SAND2012-4067P

Bioethics

Instructor Guide

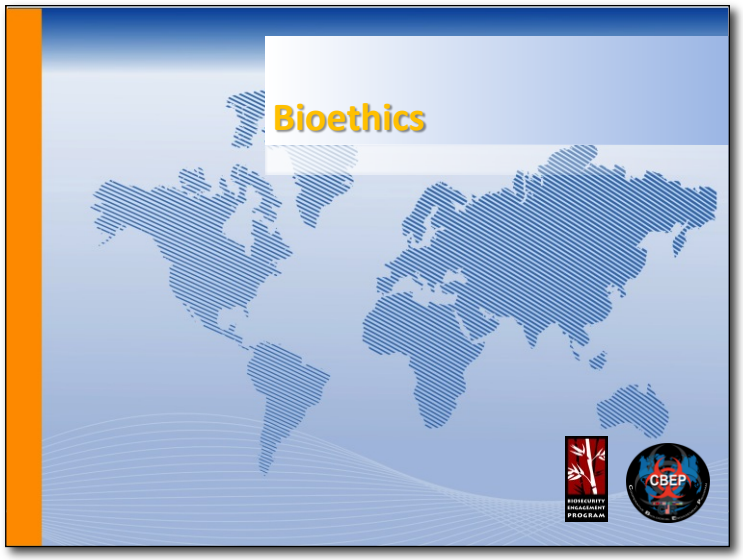
Sandia National Laboratories
International
BIOLOGICAL THREAT REDUCTION

BIOSECURITY ENGAGEMENT PROGRAM

CBEP
Cooperative Biological Engagement Program

Welcome & Introductions

Slide 1



Introduce Instructor(s):

[Introduce others associated with the training, as appropriate]

Name

Affiliation

Representation (I'm here on behalf of. . .)

Quick Experience Glimpse

Relevancy of the Course to your experience

Welcome & Introductions

Before you introduce yourselves, I'd like to provide some reminders about this facility and the training:

1. Restrooms are . . .
2. Exits are . . .
3. Evacuation procedures are . . .
4. [any escort or restricted access procedures]
5. We will have intermittent breaks during the course, but please feel free (or not) to take a quick break if you need to at other times during the course
6. Beverages and snacks will be available at (time) and at (location). You may/may not eat and drink in this room
7. Please silence any cell phones or other noise-making devices.
8. Others . . .

Slide 2

Welcome & Introductions

Let's go around the room and let each of you introduce yourself. Please tell us your name, where you work (organization and/or title, as appropriate), and what you hope to gain from the course.

Ground rules

This will be a very interactive session and you will learn the most if you participate fully. We will not intentionally force any one to speak or to do an activity that embarrasses them – if you are uncomfortable, please speak to one of the leaders. For those of you who like to talk, please share your expertise but are aware of those around you who may be quieter and give them time to share their opinion as well. We ask that everyone respect the break times and report back promptly when asked to do so. But most of all, we want to make this a fun time to learn, so remember to smile and enjoy yourself!

Transition to Objectives

Goal

To review the Action Plan and Learning Objectives for the course and to solicit any additional learning goals from the participants.

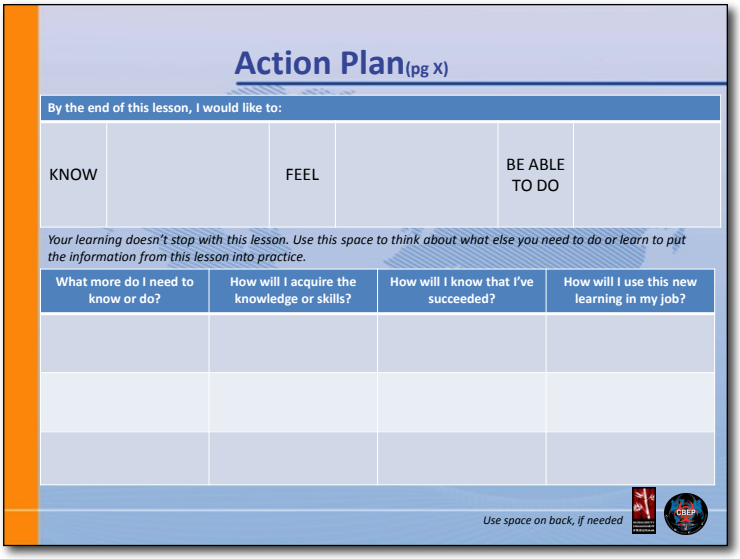
Time

20 minutes

Welcome & Introductions

1. Each individual is responsible for his or her own behavior.
2. Ethical conduct is not only a key to personal integrity but reflects on the integrity of the institution.
3. Bioethics is not a separate task to research but an integral part to all activities.
4. While “does no harm” is important, it is more critical to “do good while minimizing harm.”
5. In the absence of legal constraints, ethic conduct is still important as a societal benefit.

Slide 3

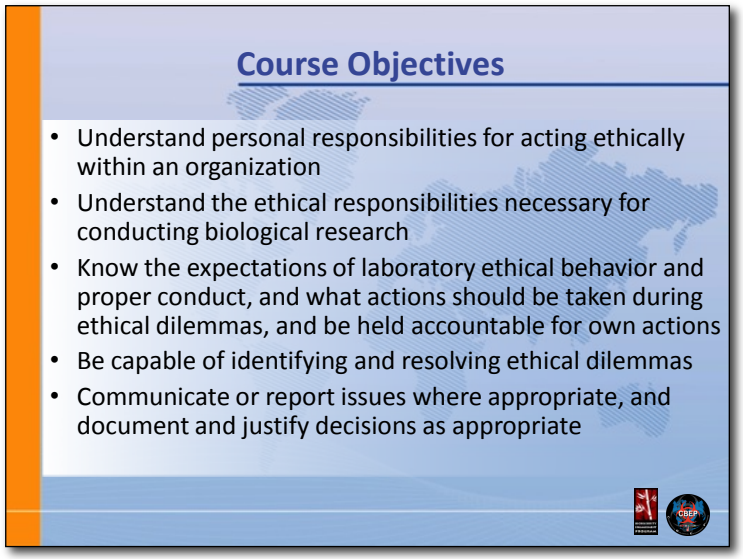


Welcome & Introductions

Instructions for the Action Plan handout:

- The Action Plan handout is on page X of the student guide.
- Go over each section of the Action Plan. . .
- Ask each participant to think about what they would like to be able to KNOW, FEEL, and DO once this lesson is completed
- Tell them that there is a place on the Action Plan for them to write down their thoughts on next steps or additional training they need/want.
- Tell them that this is their own Action Plan that they do not need to share with anyone. They can use it during the course of the lesson to add to their list or change anything.
- Allow 5 minutes

Slide 4



Welcome & Introductions

Background Information for Instructor

Review the course objectives, these can be read from the slide. Check for understanding and verify that these objectives are consistent with student expectations. Questions to ponder:

- How you, as individual, are responsible for upholding bioethical principals
- Understanding what those principals are
- Applying those principles so that you act appropriately in new situations

Capture any additional KNOW, FEEL, or DO or other learning goals

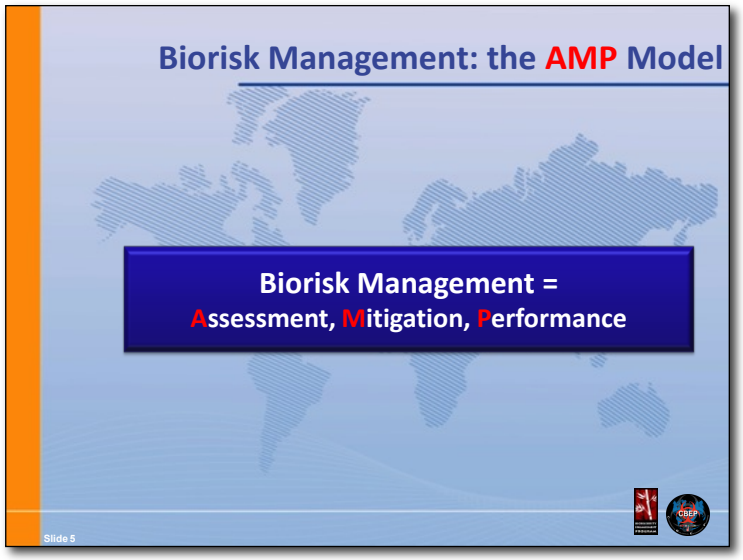
Capture any learning goals that will supplement course objectives and address any that are outside the scope of the course.

This course is flexible in nature. If there is a learning goal that is easily incorporated into the course, feel free to add it. Please note successful additions and consistently requested learning goals in the evaluation portion of this course and/or to GBRMC administrators.

