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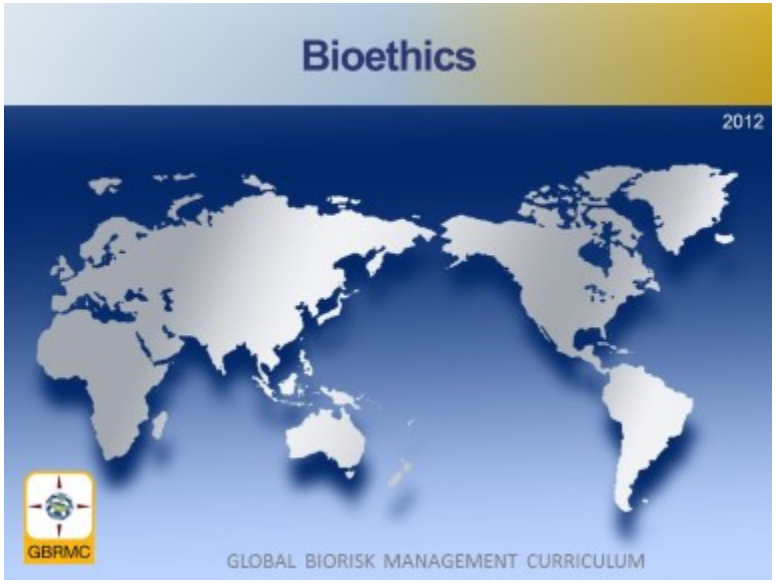
Bioethics

Student Guide

2012

GLOBAL BIORISK MANAGEMENT CURRICULUM


Bioethics
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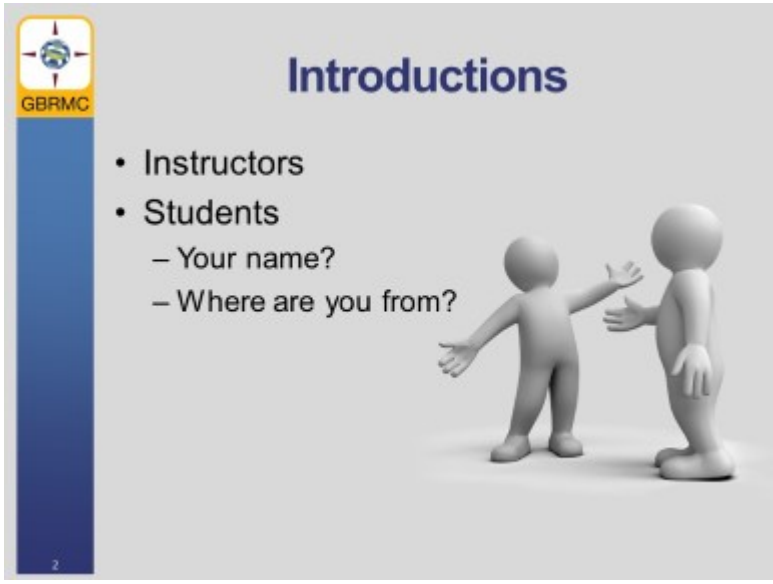
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Introductions
• Instructors
• Students
– Your name?
– Where are you from?

Action Plan

By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.

What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?

Use space on back, if needed

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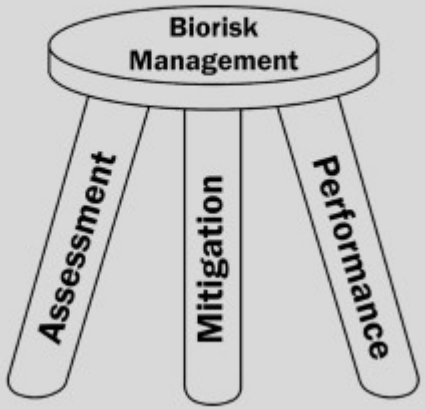
Key Messages

- Each individual is responsible for their own behavior.
- Ethical conduct is not only a key to personal integrity but reflects on the integrity of their institution.
- Bioethics is not a separate task to research but an integral part to all activities.
- In the absence of legal constraints, ethical conduct is still important as a societal benefit.

