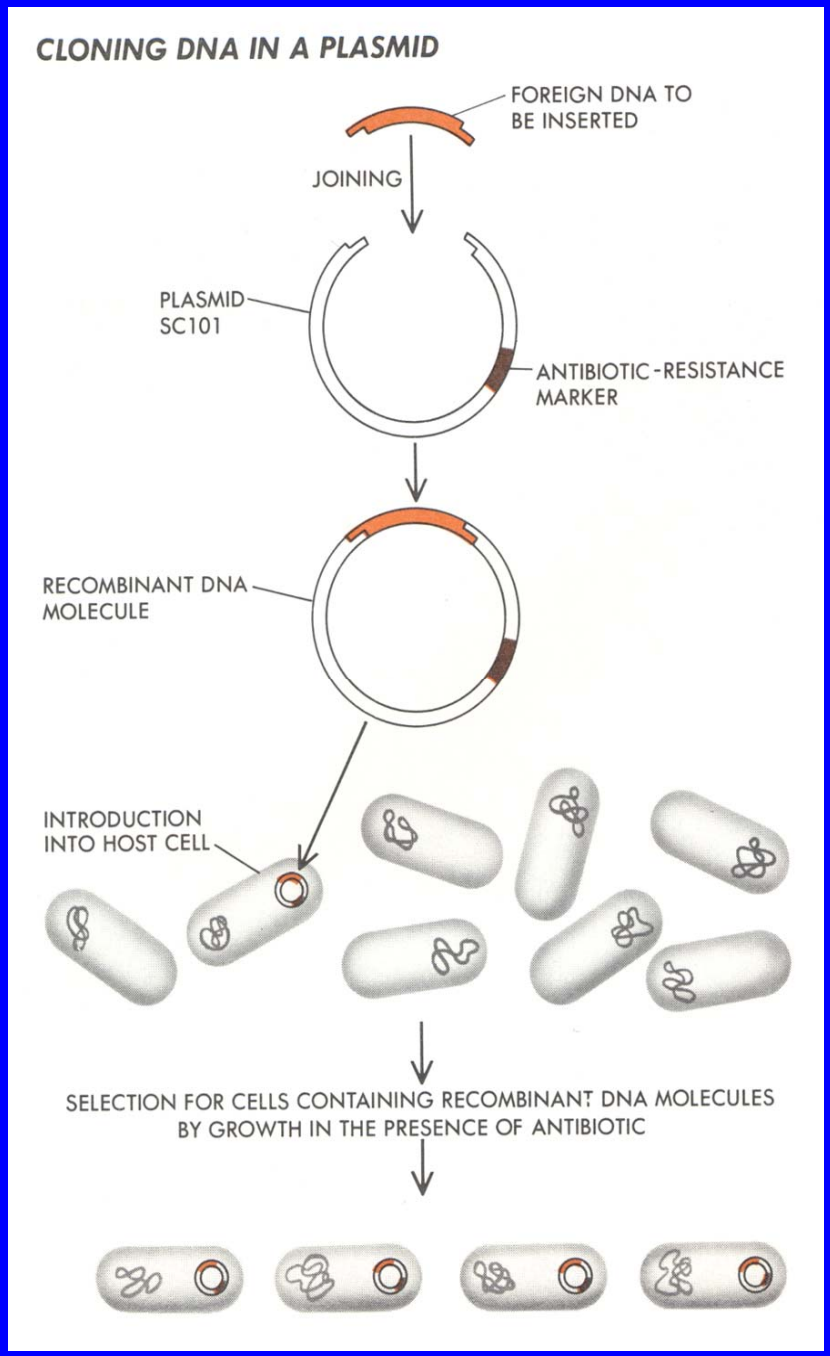
- IBCs that reside outside of traditional medical centers
- Increasing role of private sector
- Outsourcing of IBCs
- IBC consortia (regional?)
- Virtual IBCs

Issues Affecting the Landscape

- Intentional release of organisms into the environment
- Increasing use of recombinant virus vectors for gene therapy
- Growth of the private biotech sector
- Issues surrounding stem cells?
- Recent importance of bioweapons?
- Accountability and reporting practices

Key Questions about IBCs

- What?
- Why?
- Where?
- When?
- Who?


CLONING DNA IN A PLASMID
FOREIGN DNA TO BE INSERTED
JOINING
PLASMID SC101
ANTIBIOTIC-RESISTANCE MARKER
RECOMBINANT DNA MOLECULE
INTRODUCTION INTO HOST CELL
SELECTION FOR CELLS CONTAINING RECOMBINANT DNA MOLECULES BY GROWTH IN THE PRESENCE OF ANTIBIOTIC

What is the purpose of an IBC?