Transition to Biorisk Management Touchstone

Biorisk Management

Slide 5

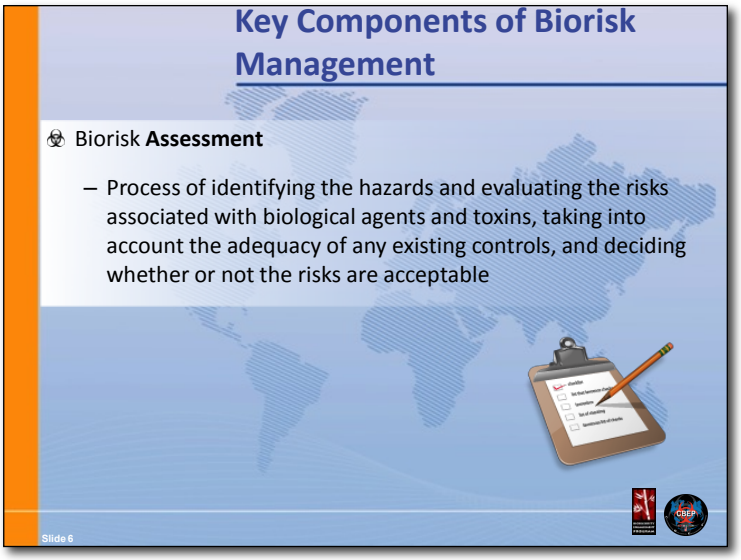


Background Information for Instructor

- Review the AMP model of Biorisk Management with the participants.
- The following three slides provide specific definitions for A, M, and P.
- Integration of laboratory biosafety (protect people from pathogens) and laboratory biosecurity (protect pathogens from people)

Biorisk Management

Slide 6



Background Information for Instructor

The instructor uses the following three slides: Biorisk Assessment; Biorisk Mitigation; and Performance to define key components of biorisk management

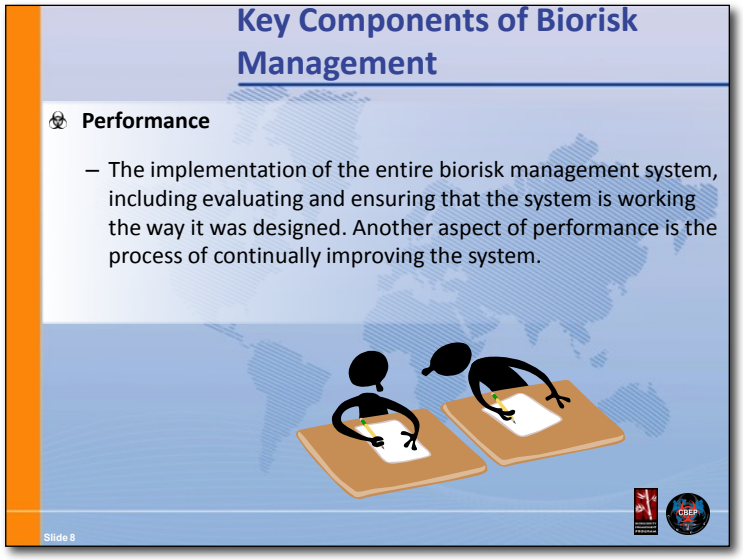
Slide 7

Biorisk Management

Background Information for Instructor

The instructor uses this slide and following slide (Performance) to define key components of biorisk management

Slide 8



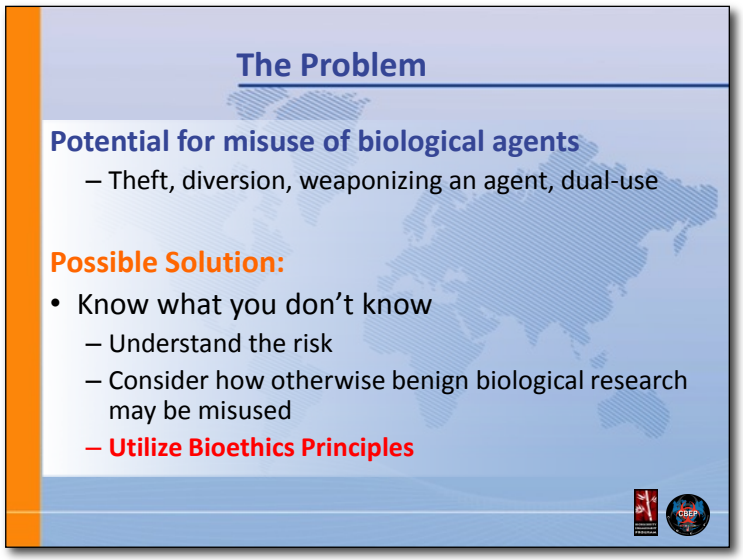
Lecture

Taken together, the three elements of AMP constitute a complete biorisk management system. The elements of the AMP model also underpin CWA 15793:2011 – Laboratory Biorisk Management Standard

Transition to Introduction to Bioethics

Introduction to Bioethics

Slide 9



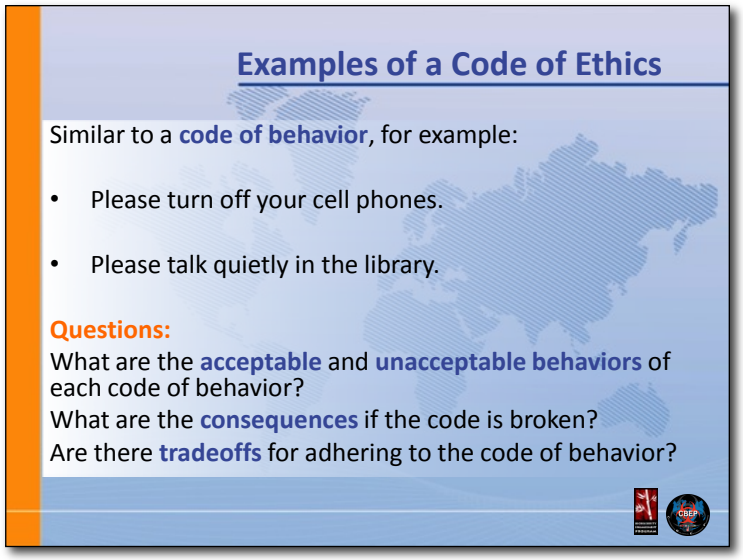
Background for Instructor

In biological work, there is potential for misuse of biological agents. In 2004 the US National Intelligence Council found a concerning trend by terrorist groups to acquire weapons of mass destruction, including biological weapons. Biological attack could include: Theft, diversion, weaponizing an agent, dual-use

Various committees, commissions, and reports have focused on solving the problem of potential misuse of biological agents. The goal was to find a solution that will defend against a biological attack. The analysis succeeded largely by identifying the most dangerous unknowns: the level of risk in constantly evolving field, and how otherwise benign biological research may be used for nefarious purposes. One of the more effective solutions to the problem was found in the field of biological ethics.

Introduction to Bioethics

Slide 10



Lecture

A code of ethics is very similar to a "code of behavior" or a "code of conduct". In today's class we have already adhered to a code of behavior – the instructor made a request (presumably) for the students to switch off their cell phones. That request, when met by all, means everyone has agreed to meet a standard of behavior – a code of behavior.

Another example of a code of behavior is to only talk quietly in the library.

In plenary, ask students:

For these two examples: 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.

Introduction to Bioethics

Expected Responses

Please turn off your cell phones:

- Acceptable behavior: Silenced phone to avoid interrupting the speaker/class if the phone rings.
- Unacceptable behavior: Ringing phone
- Consequences: Class is disturbed. Phone may be taken away. Unfavorable reaction from instructor/students.
- Tradeoffs: Compromise missing a call for a better learning environment experience.

Please talk quietly in the Library:

- Similar to the cell phone example. The code is adhered to for the greater good.

New Responses from Students:

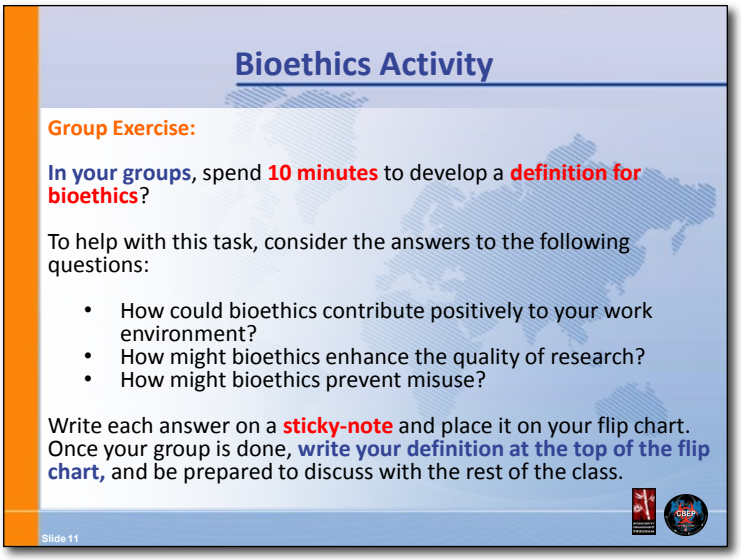
Background Information for Instructor

Transition to the following activity and to a code of ethics by asking the students to think about these questions:

"What type of environment might you want to promote, how might bioethics prevent misuse, how might bioethics encourage good research?"

