Mock Research Review Exercise

Exercise Instructions

Training Goal

The mock review exercise uses team-based learning and role-playing approaches to train scientists to identify and analyze risks and benefits of a research project. This exercise does not involve the use of a reference list of high-risk experiments or research to assist with the reviews. Instead, this exercise is designed to promote critical thinking about biosafety and biosecurity risks associated with research, benefits of research, and strategies for mitigating risks and maximizing benefits.

Lead Developing Organization

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Mock Research Review Exercise MENA Training Event

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Outcome

At the end of this exercise, students should be able to identify critical questions that enable critical evaluation of potential biosafety and biosecurity risks of research activities and potential benefits. Students should be able to analyze the feasibility of potential risks and benefits (i.e., whether knowledge, skills, technologies, and resources exist to realize potential risks or whether barriers exist to realize potential benefits), and weigh potential risks and benefits of research. Students should be able to integrate these analyses to identify strategies to mitigate risks and maximize benefits.

Output

The mock research review exercise results in the identification of questions that can be used by researchers and reviewers to identify and evaluate risks, benefits, and mitigation strategies for each of the three notional research projects. In addition, this exercise results in a list of risks, benefits, and risk mitigation strategies for each mock research project, the students' reasons for their analyses.

Materials

Copies of Exercise Worksheets Pens

Process

To facilitate the mock review exercise, instructors will follow the steps below. This exercise works best with 5 to 7 individuals and on topics with which students have some familiarity through formal coursework or research experience. One or two students should serve as the researcher and the remaining students should serve as reviewers. The instructor should describe ground rules for participating in this interactive exercise. These rules include overcoming deference to hierarchy or status, and ensuring that discussions among trainees is constructive rather than combative or judgmental.

<u>Planning and Preparation</u>

Step 1: The instructor defines the learning goals and objectives for this exercise. The learning goals should be outcome-based and address a training need. The instructor should limit the number of learning goals to a maximum of two per exercise. The learning goals should be key concepts that the exercise addresses, such as learning how to identify and assess risk and benefit of research projects. The instructor should limit the number of learning objectives to a maximum

of four per learning goal. The learning objectives should be specific actions that inform student expectations for the exercise.

Step 2: The instructor identifies the risks that students must recognize and evaluate, and determines whether existing training materials address those risks or new materials are needed. The instructor can choose to use existing materials or develop his/her own materials (Step 3). In addition, instructors may choose to have all groups evaluate the same notional project or have groups evaluate different notional projects. If existing materials do not enable critical evaluation of the identified risks, the instructor may choose to develop his/her own materials (Step 3). The training materials include a one-page description of a notional research project, which can be derived from real-life examples, and a worksheet for students to document risks, benefits, and questions asked during the mock review exercise.

Step 3: If existing training materials are needed, the instructor develops a one-page description of a

notional research project that prompts students to recognize and evaluate the risks of interest. Each new notional research project description should include an abstract of the purpose and goals of the project, the experimental approach, and results. For each description, the instructor should provide sufficient detail for the students to analyze associated risks and benefits of the overall project, experimental approach, materials, and results. A template is included at the end of these instructions. The instructor also prepares a worksheet on which students document the questions asked (if playing the role of reviewers), risks identified, benefits identified, and mitigation strategies used. Instructors may have students develop their own notional research project concepts, which would be provided to other students to review.

Step 4: The instructor develops a plan for conducting the exercise. Based on the size and duration of the training session, the instructor should determine whether the exercise should be conducted in small groups and whether each group will be asked to review the same or different notional projects. If small groups are used for this exercise, the instructor should consider assigning students to each group to distribute the expertise and experience among all groups. The instructor can assign each student a role of reviewer or researcher, or let the groups decide for themselves. In addition, instructors may choose to have all groups evaluate the same notional project or have groups evaluate different notional projects. If students are not familiar with research review processes and/or with role-playing exercises for training purposes, the instructor may choose to conduct a brief mock review exercise to illustrate how it should be conducted and answer any questions students may have before the small group discussions.

Exercise

Teaching Tidbits

Instructors can develop their own notional studies for students to evaluate in this mock review.

If students are not experienced scientists, instructors can have students develop their own notional study plans which other groups of students will review. This process ensures that the notional projects are at a scientific level appropriate for the audience.

If students are not trained, instructors can develop their own notional study plans that are at the appropriate scientific level of the students.

Notional studies should reflect the scientific level in the country, at the institution, and for the specified audience.

Please send other ways of tailoring the exercise to mena@gryphonscientific.com.

The duration of this exercise, as outlined below, is approximately 1.5-3.0 hours long. The actual time required depends on the number of small groups and the need for a demonstration of the exercise.

Step 5: The instructor should explain the objective and expectations of the exercise to students. The instructor should describe the learning goals of the mock research review exercise and expectations of students. This information enhances student understanding about the exercise itself and his/her role in the exercise. The instructor should inform students that the scenario is simulation-based and not real, but was designed to be realistic and focus on critically thinking about risk and benefit of research activities. The instructor should inform students that they are expected to primarily consider the problem described in the notional research projects, but they can be informed by their own experiences in the laboratory during the small and large group discussions. The instructor should stress the importance of welcoming different viewpoints during the discussion, promoting a supportive environment for students to share ideas openly and without hesitation.

Step 6: The instructor should provide participants 10 minutes to review the notional research project. During this time, students should review: a) the purpose and goals of the project, which provide insight into possible benefits of the research project; b) the experimental approach in the abstract and specific aims, which provide some indication about the types of risks expected or anticipated; c) the biological materials involved in the notional project to determine agent or material-specific risks and/or measures; and d) the results, which provide insight about potential risks associated with the information. Many details will be missing from this one-page description so participants will have to make assumptions based on the information provided. For this reason, student familiarity with the research topic is necessary for ensuring educational value of the exercise. The instructor can increase the duration of this step to allow students more time to review the notional research project.