- To ensure adequate containment of potentially hazardous biological agents
- To add a level of expert review and monitoring of potentially hazardous experiments
- To inform the public about experimental plans that have a potential to be hazardous
- To provide a means of communication among researchers and healthcare providers about potentially hazardous protocols

What long-range goals are facilitated by having an IBC?

- To conduct potentially hazardous research under controlled conditions
- To safely investigate disease processes
- To design new experimental organisms
- To devise novel biological vectors
- Others

"Somehow I was hoping genetic engineering would take a different turn."

Why is an IBC needed?

- To protect the public
- To protect the environment
- To protect the investigator
- To protect the staff

Where are IBCs needed?

- At any institution or organization funded by the U.S. Government and using recombinant DNA
- Institutions or organizations that participate voluntarily via government guidelines
- Predominantly reside in academic institutions

When is the IBC needed?

- Prior to initiation of the research
- At regular intervals during the activity
- When a change of protocol occurs
- When new technologies are introduced

Responsible units within the academic setting

- Dean
- Vice Dean for Research
- Office of Grants & Contracts
- Safety Officer
- Biosafety Committee (IBC)
- Principal Investigators

Who participates in an IBC?

- Principal Investigators
- Departmental Chairs
- University Safety Officers
- Grants & Contracts Office Staff
- The Public

Section IV-B-2-a-(1). The Institutional Biosafety Committee must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, *Physical and Biological Containment for Recombinant DNA Research Involving Plants*, require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, *Physical and Biological Containment for Recombinant DNA Research Involving Animals*, require Institutional Biosafety Committee prior approval. When the institution conducts recombinant DNA research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see Section IV-B-3, *Biological Safety Officer*). When the institution participates in or sponsors recombinant DNA research involving human research participants, the institution must ensure that: (i) the Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary); (ii) all aspects of Appendix M have been appropriately addressed by the Principal Investigator; (iii) no research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*); and (iv) final IBC approval is granted only after the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*). Institutional Biosafety Committee approval must be obtained from the institution at which recombinant DNA material will be administered to human research participants (rather than the site involved in manufacturing gene transfer products).

Membership Requirements of IBCs

- At least five members with expertise in recombinant DNA, of which there are:
- Two or more local members are not affiliated with institution
- One expert in plant biology
- One expert in animal containment principles
- A Biological Safety Officer if BL3, 4 or large scale production is used

Membership Recommendations for IBCs

- Persons with expertise in DNA, biological safety and physical containment
- Persons knowledgeable in institutional commitments, policies, laws, standards, community issues, etc.
- A member of the laboratory technical staff

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Section IV-B-2-a-(1). CONTINUED

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(i) the Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary);

(ii) (ii) all aspects of Appendix M have been appropriately addressed by the Principal Investigator;

(iii) (iii) no research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*); and

(iv) (iv) final IBC approval is granted only after the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*).

(v) Institutional Biosafety Committee approval must be obtained from the institution at which recombinant DNA material will be administered to human research participants (rather than the site involved in manufacturing gene transfer products).

Part I: What do IBCs do?

- Examine experimental protocols that are submitted with grant applications
- Evaluate the expertise of the Principal Investigator and staff to conduct the work
- Evaluate the potential dangers of the work
- Evaluate the biological containment plan and facilities per the NIH Guidelines