Biorisk Management: the AMP Model

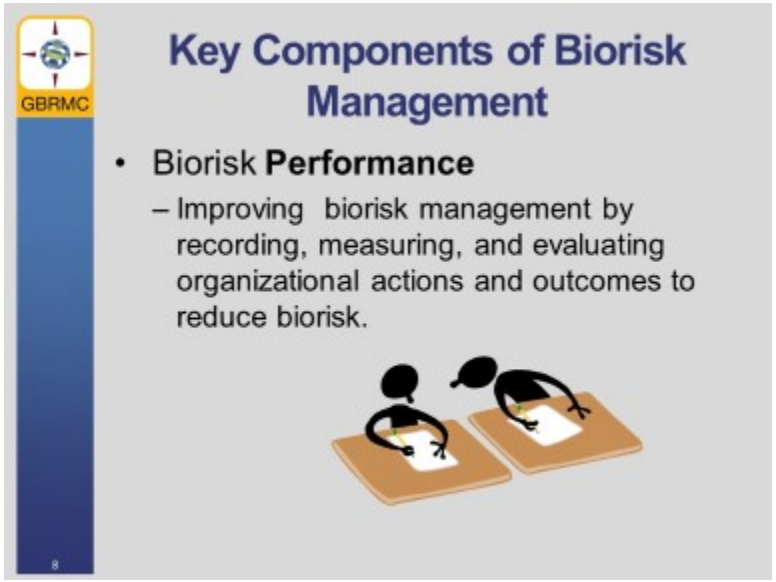


Key Components of Biorisk Management

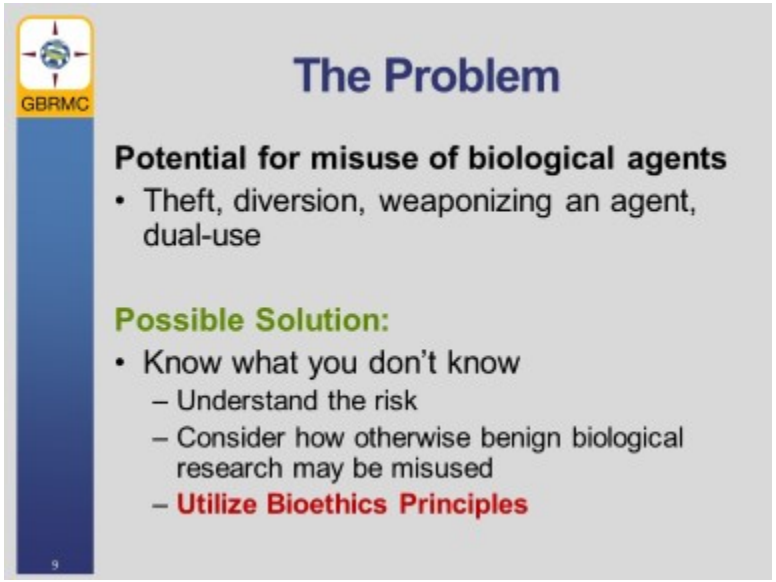
- Biorisk **Assessment**
  - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable

Key Components of Biorisk Management

- Biorisk **Mitigation**
  - Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins

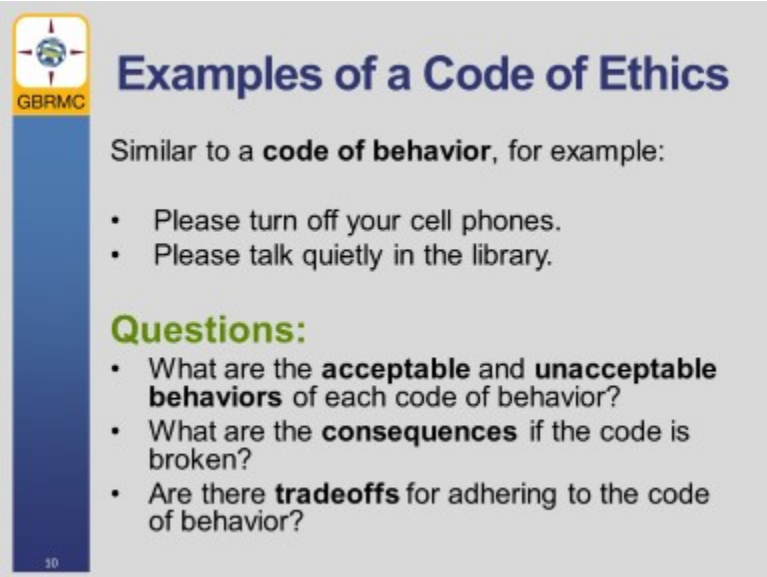


Define Performance:



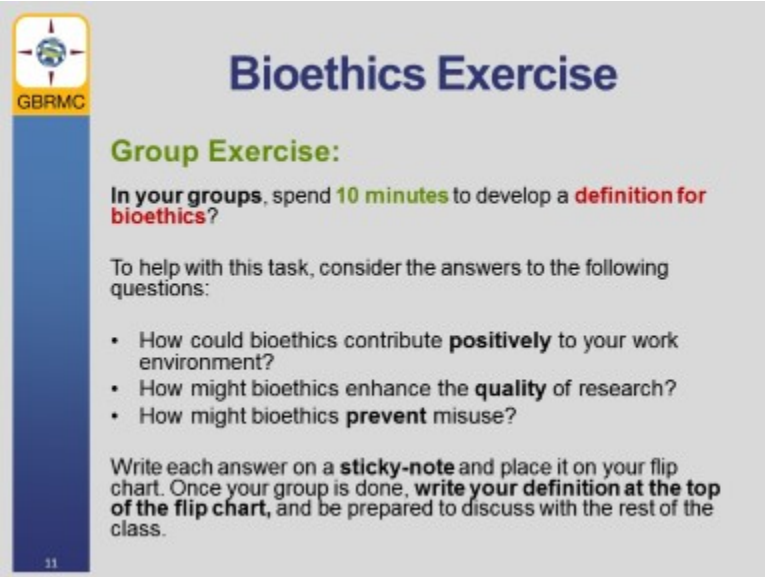
What is the problem?

What is the solution?



How are societal habits like turning off your phones during a movie or theater codes of behavior?

Can you think of another example?



Bioethics is:

How could bioethics contribute positively to your work environment?