Step 7: The instructor should provide students 15 minutes to prepare for the exercise using the information provided in the exercise worksheets. The students serving as reviewers should prepare a list of questions to help identify and discuss potential risks and benefits of the notional research project. These students may choose to consult each other to develop a single list of questions. Students are not restricted to asking only these questions once the exercise starts, but they provide a guide for identifying and evaluating risks, benefits, and risk mitigation strategies. The students serving as researchers should prepare a list of risks, benefits, and risk mitigation strategies. If more than one student is playing the role of a researcher, they should discuss identified risks, benefits, and risk mitigation strategies. During this process, the instructor should have students consider biosafety, biosecurity, and dual use research of concern risks of the notional research project and associated knowledge, skills, and materials. In addition, students may consider protection of animal and human participants and safety of genetic engineering as part of their risk identification. For benefits, students should consider benefits that may be described explicitly in the project description or inferred based on their knowledge of the topic. In addition, students should be encouraged to consider whether any hurdles or barriers exist for realizing risks or benefits. This additional information is critical to evaluating and comparing risk and benefit.

Step 8: The instructor should provide students 45 minutes for the mock review portion of the exercise. The mock review exercise is discussion-based where students serving as reviewers engage the students serving as researchers in discussion about the notional research project, potential risks, potential benefits, and risk mitigation strategies. The exercise begins with student-researchers briefly describing the key information of the research projects, after which the student-reviewers pose questions to the student-researcher(s). Reviewers should ask one question at a time, allowing the researcher to answer and providing opportunities for follow-up questions and inquiries of additional information. The questions should focus on informing risks and benefits of the research, allowing reviewers to discuss the feasibility and immediacy of the risks, the consequences if risks are realized, expected benefits, and anticipated obstacles to realizing the barriers. From this information, the instructor should have students discuss the potential risks and benefits they identified to determine whether the risks outweigh the benefits or benefits outweigh the risks. If student reviewers think the risks outweigh the benefits, they should indicate whether they would approve with no changes, approve with appropriate risk mitigation strategies, or reject the projects. If student-reviewers think the benefits outweigh the risks, they should indicate whether they approve the project with no change or approve the project with risk mitigations strategies. Finally, the instructor should have students discuss measures for reducing the identified risks. Students should document these strategies and the risks they address. Students should indicate whether these measures reduce the potential application of the findings, effectively reducing the potential benefits of the research. Throughout these discussions, students should document the key information on the worksheet. If students are divided into small groups, this step is conducted within small groups.

Step 9: The instructor should provide students 10 minutes to document the key questions asked during the discussions and to review their information on the worksheets. This step provides each group an opportunity to discuss the information included on the worksheet, ensuring it is complete and reflects the views of the student-reviewers and student-researchers in each group. In addition, this step allows students to think about the questions asked, highlighting those questions that enabled them to identify and evaluate risks, benefits, and risk mitigation strategies.

Step 10: The instructor should engage all students in discussion about the outcomes from each mock review exercise. The instructor should facilitate a discussion about the most informative questions asked, risks identified, benefits identified, risk mitigation measures identified, results of their risk/benefit analysis, and reasons for their decision about approval or rejection of the research project. During this step, the instructor and students have an opportunity to ask follow-up questions and provide additional comment. If students were divided into smaller groups to conduct these exercises, each group should have an opportunity to summarize their results to the larger group. The instructor should try to limit discussions for each group to 10-15 minutes to ensure all groups have an equal chance to discuss their outcomes. If groups were given different notional research projects to review, the instructor should provide a 5-minute summary of the project before every group that reviewed that project shares their outcomes.

Step 11: The instructor should end the exercise by highlighting the key questions that enabled identification and analysis of risks and benefits of research, and identification of risk mitigation strategies. The instructor should summarize the key questions asked by student-

reviewers, highlighting any that were common among different groups and reviews of different notional research projects. Students can use these questions as a starting point for evaluating research projects. In addition, students and instructors can discuss strategies for supplementing these questions with others that are project specific during the research evaluation process.

The output from Step 11 is a list of questions that can be used by researchers and reviewers to guide their identification and evaluation of risks, benefits, and mitigation strategies of research projects.

Working with Large Groups

For trainings that involve more than 10 students, these steps should be modified to achieve the intended goals. Specifically, students should be divided into groups of 5-7 and provided with notional research projects on topics with which they are familiar. After each group has had an opportunity to discuss their answers, a representative from each of the smaller groups should share their answers with the whole group, after which the instructor should engage the entire group in discussion to arrive at one list of risks and practices and the primary output.

Mock Review Notional Research Project Template

Project Title: [Include a realistic title for the notional research project.]

Brief Summary: [In abstract format, briefly summarize the notional project for which researchers are seeking approval. This paragraph should include a description of the purpose of the project, the research activities (including specialized experimental methodologies such as challenge experiments), biological materials involved, and research animals involved.]

Project Goal: [Briefly describe the goal of the notional project. This description will help trainees evaluate potential benefits of the notional research project during the exercise.]

Specific Aims: [Include approximately 2 to 4 objectives (or specific aims) of the notional project. Each objective should start with an action work, such as develop, examine or test. Each specific aim should include the overall objective followed by key information about the experiments to test or achieve the objective. The descriptions of the specific aims will help trainees evaluate potential risks of the notional research project during the exercise.]