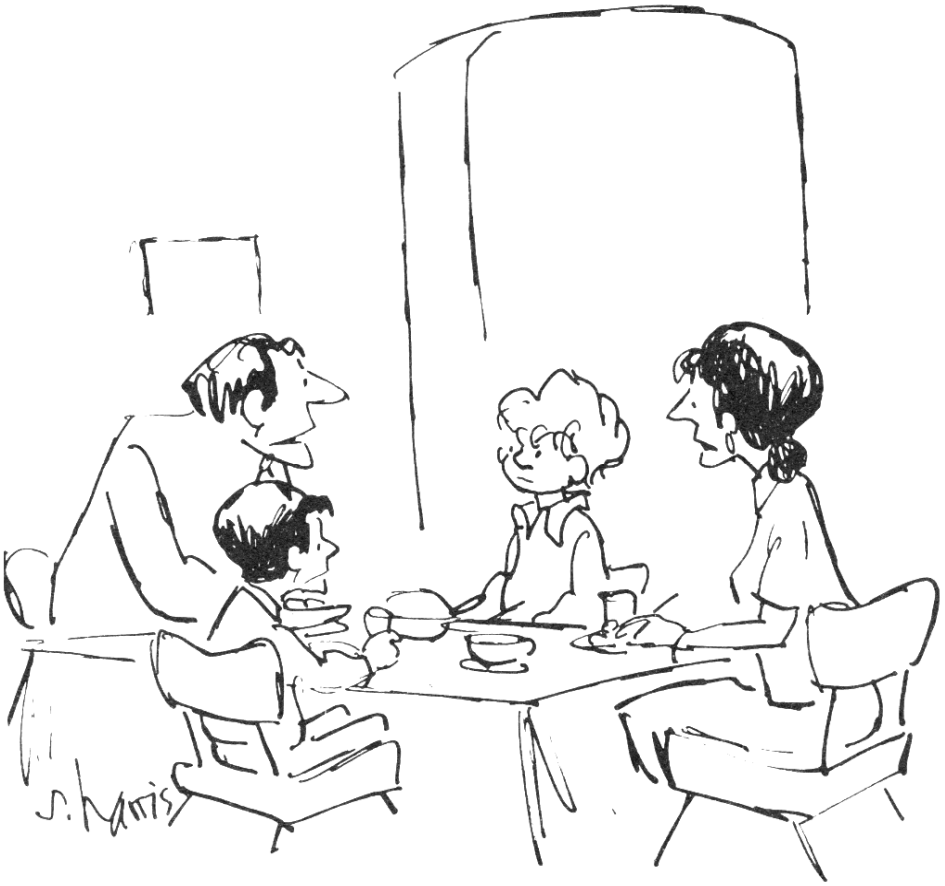
Part II: What do IBCs do?

- Determine whether additional expertise should be consulted
- Determine whether health surveillance of laboratory staff is necessary
- Request additional information from PI
- Approve or disapprove the protocol

Section III-D. Experiments that Require Institutional Biosafety Committee Approval Before Initiation

Prior to the initiation of an experiment that falls into this category, the Principal Investigator must submit a registration document to the Institutional Biosafety Committee which contains the following information:

(i) the source(s) of DNA; (ii) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions that will be implemented as specified in the *NIH Guidelines*. For experiments in this category, the registration document shall be dated, signed by the Principal Investigator, and filed with the Institutional Biosafety Committee. The Institutional Biosafety Committee shall review and approve all experiments in this category prior to their initiation. Requests to decrease the level of containment specified for experiments in this category will be considered by NIH (see Section IV-C-1-b-(2)-(c), *Minor Actions*).



'Son, I hear you failed genetics!'

Exceptions and Exemptions

- When using less than half of a virus genome
- When the host is E.coli K12 with non-conjugation proficient plasmids or phage
- If the insert does not encode a toxic protein
- When the culture has less than 10 liters
- When cloning small fragments or other innocuous components