How might bioethics enhance the quality of research?

How might bioethics prevent misuse?

Instilling Positive Bioethics

There are a number of ways to instill positive bioethical practices. Both **Regulations** and **Codes of Conduct** have been effective in promoting bioethics.

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Instilling Positive Bioethics

Regulations

- Formally using systems of **laws** or **policies** to create systems of bioethics that carry fines or other **punitive measures** if violated
  - Examples of regulatory bodies: Institutional Review Board, Biosecurity and Biosafety Commission, Animal Testing Regulations (specific regulations vary by country)

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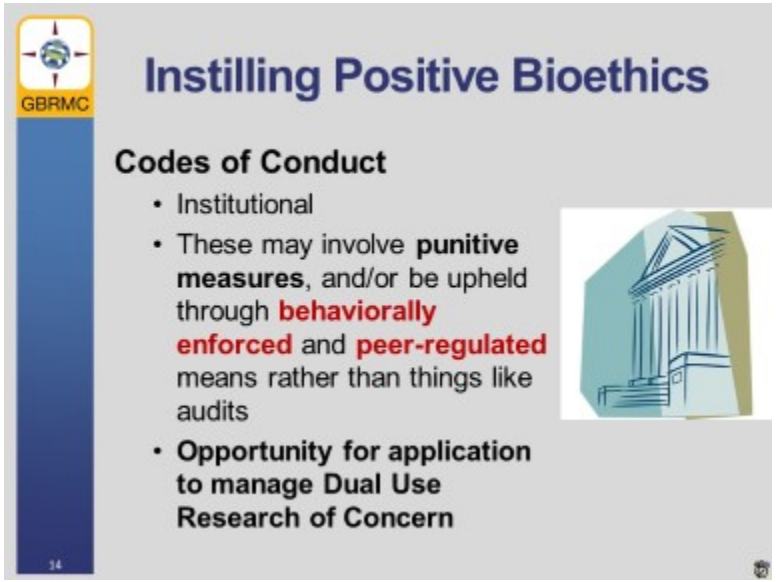
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Instilling Positive Bioethics
Codes of Conduct
• Institutional
• These may involve punitive measures, and/or be upheld through behaviorally enforced and peer-regulated means rather than things like audits
• Opportunity for application to manage Dual Use Research of Concern
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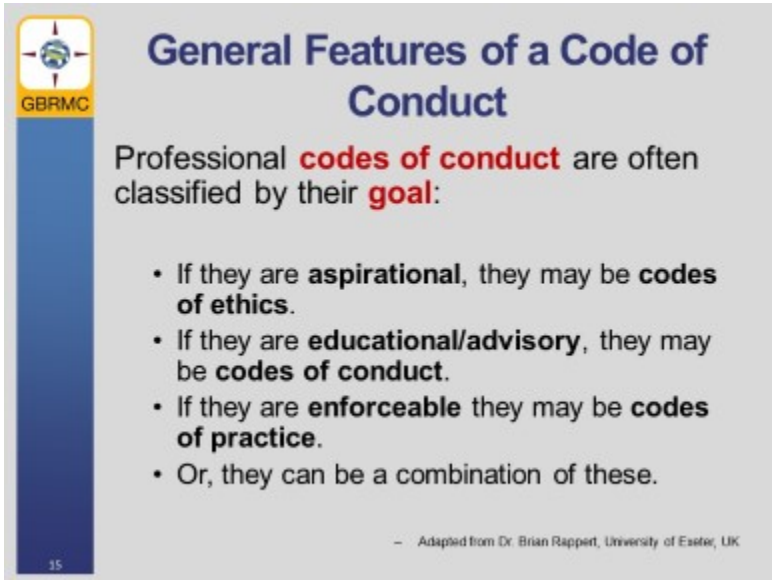
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General Features of a Code of Conduct
Professional codes of conduct are often classified by their goal:
• If they are aspirational, they may be codes of ethics.
• If they are educational/advisory, they may be codes of conduct.
• If they are enforceable they may be codes of practice.
• Or, they can be a combination of these.
– Adapted from Dr. Brian Rappert, University of Exeter, UK
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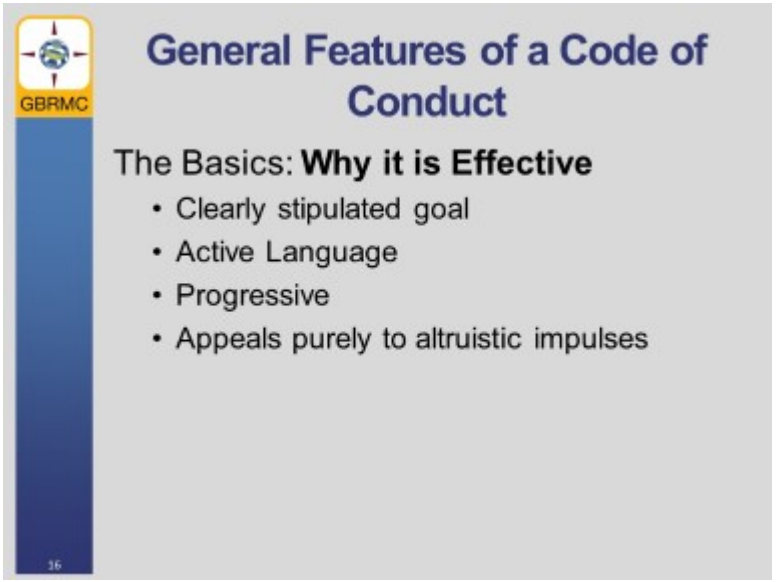
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General Features of a Code of Conduct
The Basics: Why it is Effective
• Clearly stipulated goal
• Active Language
• Progressive
• Appeals purely to altruistic impulses
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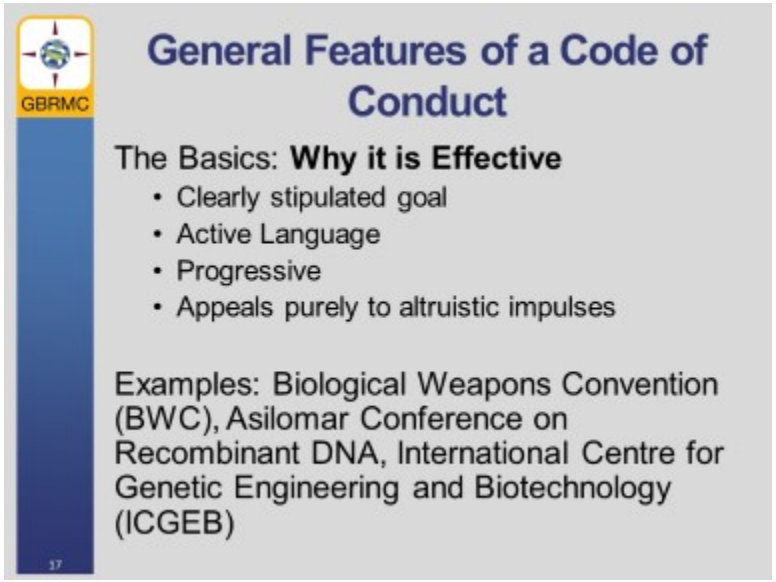
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General Features of a Code of Conduct
The Basics: Why it is Effective
• Clearly stipulated goal
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Examples: Biological Weapons Convention (BWC), Asilomar Conference on Recombinant DNA, International Centre for Genetic Engineering and Biotechnology (ICGEB)
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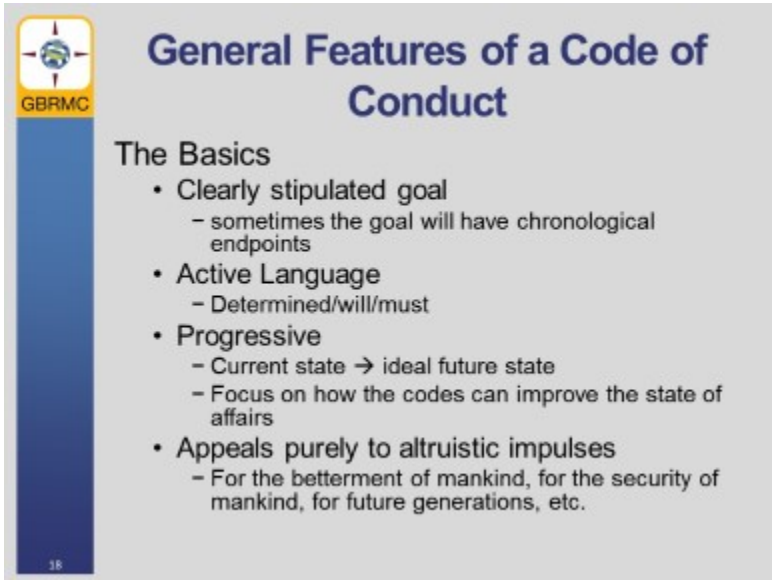