Introduction to Bioethics

Slide 11



Small group activity (15 minutes).

Activity Instructions (to students)

- 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 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.

Introduction to Bioethics

You have 15 minutes to complete this activity

Directions for Instructor:

- After 10 minutes, ask the students to stop working on the exercise
- Lead a 5-minute plenary discussion. Begin by asking the students to report their definition of Bioethics and the answers to the questions that helped them form their definition.
- Continue around the room, asking each group to report their answer (as time allows).
- Discuss the common factors and differences between the definitions and be sure to highlight any similarities, differences or unique answers.

Introduction to Bioethics

Expected Responses

Bioethics Definition:

Bioethics can promote policies and practice to ensure that the areas of science, health and innovated engineering fields are conducted in a socially and ethical manner.

Bioethics is the promotion of responsible and good research practices, the provision of tools and practices to scientists and institutions that allow them to discuss, analyze and resolve in an open atmosphere the potential dilemmas they may face in their research, including those related to the possibility of accidents or misuse of the life sciences. (adapted from the World Health Organization)

How could bioethics contribute positively to your work environment?

- Everyone working toward a common goal with out distractions.
- Rules with set guidelines and consequences if they are broken.
- Better regard for co-workers

How might bioethics enhance the quality of research?

- Yield robust and repeatable research
- Streamlined processes – more efficient
- Highly regarded – sets a high standard

How might bioethics prevent misuse?

- Outlines consequences of misuse
- Helps to identify and report misuse appropriately
- Increases transparency

New Responses from Students:

Introduction to Bioethics

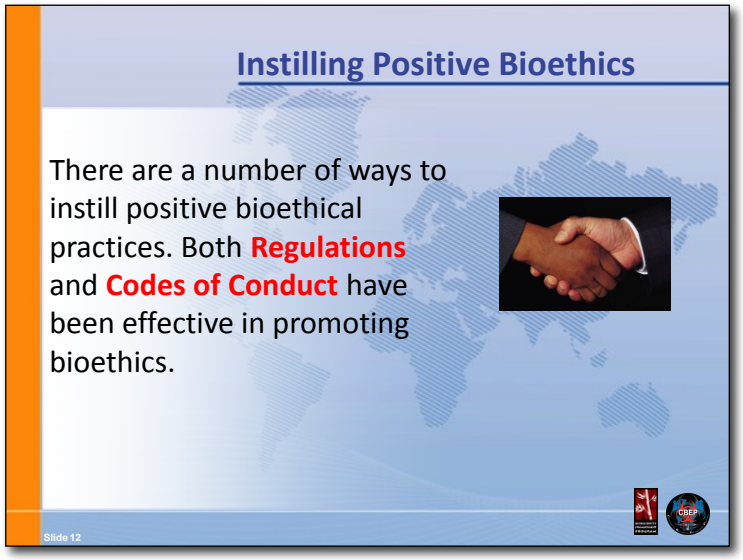
In plenary, ask students:

How the below formal definition for bioethics matches their definition?

Bioethics is the promotion of responsible and good research practices, the provision of tools and practices to scientists and institutions that allow them to discuss, analyze and resolve in an open atmosphere the potential dilemmas they may face in their research, including those related to the possibility of accidents or misuse of the life sciences. (Adapted from the World Health Organization)

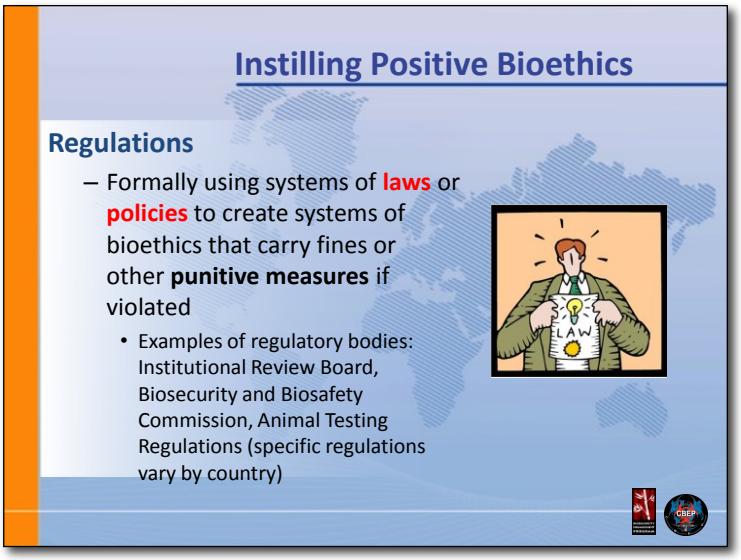
- How does this definition compare to your group's definition?
- What are the differences?
- Do you agree?

Slide 12



Introduction to Bioethics

Slide 13



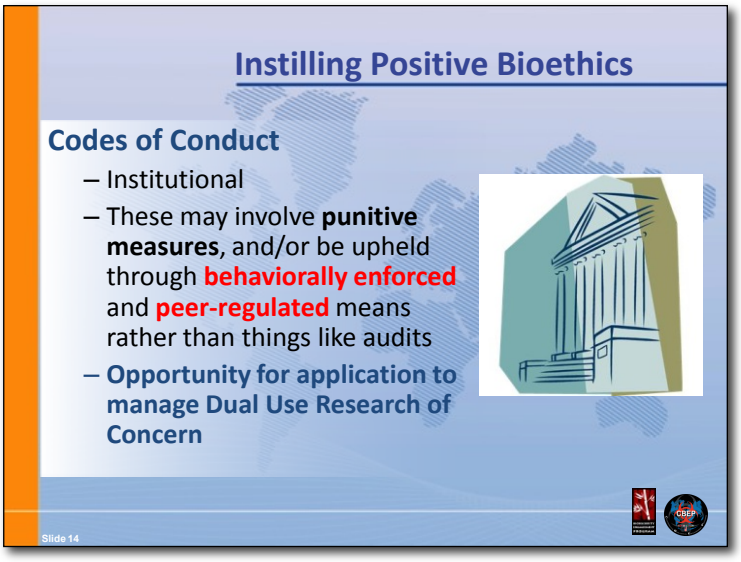
Lecture

There are several ways to instill good bioethics some examples will be discussed in the next few slides.

One of the more common ways to instill good bioethics involves the establishment of regulatory bodies that regulate human behavior in the life sciences. These bodies use formal systems of laws or policies to create systems of bioethics, and carry fines or other punitive measures if the prescribed ethical norms are violated. The norms they regulate can involve anything from the regulation of pieces of DNA, to animal testing, to human testing.

Introduction to Bioethics

Slide 14



Introduction to Bioethics

Lecture

Another way to instill positive bioethics is to establish a Code of Conduct. This may or may not involve punitive measures, and may be upheld through behaviorally enforced and peer-regulated means rather than things like audits.

Ask the students in plenary the following questions:

- What does a code of conduct achieve?
- Why is it valuable?
- How does it forward the aims of increasing awareness regarding dual use research of concern?

(Gather suggested answers from the class – collect on a flip chart if desired).

There have been several attempts made to manage the challenge posed by dual use research of concern. One example is through the implementation of a code of conduct, which has occurred at an international level down to an institutional level.

We will focus on the general features of a code of conduct as well as begin developing a code of conduct to help facilitate good bioethics in the next sections.

Ask: Any questions on defining bioethics?

Take a Break (10 minutes)

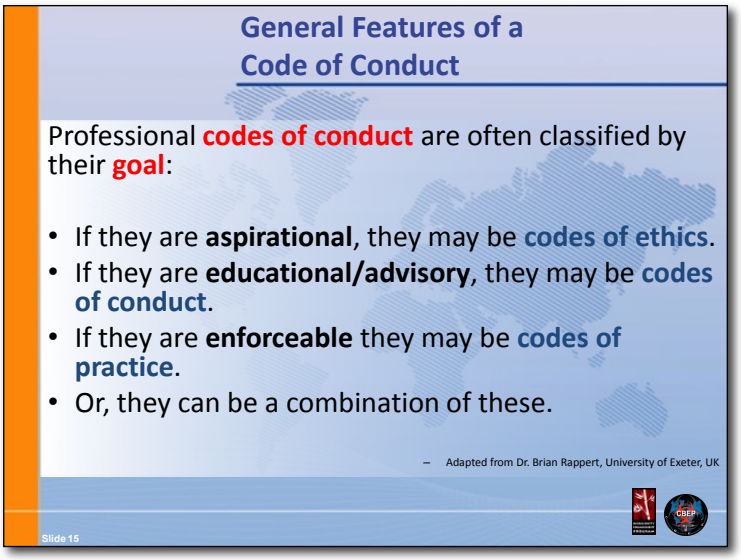
Time Check

You should be approximately __ hour and __ minutes into the course.
You have __ hours of the course remaining.

