



Bioethics

Student Guide

2012



GLOBAL BIORISK MANAGEMENT CURRICULUM

Bioethics



Welcome & Introductions

Introductions

- Instructors
- Students
 - Your name?
 - Where are you from?

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The slide has a grey background with a blue vertical bar on the left. It includes the GBRMC logo, the title 'Introductions', a bulleted list for instructors and students, and an illustration of two 3D white figures. A small number '2' is in the bottom left corner.

Action Plan


By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
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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?

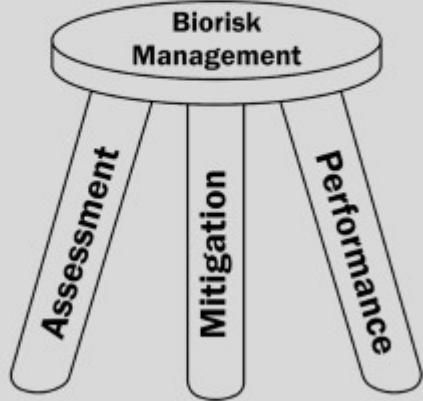
Use space on back, if needed

 **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.

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 **Biorisk Management: the AMP Model**




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 **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



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 **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




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Key Components of Biorisk Management

- **Biorisk Performance**
 - Improving biorisk management by recording, measuring, and evaluating organizational actions and outcomes to reduce biorisk.



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Define Performance:



The Problem

Potential for misuse of biological agents

- Theft, diversion, weaponizing an agent, dual-use

Possible Solution:

- Know what you don't know
 - Understand the risk
 - Consider how otherwise benign biological research may be misused
 - **Utilize Bioethics Principles**

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What is the problem?

What is the solution?



Examples of a Code of Ethics

Similar to a **code of behavior**, for example:

- Please turn off your cell phones.
- Please talk quietly in the library.


Questions:

- What are the **acceptable** and **unacceptable behaviors** of each code of behavior?
- What are the **consequences** if the code is broken?
- Are there **tradeoffs** for adhering to the code of behavior?

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

Can you think of another example?



Bioethics Exercise

Group Exercise:

In your groups, spend 10 minutes to develop a definition for bioethics?

To help with this task, consider the answers to the following questions:

- How could bioethics contribute **positively** to your work environment?
- How might bioethics enhance the **quality** of research?
- How might bioethics **prevent** misuse?

Write each answer on a **sticky-note** and place it on your flip chart. Once your group is done, **write your definition at the top of the flip chart**, and be prepared to discuss with the rest of the class.


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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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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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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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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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General Features of a Code of Conduct

The Basics: **Why it is Effective**

- Clearly stipulated goal
- Active Language
- Progressive
- Appeals purely to altruistic impulses

Examples: Biological Weapons Convention (BWC), Asilomar Conference on Recombinant DNA, International Centre for Genetic Engineering and Biotechnology (ICGEB)

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General Features of a Code of Conduct

The Basics

- Clearly stipulated goal
 - sometimes the goal will have chronological endpoints
- Active Language
 - Determined/will/must
- Progressive
 - Current state → ideal future state
 - Focus on how the codes can improve the state of affairs
- Appeals purely to altruistic impulses
 - For the betterment of mankind, for the security of mankind, for future generations, etc.

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Examples:

Clearly stipulated goal:

Active Language:


Progressive

Appeals purely to altruistic impulses:

 **General Features of a Code of Conduct**

Consider the BWC, Asilomar Conference on Recombinant DNA, ICGEB

- How did the features of the **International Codes of Conduct** mentioned **help the global community**?
 - Altruistic concepts: counter proliferation/assisting developing nations
 - Both help future generations, improve the global community



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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?

 **General Features of a Code of Conduct**


Codes of Conduct:

- **Nations: Global Community**
as
- **Individuals: Institution**
 - Examples:
 - Guidelines for ethical treatment of humans or animals
 - Biosafety and Biosecurity Guidelines
 - » US: Institutional Review Board, Institutional Biosafety Committee



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



Code of Conduct Exercise

Exercise:

Individually, spend **5 minutes** to think about the **factors that make a successful code of ethics** and how they are implemented, or could be implemented, at **your institution**.

To help with this task, consider the answers to the following questions:

- Is there a **code of conduct** at your institution?
- If you had to create a **code of ethics** what specific factors would you include?


Write your answers in your **student guide**.

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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?



Dual Use Traditional Definition

“Goods and technologies are considered to be dual-use when they can be used for both civil and military purposes.”


- » European Commission – Trade Website
<http://ec.europa.eu/trade/creating-opportunities/trade-topics/dual-use/>

“Dual-Use items’ shall mean items, including software and technology, which can be used for both civil and military purposes, and shall include all goods which can be used for both non-explosive uses and assisting in any way in the manufacture of nuclear weapons or other nuclear explosive devices”

- » Council Regulation (EC) No 428/2009


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What is your definition for Dual Use?


 **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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Dual Use Research of Concern

Question:

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

To help with this task, consider the following questions:

- What about the experiment makes it **Dual Use**?
- How could this information be **misused**?

In your group, please spend **10 minutes** to answer the above question. Be prepared to report your answers to the class.

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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?


Bioethics

Dual Use Research of Concern

 **Dual Use Research of Concern**

Examples:

- Vaccine Research
- Studying antibiotic resistance in bacteria to create new drugs
- Virulence and pathogenesis for drug interventions



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Examples:

Vaccine Research:

Studying antibiotic resistance in bacteria to create new drugs:

Virulence and pathogenesis for drug interventions:

Bioethics

Dual Use Research of Concern



Dual Use Research of Concern

Examples Continued:

- Transmissibility and Aerosol studies
- Host Range of a Pathogen
- Synthetic Biology
- Do-It-Yourself Biology (DIYBio)



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Examples:

Transmissibility and aerosol studies:

Host range of a pathogen:

Synthetic Biology:

Do-it-Yourself-Biology:



Case Study #1

Group Exercise:

In your groups, please spend **10 minutes** to read the case study. Highlight **specific issues** in the case study that alarmed you or that you felt could have been handled differently. Then consider the following questions:

- **Why** could they be **handled differently**?
- **How** might you **improve them**? (give 1 to 2 examples)

Be prepared to discuss your answers with the rest of the class.

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What are the bioethical issues in the case study?


Why could they be handled differently?

How might you improve them?



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.



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:



Case Study #2

Group Exercise:

In your groups, please spend **10 minutes** to read the case study. Highlight **specific issues** in the case study that alarmed you or that you felt could have been handled differently. Then consider the following questions:

- **Why** could they be **handled differently**?
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What are the bioethical issues in the case study?

Why could they be handled differently?

How might you improve them?



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 be 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?"

Bioethics

Roles & Responsibilities



Bioethics - Individual Role

Each individual is **responsible** for their own behavior.

While "**do no harm**" is important, it is more critical to "**do good while minimizing harm.**"

Each individual has a responsibility to **report** or **formally address** ethical violations to preserve their personal integrity, and protect the integrity of their institution



Address ethical dilemmas


- In the absence of legal recourse, the society will benefit from ethically conduct research

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What are individual responsibilities to uphold bioethics?


Bioethics

Roles & Responsibilities



Bioethics - Institutional Role

Each institution is **responsible** for ensuring proper oversight and training to manage dual use research of concern




The institution is **required to address any ethical dilemmas** brought to its attention by one of its researchers in a discrete and timely manner

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What are institutional responsibilities to uphold bioethics?

How do these compare to individual responsibilities?




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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