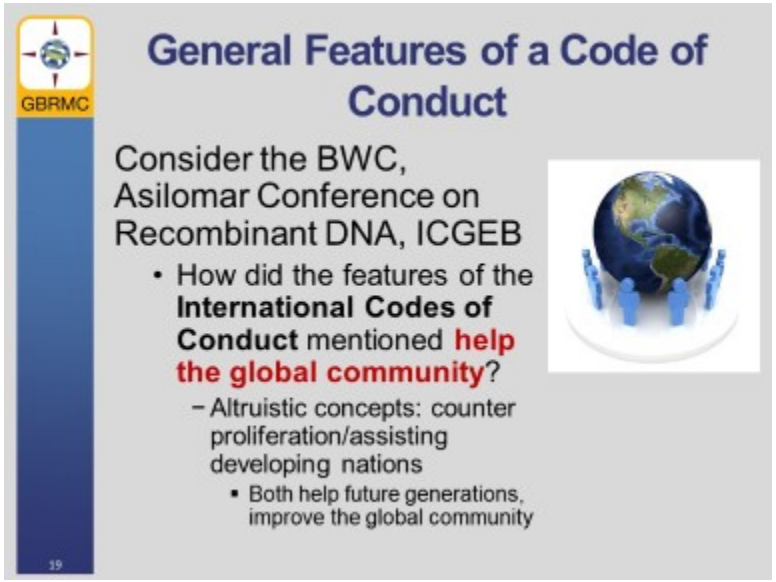
Examples:

Clearly stipulated goal:

Active Language:

Progressive

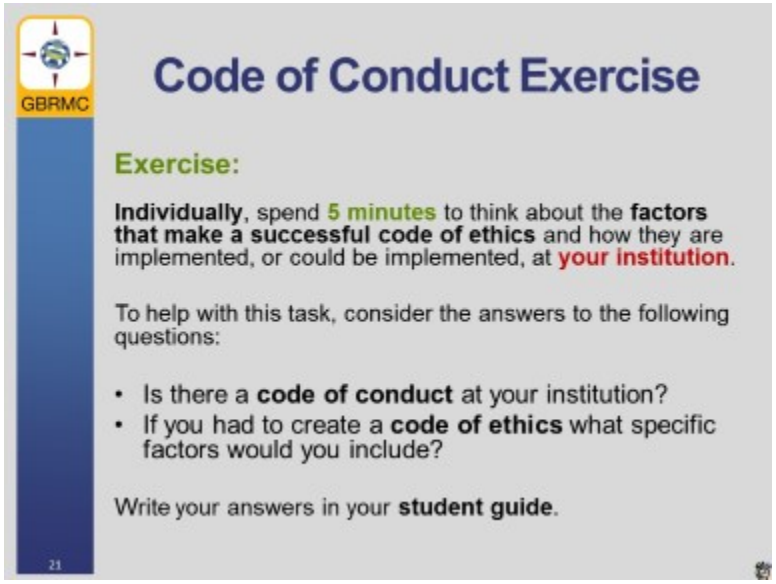
Appeals purely to altruistic impulses:



Name a few ways the examples were effective, based on the parameters outlined earlier:

Can you think of other examples that did not work? If so, why were they ineffective?

Explain why there is a two-way relationship when upholding a code of behavior. What does this mean to you?



How can you apply the factors that make a successful code of ethics at your own institution?

Is there a current code of ethics?

If you had to create a code of ethics what specific factors would you include?

What is your definition for Dual Use?

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Dual Use Updated Definition

National Security Advisory Board for Biosecurity (NSABB):

- It can be argued that virtually **all life sciences** research has dual use potential.
- Research that has the **highest potential** for misuse is classified as **Dual Use Research of Concern**.

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Identifying Dual Use Research of Concern

Criterion:

Research that…can be **reasonably anticipated** to provide knowledge, products, or technologies that could be ***directly*** misapplied by others to **pose a threat** to public health and safety, agricultural crops and other plants, animals, the environment, or material.

» NSABB

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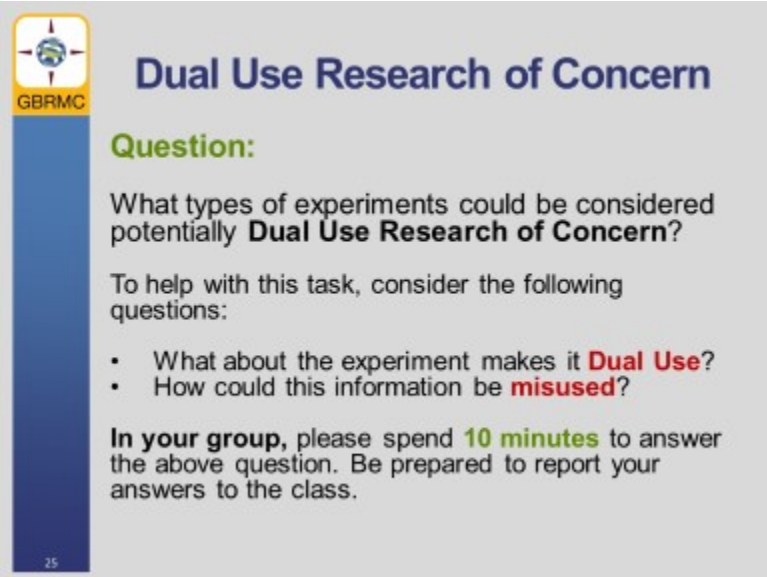
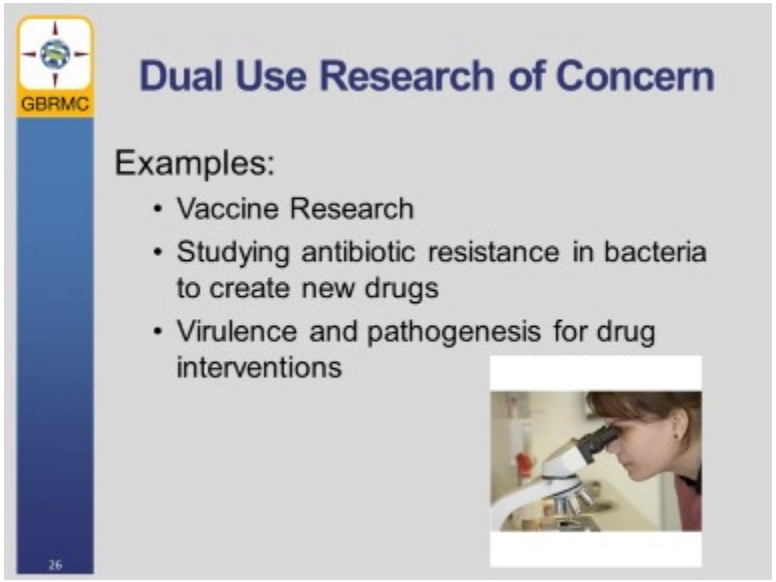


What types of experiments could be considered potentially Dual Use Research of Concern?