Transition to Codes of Conduct

Codes of Conduct

Slide 15



Lecture

As you can see, there is a tremendous amount of overlap among the terminology for a code of conduct depending on the overall goal. Keep this in mind as we move forward. The important thing is that the Code of Conduct has some general features that we will be discussing in the next few slides that make them very effective at achieving these goals.

Codes of Conduct

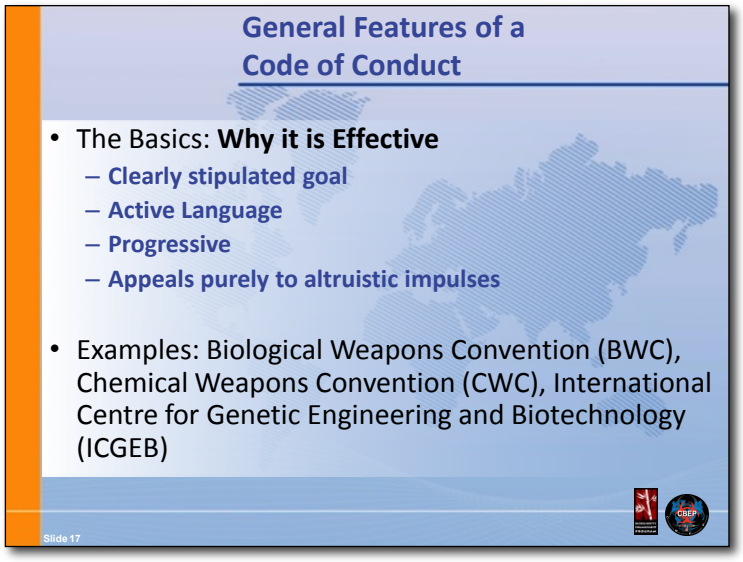
Slide 16

Lecture

These are the basic features of a code of conduct and what makes it effective. We will discuss these factors in detail and spend some time analyzing the mechanics of each, to better understand the success of those documents.

Codes of Conduct

Slide 17



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Lecture

There are some well-known examples of codes of conduct that have been effective over the years. These include the Biological Weapons Convention, the Chemical Weapons Convention, and the International Centre for Genetic Engineering and Biotechnology's codes of Conduct. These codes of conduct have been effective on the international scale to have state signatories agree to the conditions of the agreement because of these four common factors.

Codes of Conduct

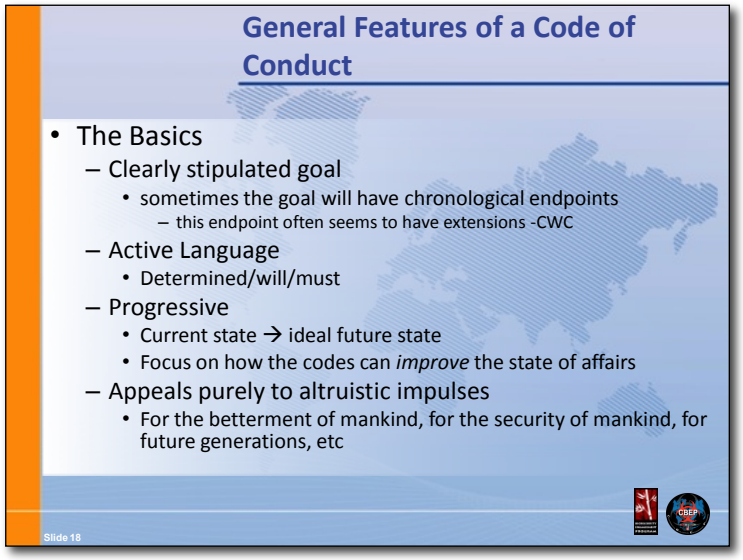
Background Information for Instructor

There are already examples guiding international codes of conduct, like the international treaties and conventions mentioned previously: the Biological Weapons Convention (BWC) and the Chemical Weapons Convention. Here, the globe has agreed to a prescribed behavior as it pertains to the responsible handling of dangerous pathogens and chemicals.

More recently, the International Centre for Genetic Engineering and Biotechnology (IGCEB) created a code of conduct for Scientists in Relation to Safe and Ethical Use of Biological Sciences.

These documents all sought out to achieve the same goals, with states parties, organizations within those parties, and individuals agreeing to uphold tenants of an international convention, though it may involve a small inconvenience like the submission of an annual audit. A small sacrifice for the greater good to maintain a global ethical norm.

Slide 18



Codes of Conduct

Lecture

Clearly Stipulated Goal

Codes of conduct have clearly stipulated goals; whether it is the reduction of biological weapons, chemical weapons, or helping developing nations achieve better access to biotechnology.

Some of these codes of a chronological endpoint if it involves something like destruction of old weapons as part of the agreement like the CWC, which will also have a provision for an extension, but larger goal (for the CWC – no chemical weapons) will still be timeless.

Active Language

The second feature is very active language. These treaties are all very "determined" and "driven" to meet their goal to motivate their states parties if only by language alone, but in reading them the goal in that is to further motivate the reader to carry out the goal through the use of such emphatic language.

Progressive

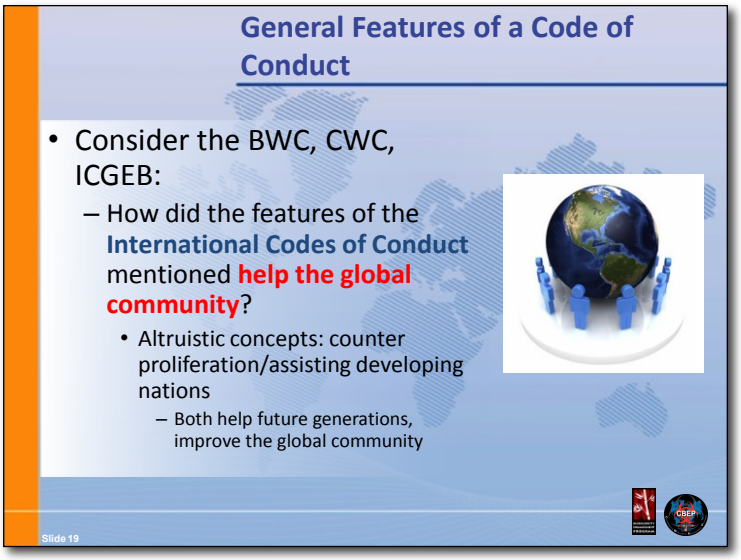
Codes of conduct are progressive in that while they were formed to address a void of formal conduct in the past, they do not focus on that but on a future state where they have in effect made themselves obsolete. This is partly achieved by continually focusing on how the codes can improve the current status quo.

Appeals Purely to Altruistic Impulses

Codes of conduct also appeal to positive human traits: humanitarian and altruistic impulses, such as the betterment of mankind. This may be through the promise of bringing technology to developing nations, or countering the proliferation of weapons helping global security. There are no negative motivators: political or economic reprisal, as it is more divisive.

Codes of Conduct

Slide 19



Lecture

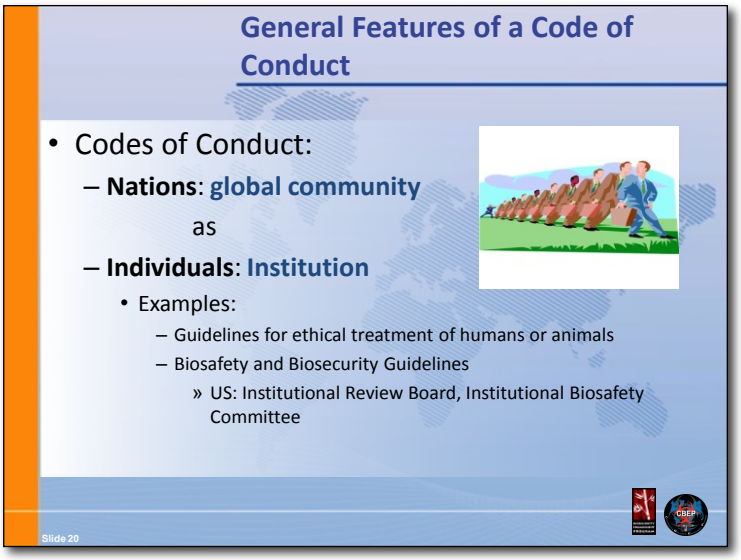
To recap, these international agreements require only small actions taken on the part of the individual signatories, which serve to uphold the greater good.

The end goal (altruism, counter proliferation) greatly outweighs the inconvenience of even the most burdensome clause of any single agreement (inspections, written documentation), which therefore enabled their implementation.