Protective Procedures

Biological Containment
And
Physical Containment

Biological Risk Groups for classification of agents

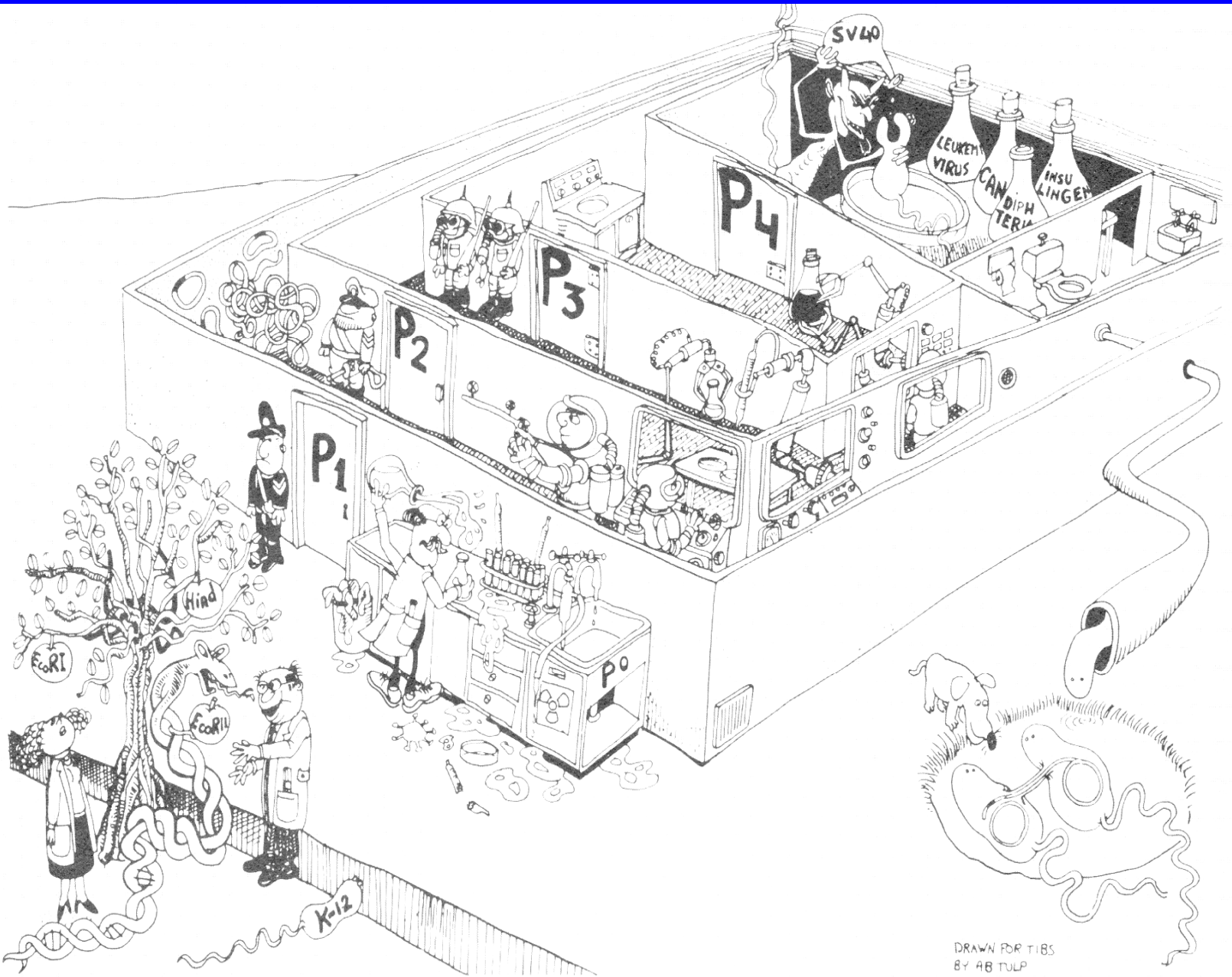
- RG1: not associated with human disease
- RG2: diseases not serious or treatable
- RG3: serious disease but likely treatable
- RG4: serious or lethal disease and treatment is questionable

Biological Containment

- Host-Vector Systems: Escherichia coli K12 using plasmids that are non-mobilizable or those that perpetuate plasmid or phage DNA in less than one in 10^8 cells
- Certification of H-V System by RAC and the Director of the NIH

Physical Containment

- Biosafety Level 1
- Biosafety Level 2
- Biosafety Level 3
- Biosafety Level 4


SV40
LEUKEMIA VIRUS
CAN
DIPH TERIA
INSU LINGEN
P4
P3
P2
P1
P0
EcoRI
HindIII
EcoRII
K-12
DRAWN FOR TIBS
BY AB TULP

Biosafety Level 1 (BL1)

- Limited access to lab
- Frequent decontamination of surfaces
- Autoclaving of waste
- Mechanical pipetting; minimize aerosols
- No food
- Hand washing
- No rodents, insects

Biosafety Level 2 (BL2)

- All BL1 requirements, plus:
- Waste is decontaminated off-site from lab
- Biosafety signs on door
- Protective clothing required
- Accidents and exposure must be reported
- May have serum testing for lab staff

Biosafety Level 3 (BL3)

- All BL1 and BL2 requirements, plus:
- Restricted access and biohazard signs
- Rigorous decontamination
- Facilities: biological safety cabinets, HEPA filters, sinks, doors, airlocks, etc.
- Protective activities: clothing, insect control, animal handling, autoclaving, other

Biosafety Level 4 (BL4)

- All BL1-BL3 requirements, plus:
- Special decontamination, dunk tanks, fumigation chambers, double doors, airlocks
- High security access, logbook, clothing changes, shower required
- Special accident reporting
- High containment animal cages
- One-piece positive pressure life-support suits available
- Maximum containment facility, double-doored autoclaves, airflow requirements and monitors

In practice, combinations of containment devices and procedures may apply and these should be evaluated by the IBC and other responsible parties

Disclaimer

The information presented here constitutes a brief synopsis. You are advised to read:

NIH Guidelines For Research Involving Recombinant DNA Molecules