What about the experiment makes it Dual Use?

How could this information be misused?

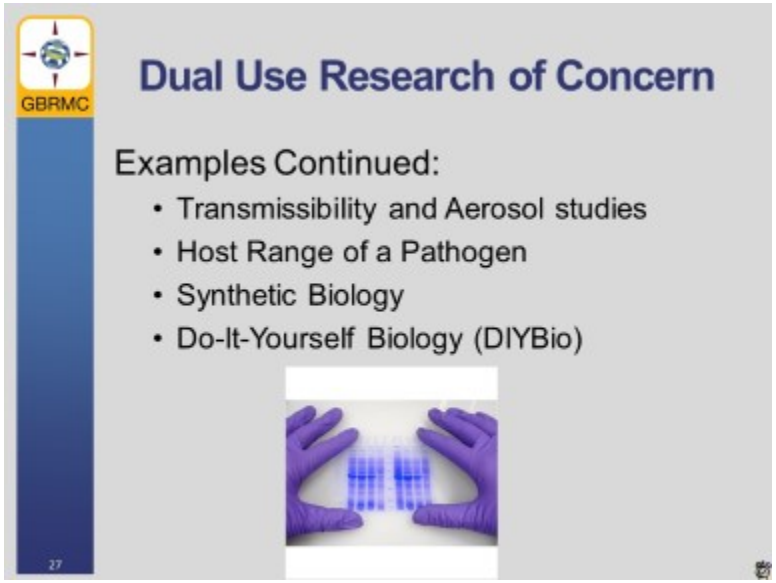


Examples:

Vaccine Research:

Studying antibiotic resistance in bacteria to create new drugs:

Virulence and pathogenesis for drug interventions:



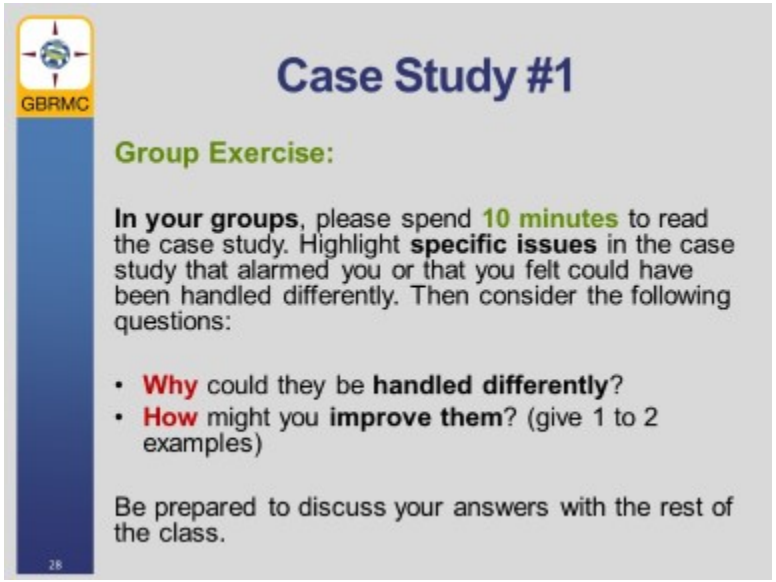
Examples:

Transmissibility and aerosol studies:

Host range of a pathogen:

Synthetic Biology:

Do-it-Yourself-Biology:



What are the bioethical issues in the case study?

Why could they be handled differently?

How might you improve them?

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Case Study #1

Research Lab A has been told by a safety committee to get rid of several pieces of equipment because they are old or outdated for the purposes of the experiments performed. The equipment includes Biosafety Cabinets, a broken lyophilizer, and a centrifuge. Scientists from nearby Research Lab R have experienced funding cuts, and have been coming to Research Lab A at night to use the facilities. They find out about the equipment up for disposal and offer to buy it. However, when one of the scientists from Research Lab A calls Research Lab R to ask when to deliver the equipment, Research Lab R has no record of the scientists in question. Research Lab A simply assuming there has been a mistake. The next evening, the scientists from Research Lab R show up to pick up the equipment.