In any code of ethics or code of behavior, this balance has to be sufficiently compelling otherwise the individual actors in question may be less likely to comply with the code in question – professional, international, or personal.

Codes of Conduct

Slide 20



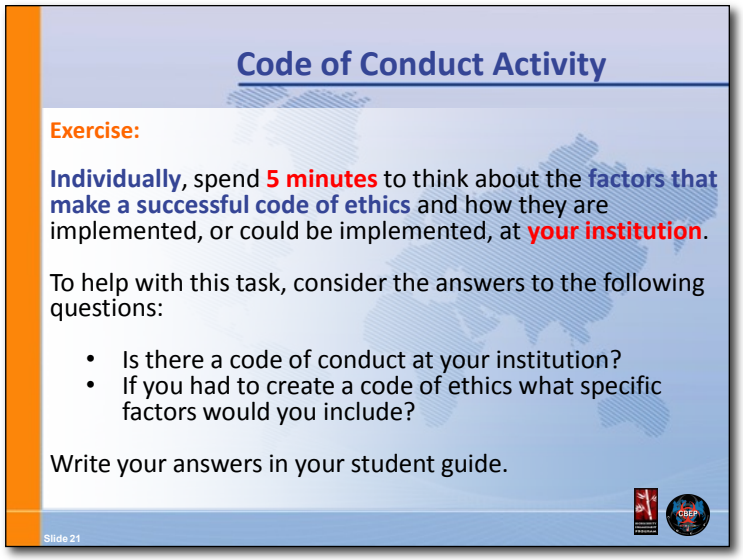
Lecture

An INTERNATIONAL Code of Conduct proved an effective tool for describing nations responsibility to the global community to uphold a norm regarding the reduction of biological weapons, chemical weapons, and encouraging the development of biotechnology in developing nations. It is important to recognize that the relationship is two ways: each nation is individually responsible for its own behavior and for reporting, but the global community and the committee is also in charge of ensuring each party upholds their part of the agreement.

In a smaller context, it can outline an individual's role within an institution and guide his or her conduct while conducting research. Examples of this kind of code of conduct can include the guidelines regarding the ethical care of animal or human subjects, proper submission of research protocols to the Institutional Review Board, or proper safety procedures for a given study. The individuals are responsible for upholding the procedures laid out by the institution, and reporting and misconduct they see to the institution.

Codes of Conduct

Slide 21



Individual activity (5 minutes).

Activity Instructions (to students)

- 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.

Ask: Any questions on the codes of conduct?

Codes of Conduct

Take a Break (10 minutes)

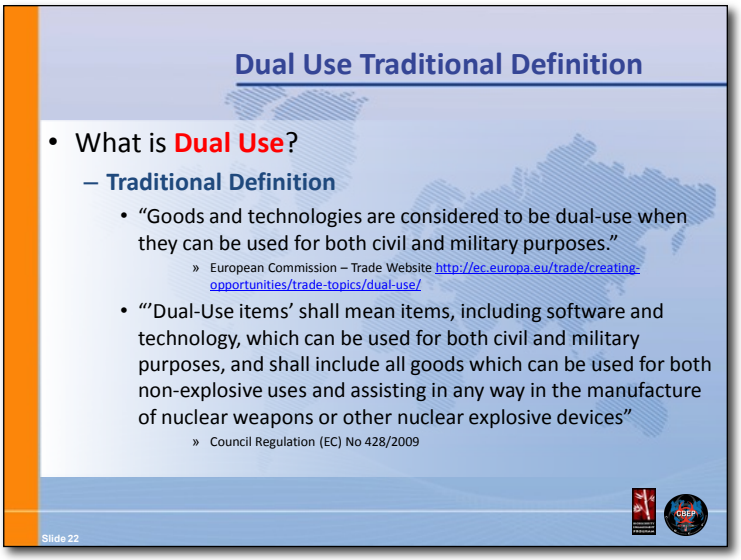
Time Check

You should be approximately __ hour and __ minutes into the course.
You have __ hours of the course remaining.

Transition to Dual Use Research of Concern

Dual Use Research of Concern

Slide 22



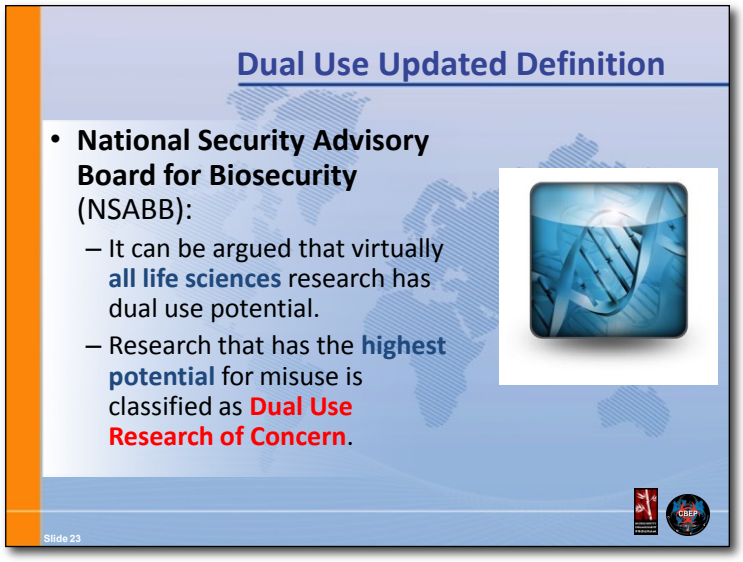
Lecture

Historically, dual use has referred to technologies that can be used for both military and peaceful aims. This is often in reference to nuclear reactors (plutonium production or power generation), rocket technologies (Intercontinental Ballistic Missiles or Space travel), or potentially some biotechnologies.

Concerns over dual use as used in this definition arose prominently during the Cold War and continue today and are captured in reference to Nuclear Weapons through the Nuclear Non-Proliferation Treaty.

Dual Use Research of Concern

Slide 23



Lecture

The NSABB was formed in 2003 to oversee the increasing threat posed by dual use research following the National Academies of article, Biotechnology Research in an Age of Terrorism, also called “The Fink Report.” The NSABB is mandated to promote awareness of dual use awareness within two of the most challenging audiences: amateur scientists, and scientists who are in non-life fields like synthetic biology. (NSABB)

Dual Use Research of Concern

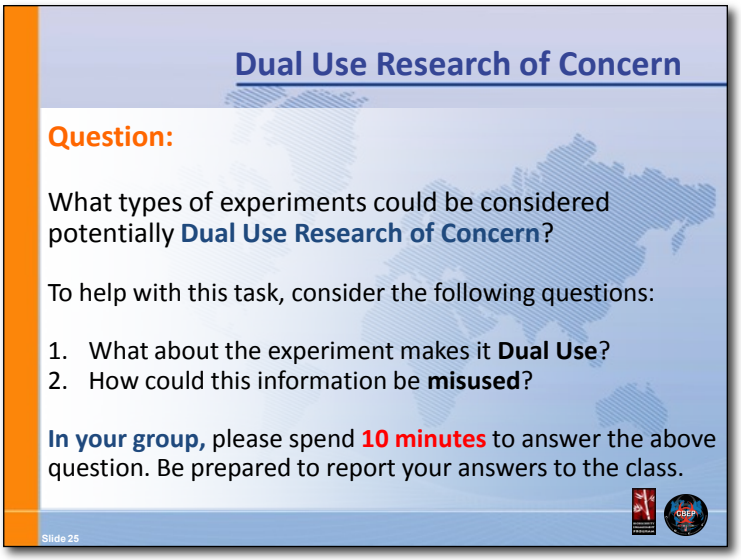
Slide 24

Lecture

The criterion provided by the NSABB for identifying Dual Use Research of Concern is a well-balanced example of the confluence of institutional and individual responsibility. While the researcher must admit to the possibility that his or her research has dual use potential, it is also the responsibility of institution to provide the proper advisory boards and review processes to ensure that a researcher carries out their research with awareness.

Dual Use Research of Concern

Slide 25



Small group activity (15 minutes).

Activity Instructions (to students)

- In your groups, spend 10 minutes to answer the following questions:
- 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?
- Be prepared to report your answers to the class.

Dual Use Research of Concern

You have 15 minutes to complete this activity

Directions for Instructor:

- After 10 minutes, ask the students to stop working on the exercise
- Lead a 5-minute plenary discussion. Begin by asking the students to report out their answers.
- Continue around the room, asking each group to report their answer (as time allows).
- Discuss the common factors of experiments that would be considered Dual Use Research of Concern.

Dual Use Research of Concern

Expected Responses

Specific Examples of Experiments Could Include: (this list was generated from NSABB)

- Enhance the harmful consequences of a biological agent or toxin.
- Disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification.
- Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies.
- Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin.
- Alter the host range or tropism of a biological agent or toxin.
- Enhance the susceptibility of a host population.
- Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent.