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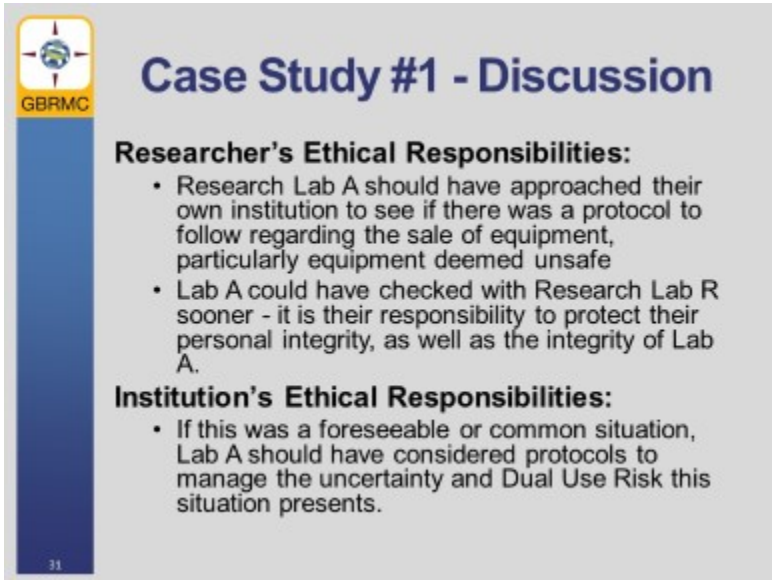
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Case Study #1 - Discussion
Researcher's Ethical Responsibilities:
• Research Lab A should have approached their own institution to see if there was a protocol to follow regarding the sale of equipment, particularly equipment deemed unsafe
• Lab A could have checked with Research Lab R sooner - it is their responsibility to protect their personal integrity, as well as the integrity of Lab A.
Institution's Ethical Responsibilities:
• If this was a foreseeable or common situation, Lab A should have considered protocols to manage the uncertainty and Dual Use Risk this situation presents.
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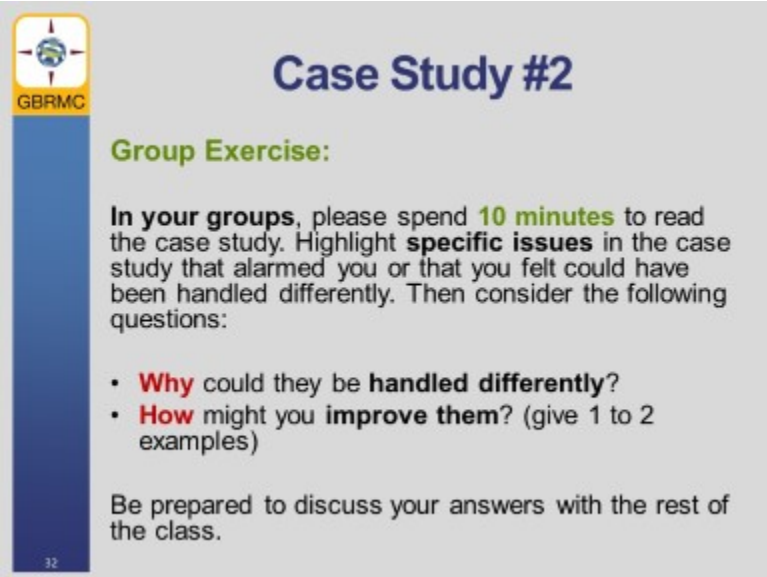
Notes:



What are the bioethical issues in the case study?

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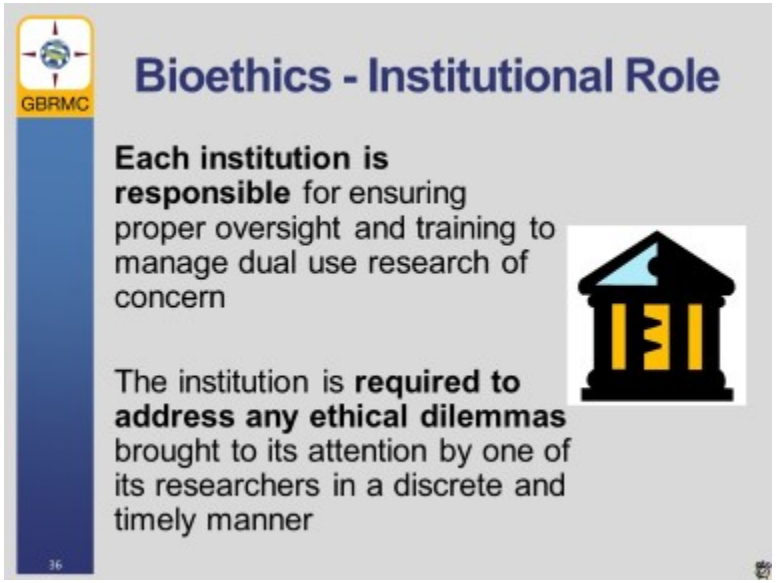
Case Study #2

You have just discovered the key to multi-drug antibiotic resistance by proving that those genes can be easily prompted to move in and out of any bacterial species. The idea that resistance can potentially pushed in and out of bacteria at will was groundbreaking, and the paper was published online in last month's New England Journal of Medicine.

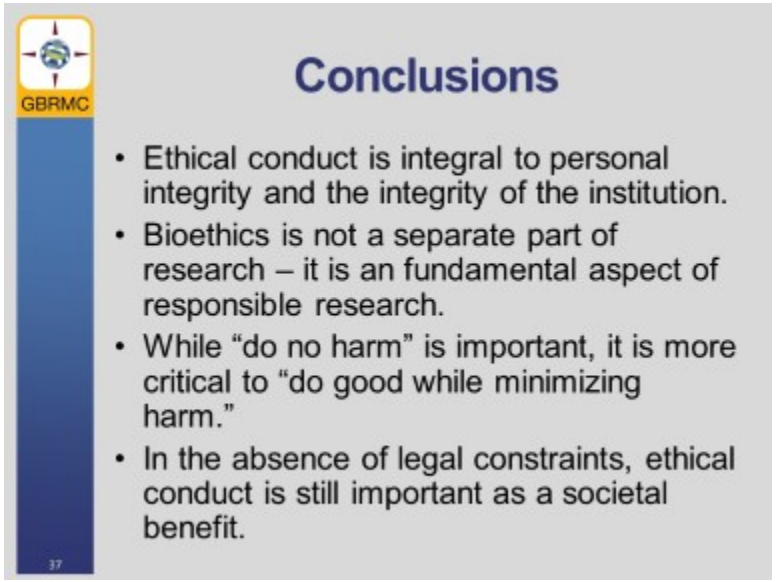
A few weeks later, in a coffee shop near your research lab, you are approached by someone interested in discussing your recent paper with you. The conversation strikes you because although the individual is well-spoken and claims to be an MD in your field, he demonstrates a limited understanding of the science in your paper. Chalking it up to nerves and youth, you give him your card. You later receive an email from him, first asking about the results, then asking detailed questions about materials, methods, and equipment necessary to perform the experiment. You ask about his specific experiment to be of greater assistance, and learn he wants to test your hypothesis using a bacillus species that frequently affects buffalo in his country, moving antibiotic resistance genes into the animal strain. You find the experiment odd, but decide it's a poor translation into your language despite his earlier eloquence. You help bridge the gaps in his knowledge, but never hear from him again. You finally mention the encounter to a researcher who is a vet, and she remarks "That's odd, buffalo commonly suffer from bacillus anthracis (anthrax) – he wasn't making resistant strains of that, was he?"

What are individual responsibilities to uphold bioethics?



What are institutional responsibilities to uphold bioethics?

How do these compare to individual responsibilities?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Conclusions
• Ethical conduct is integral to personal integrity and the integrity of the institution.
• Bioethics is not a separate part of research – it is an fundamental aspect of responsible research.
• While "do no harm" is important, it is more critical to "do good while minimizing harm."
• In the absence of legal constraints, ethical conduct is still important as a societal benefit.
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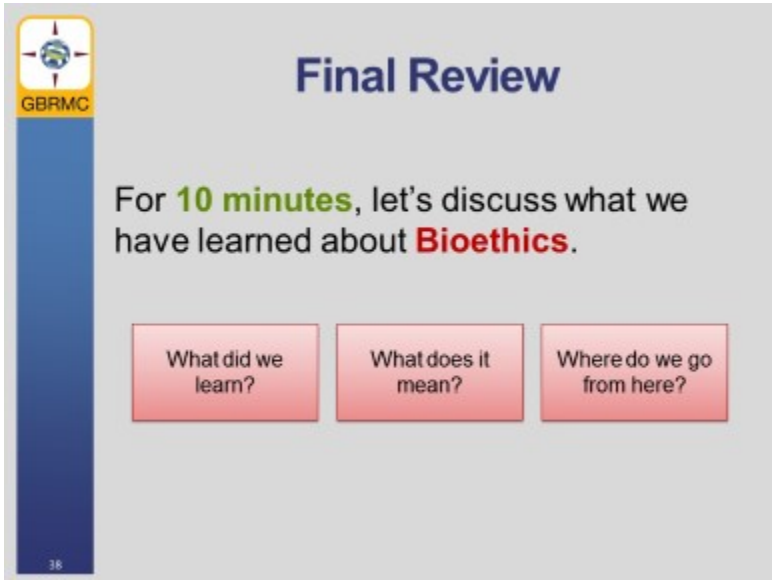
Notes: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Final Review
For 10 minutes, let's discuss what we have learned about Bioethics.
What did we learn?
What does it mean?
Where do we go from here?
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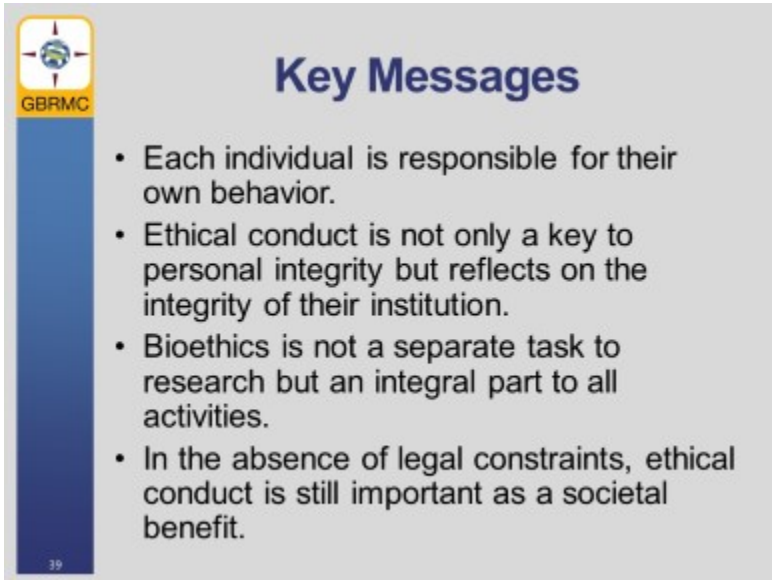
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KNOW		FEEL		BE ABLE TO DO	

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