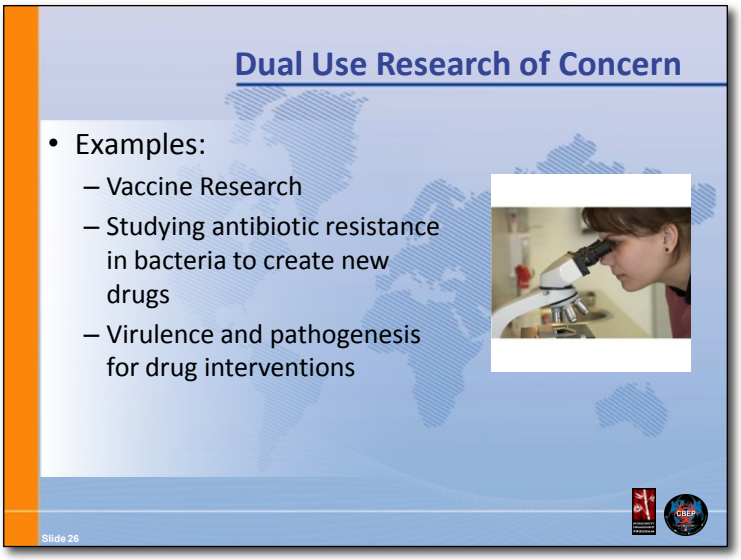
More general categories of experiments could include: (note all of these will be discussed in greater detail in the following slide).

- Vaccine Research
- Studying antibiotic resistance in bacteria to create new drugs
- Virulence and pathogenesis for drug interventions
- Transmissibility and Aerosol studies
- Host Range of a Pathogen
- Synthetic Biology
- Do-It-Yourself Biology (DIYBio)

New Responses from Students:

Dual Use Research of Concern

Slide 26



Dual Use Research of Concern

Lecture

It is important to understand what the boundaries are for Dual Use Research of Concern. Technically, the following are all considered Dual Use Research of Concern.

Vaccine Research

Attempting to render a particularly harmful organism benign can accidentally increase the magnitude of its effect. Conversely, the isolation of what makes that organism virulent can allow others to take advantage of the discovery by obtaining the naturally occurring organism and magnifying its virulence.

Studying Antibiotic Resistance in Bacteria to Create New Drugs

Antibiotic resistance in bacteria in an increasing problem, so studying exactly *how* a bacteria becomes resistant to a certain antibiotic that to try to make new antibiotics that might evade that mechanism is a genuinely benign scientific venture. However, this can be misused to deliberately create increasingly resistant strains of bacteria as well.

Virulence and Pathogenesis for Drug Interventions

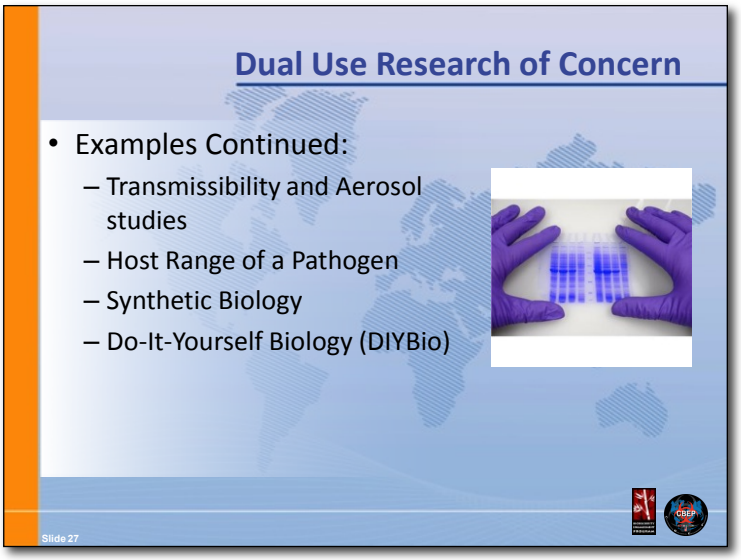
It is important for the public health to understand why certain organisms are more harmful than others (virulence), which is usually observed through the pathways and molecules they use when they infect humans (pathogenesis). While this often yields great inroads for the discovery of novel drug interventions to defeat the more virulent pathogens, it can create an opportunity for those highly pathogenic molecules to be added to another organism in the new arena of synthetic biology.

Transmissibility and Aerosol Studies

Many emerging infectious diseases whose origins and routes of transmission are unknown undergo tests to see if their likely favored route of transmission can be discovered. This can involve an aerosol study, to rule out transmission through the air for, for example, a hemorrhagic fever that is spread by close, physical contact. While of great utility to the public health, a study like that has the potential to be misused.

Dual Use Research of Concern

Slide 27



Dual Use Research of Concern

Lecture

Examples Continued

Transmissibility and Aerosol Studies

Many emerging infectious diseases whose origins and routes of transmission are unknown undergo tests to see if their likely favored route of transmission can be discovered. This can involve an aerosol study, to rule out transmission through the air for, for example, a hemorrhagic fever that is spread by close, physical contact. While of great utility to the public health, a study like that has the potential to be misused.

Host Range of a Pathogen

The host range for a pathogen is simply the variety of species it is able to infect, for example, ducks and pigs, or people and horses. To study why that is, scientists will look at what about that organism allows it to have such a large host range, and see if they understand it well enough to expand it, narrow it, etc, to see if blocking it may prevent infection in humans as a preventative measure perhaps. However, studies like this have potential to be misused as a greater understanding of how to expand a host range may mean the ability to expand a virulent pathogen to have greater ability to infect humans, for example.

Synthetic Biology

This has the potential to create new life forms to produce useful compounds at our behest, like insulin. However, this can be manipulated for worse if genetic information inserted into extent organisms using information like host range could create a pathogen of greatly increased virulence that was potentially antibiotic resistance, vaccine resistance, or to which we had no intervention because it had only recently had its host range increased.

Do-It-Yourself-Biology

The falling cost of constituent parts decreases the ability of regulations to monitor individual actions as effectively as they do through research laboratories, universities, or hospitals. This poses the possibility of dual use research.

Dual Use Research of Concern

Ask: Any questions on Dual Use Research of Concern?

Take a Break (10 minutes)

Time Check

You should be approximately __ hour and __ minutes into the course.
You have __ hours of the course remaining.

Transition to Bioethics Case Studies

Bioethics Case Studies

Slide 28

Case Study #1

Group Activity:

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.

Slide 28

Slide 29

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.

Bioethics Case Studies

Small group activity (15 minutes).

Activity Instructions (to students)

- In your groups, please spend 10 minutes reading the case study. Highlight specific issues in the case study that alarmed you or that you felt could have ben 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.

You have 15 minutes to complete this activity

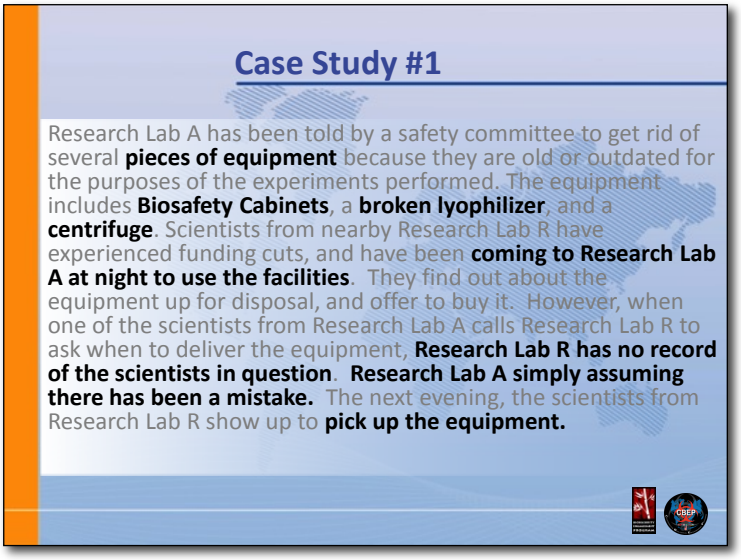
Directions for Instructor:

- After 10 minutes, ask the students to stop working on the exercise
- Lead a 5-minute plenary discussion. Begin by asking the students to report out their answers.
- Continue around the room, asking each group to report their answer (as time allows).

Bioethics Case Studies

Expected Responses

Slide 30



Here are some of the issues to focus on in the case study:

Research lab A is getting rid of old equipment that has the potential for dual use and misuse:

A biosafety cabinet, a lyophilizer and a centrifuge. These items new are expensive ordinarily, but are well within the range of scientists whose funding has been cut, and scientists and groups who may not have the best intentions whose funding is limited for lack of any formalized financial support.

The context is provided by the rest of the case:

It may be normal for one research lab to borrow another lab's facilities, especially during times of economic hardship. Funding comes and goes, and opportunities need to be seized.

However, Research Lab A called Research Lab R, and R had no record of the scientists who had been working at night at Research lab A.

In addition to being an ethical responsibility, this situation constitutes a security breach since the facility failed to perform due diligence in properly vetting/credentialing people working in its laboratory. The lab's questionable method of disposing of equipment is also a potential security breach.

Bioethics Case Studies

Expected Responses Continued

New Responses from Students:

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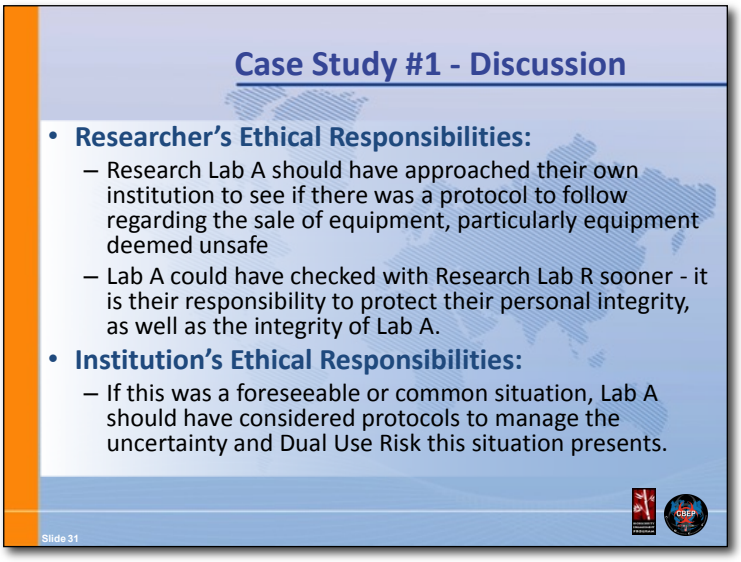


Use these points to see if they've been covered by the students' discussion. Note anything not revealed in the discussion.

Bioethics Case Studies

Slide 32

Case Study #2

Group Activity:

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.

Slide 32

Slide 33

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?"

Bioethics Case Studies

Small group activity (15 minutes).

Activity Instructions (to students)

- In your groups, please spend 10 minutes reading the case study. Highlight specific issues in the case study that alarmed you or that you felt could have ben 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.

Bioethics Case Studies

You have 15 minutes to complete this activity

Directions for Instructor:

- After 10 minutes, ask the students to stop working on the exercise
- Lead a 5-minute plenary discussion. Begin by asking the students to report out their answers. After groups have finished discussing, ask each group to report ONE (only one per group) concern as well as why they have that concern.
- Ask the other groups if they have anything else to contribute to the first group's answer.
- Ask the second group to provide another concern and the accompanying rationale for the concern, etc. Ask the other groups to add anything else to the response.
- Repeat for each group and/or until all the concerns are revealed (if time is short, you may want to limit to one per group).

Note:
Be sure to tell the students that they don't necessarily need to understand certain terms to grasp the key of the exercise. Ask them to read through it once and then ask questions.

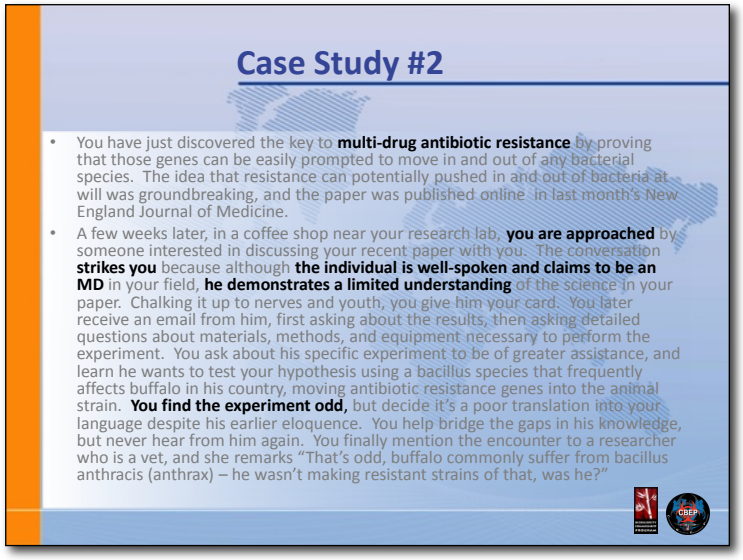
For your information, if they ask:

- All that is meant when the genes move in and out is that any bacteria can very easily gain multi-drug resistance.
- Bacillus is a rod-shaped bacterium, among which anthrax is possibly its most famous member but includes many others.

Bioethics Case Studies

Expected Responses

Slide 34



Here are some of the issues to focus on in the case study:

Facilitator:

Some of the causes for concern:

This case study is about the dual use potential of communication and its potential misuse. This case is extremely challenging. There are several aspects to it that we have to question. At the outset, your discovery is a very mobile virulence factor, and you described how to move it. You don't intend someone to misuse it, your intent is likely for doctors to use this information to develop drug targets.

For example, your work was published in a widely circulated, highly respected medical journal that many people may have had access through a variety of institutions and libraries. Your university or research affiliation would of course have been listed, as would your email. Even without personal contact, you could receive an email asking about materials and methods. Communications in this regard, are inevitable and an absolutely vital part of the scientific community.

Again, being an ethical responsibility, this situation constitutes a security breach since the facility failed to perform due diligence in properly vetting/credentialing people working in its laboratory.

Expected Responses Continued

The causes for concern:

1. Claims to be an MD in your field, but he has a poor understanding of the science of the science and the materials and methods and equipment necessary to complete and experiment. While possible, this is unlikely, and more importantly, it raised a red flag in your mind. The initial encounter struck you as odd, now this strikes you as odd – that's two things that have struck you, don't discount both.

2. Large animal studies. Why is he, presumably a microbiologist and MD, conducting a large animal study? Could you have asked what his hypothesis was instead of helping him after such a vague answer? He was notably eloquent earlier, and now you allow him the benefit of a language barrier despite your earlier impression. Incongruities that change markedly suggest someone who is not who they purport to be.

3. He may have been counting on you, as a doctor, not necessarily knowing the common origins of zoonotic diseases and their frequent intermediate animal victims or intermediate hosts. When you mentioned it to your vet friend, she also found it odd.

4. In sum, the picture that comes together is someone who doesn't seem like who they say they are. They don't seem to know enough about medicine, and they don't seem to be repeating your experiment with the right intentions. The key with communication is that you don't know for sure, you only have how things strike you – odd, normal, alarming. If it seems odd, your best bet is to stop communicating with that individual. If it is alarming, you can report them, assuming they fall within the correct jurisdiction but that is not always the case. The author may have been several countries away.

New Responses from Students:

Expected Responses Continued

What could you have done?

Ask yourself questions; don't unthinkingly act if something seems out of the ordinary.

Created and participated in a more open work environment by asking the vet's advice sooner.

Did you keep it to yourself because it bothered you?

Stop emailing him when he seemed not to have the correct scientific background or be doing the correct experiment.

What to take away:

This is an example where there may be an individual attempting to take advantage of work you published and put it to nefarious use. The point of this exercise is to teach you to trust your instincts regarding his or her odd behavior. If you are going against your "gut," or initial response, ask why you are responding that way (assuming it's not non-altruistic impulse). If you suspect someone is using your work, that you intended for good for some other purpose, you are under no obligation to keep communicating with them to help them in that purpose. It is that simple.

Ideally, you report them to appropriate legal authority, but if it is understandable that this may not always be a viable option. [??]

Be Vigilant in trusting your instincts regarding suspicious individuals who contact you and how you safeguard your pathogens according to the biosecurity and biosafety practices of your institution or lab.

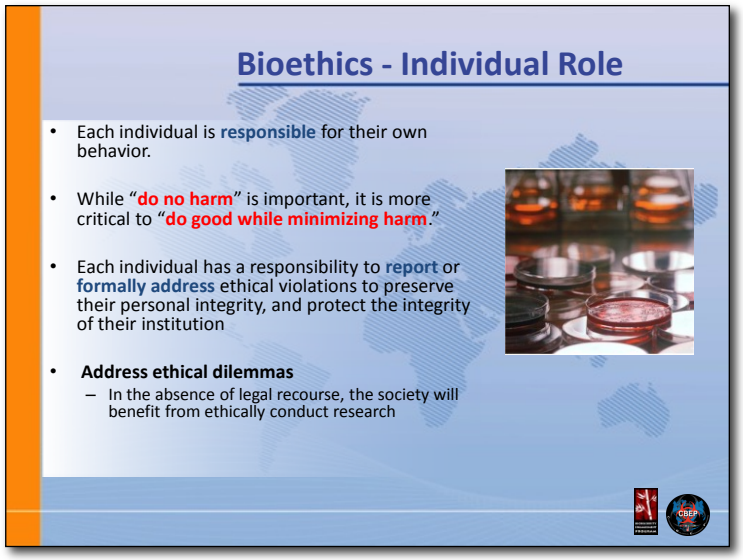
New Responses from Students:

Bioethics Case Studies

Transition to Roles & Responsibilities

Roles & Responsibilities

Slide 35



Background Information for Instructor

The following exercises have illustrated some potential dilemmas that can arise in research environments. It is important to identify what exactly the individual and the organizational responsibility is for creating a strong bioethical environment.

In upholding bioethical norms and good practices with regards to dual use research of concern, it is important to recognize the individual's role.

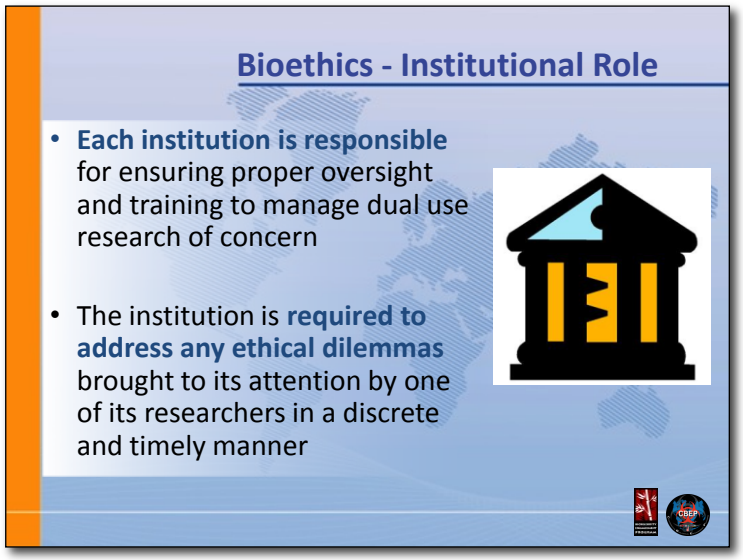
Individuals are responsible for their own behavior. This extends from the professional scientists, to the budding amateur. NSABB extended this to the DIYBio community, a difficult community to reach legislatively: "Dual use research may resonate most with this audience if embedded in broader concepts of social and personal responsibility." (NSABB Report, Strategies to Educate Amateur Biologists and Scientists in Non-Life Science Disciplines About Dual Use Research in the Life Sciences. June 2011)

Roles & Responsibilities

Ask students to REFLECT individually on the following question/statement:

Based on the previous exercises, what can you do to uphold good Bioethical practices and reduce the risks of dual use?

Slide 36



Lecture

Each institution has a responsibility to create an environment that allows the individuals working within it to express concern should an ethical dilemma come up. This includes training and where applicable, formal oversight of specific forms of research.

Should an ethical dilemma be brought to the attention of the institution, it is responsible for addressing it in a timely and discrete manner. This is to protect the person reporting the dilemma from any possible retaliatory actions and to protect the objectivity of the investigation.

Ask: Any questions on Roles and Responsibilities?

Roles & Responsibilities

Take a Break (10 minutes)

Time Check

You should be approximately __ hour and __ minutes into the course.
You have __ hours of the course remaining.

Transition to Review

Review

Goal

The purpose and goal of this section is to recap the key messages of the course and to conduct a “What? So What? Now What?” review of the course and the key messages?

Time

Allow 20 minutes to get through the Review section.

Slide 37

Review

Background Information for Instructor

Emphasize the following points:

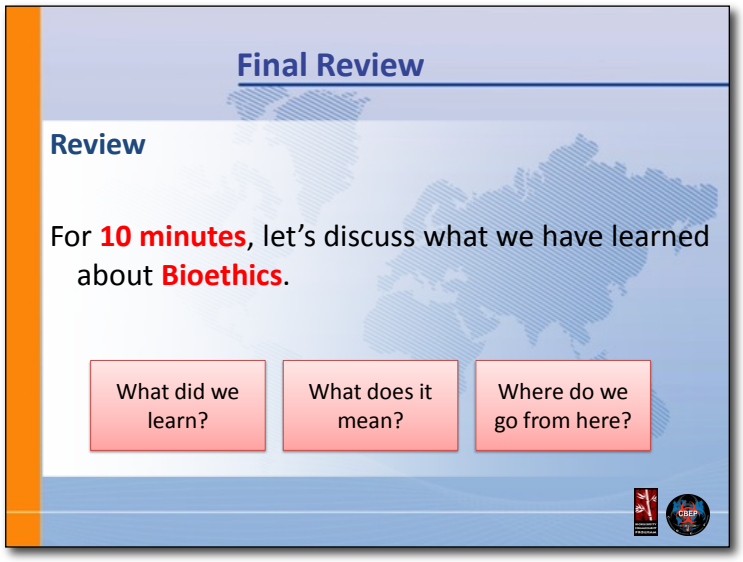
The reputation of the individual and the institution is reflected in ethical conduct. As a result, ethical conduct is integral aspect of maintaining the integrity of both.

Bioethics is taught separately from research, but ethics and responsible research are inextricable concepts. Ethics affects decisions when conducting responsible research fundamentally, so increasing awareness to this is vital.

If "do no harm" requires unethical conduct or a dangerous experiment, you must "do good while minimizing harm." "No harm" is an unobtainable goal in most circumstances.

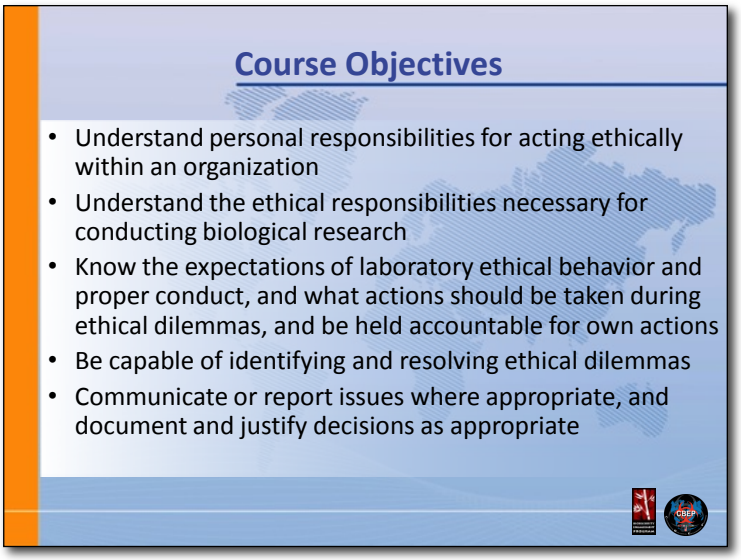
Even if ethical conduct is not formally rewarded or punished through legal means, society will largely benefit from the individuals within it acting responsibly.

Slide 38



Review

Slide 39



Review Key Messages

1. Each individual is responsible for their own behavior.

2. Ethical conduct is not only a key to personal integrity but reflects on the integrity of the institution.

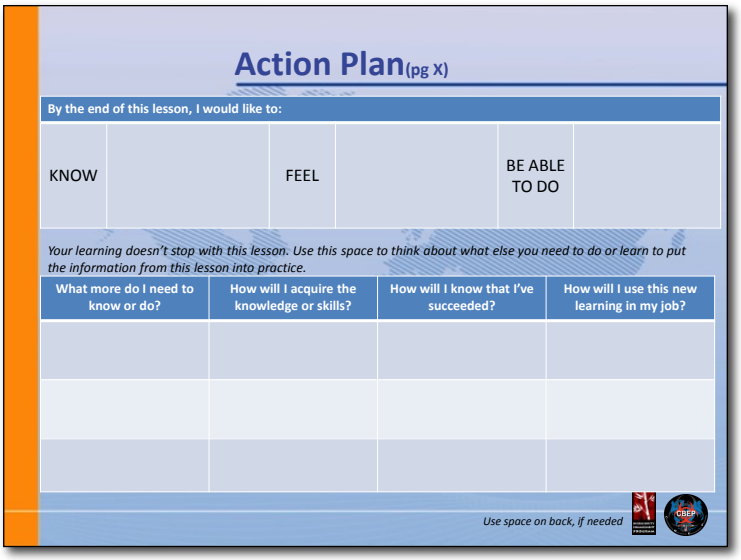
3. Bioethics is not a separate task to research but an integral part to all activities.

4. While “does no harm” is important, it is more critical to “do good while minimizing harm.”

5. In the absence of legal constraints, ethic conduct is still important as a societal benefit.

Review

Slide 40



Ask the students to take a few minutes to review and update their action plan. If they are willing to share, ask them if they identified any action items to try out when they get back to their work.

Slide 41

Review

Level 1 Evaluation

- Ask students to complete the course evaluation and to put it in the evaluation box (alternately, give students instructions for completing the evaluation on-line).