RESPONSIBLE RESEARCH PRACTICE

TUTORIALS

May 2013

The University is committed to fostering a culture of responsible research including:

* honesty and integrity
* respect for human research participants, animals and the environment
* good stewardship of public resources used to conduct research
* appropriate acknowledgement of the role of others in research
* responsible communication of research results.

Please Note: These tutorials are to be used as a teaching tool within the University of Sydney only.
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OVERVIEW

Welcome to the Responsible Research Practice tutorials.

The training should be completed online through CareerPath.

The online course comprises three parts: Manual, Tutorial, and Test.

1 The Manual section is optional. You should have an understanding of the contents of the Manual before attempting the Tutorial and Test questions.

2 The Tutorial questions section is optional. These help you understand the key requirements of your training through scenario-based questions.

3 The Test questions are mandatory. You must successfully complete the Test questions in order to complete the course.

The Manual is provided as reference material, whilst the Tutorial questions are scenario based to assist you to understand the key messages of the training.

How long will it take?

The course takes on average 10 to 45 minutes to complete, depending on your level of experience.

What is the pass mark?

The pass mark for the test is 80%. Should you fail to achieve the required pass mark, you will be required to resit the tutorial before attempting the test again.

This course was developed in collaboration with the University of Sydney’s Researchers, Research Integrity Advisers and Ethics Committee Members.
TUTORIAL 1: GENERAL PRINCIPLES OF RESPONSIBLE RESEARCH

QUESTION:

You are conducting a project which requires observation of Aboriginal primary school children in Dubbo. You decide to increase your participant numbers and conduct the project with another similar, nearby Aboriginal community. The nearby Aboriginal community heard about your project and is very keen to participate.

Is the following statement true or false?

'You do not need to consult with the nearby Aboriginal community about their specific requirements as they have expressed a desire to participate and you have already received ethics approval for a similar Aboriginal community. You may start the interviews immediately.'

ANSWERS:

Choice A: True

Choice B: False

ANSWER RESPONSES:

Response A: Incorrect Answer.
Aboriginal individuals, communities and groups vary and your research may affect each community differently, even if it has similar traditions and customs. You may not be aware of subtle but important differences. Accordingly, you will need to:
1. consider the specific requirements of your participants;
2. discuss with a representative of the new Aboriginal community before commencing your interviews for your project;
3. determine how this study would benefit the community and how you intend to give back through your project; and
4. discuss with a staff member of the HREC office to consider whether new or modified ethics approval is required (depending on the scope of the initial approval).

You also may want to review the following publications:
• Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research;
• Guidelines for Ethical Research in Indigenous Studies; and
• Keeping Research on Track: A Guide for Aboriginal and Torres Strait Islander Peoples About Health Research Ethics.

Response B: Correct Answer.
Aboriginal individuals, communities and groups vary and your research may affect each community differently even if it has similar traditions and customs. You may not be aware of subtle but important differences. Accordingly, you will need to:
1. consider the specific requirements of your participants;
2. discuss with a representative of the new Aboriginal community before commencing your interviews for your project;
3. determine how this study would benefit the community and how you intend to give back through your project; and
4. discuss with a staff member of the HREC office to consider whether new or modified ethics approval is required (depending on the scope of the initial approval).

You also may want to review the following publications:
• Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research;
• Guidelines for Ethical Research in Indigenous Studies; and
• Keeping Research on Track: A Guide for Aboriginal and Torres Strait Islander Peoples About Health Research Ethics.
TUTORIAL 2: MANAGEMENT OF RESEARCH DATA AND PRIMARY MATERIALS

QUESTION:

You have completed a funded research project on pregnancy and nutrition, publishing several papers as a result of your research. You obtained Human Research Ethics approval prior to conducting your research. A colleague has told you that all data relating to human participants needs to be destroyed following a minimum retention period. You are uncertain about what to do.

Which of the following is the best course of action for you to follow?

ANSWERS:

Choice A: You need to consider compliance with the funding agreement and the Human Research Ethics approval. In addition, you need to confirm the applicable retention period for the data under the Codes.

Choice B: You can destroy the data as the results have been published and it is no longer required.

Choice C: You should retain the data indefinitely because the research involves humans and the effect on human participants may not be well known until long after the project is completed.

ANSWER RESPONSES:

Response A: Correct Answer.

You are required to retain records and primary materials in a certain manner and form and for minimum periods. You should check the funding agreement and the Human Research Ethics approval. You should also confirm the relevant retention period and requirements by reference to the University’s Research Code of Conduct and Recordkeeping Policy, Recordkeeping Manual and Privacy Policy.

For example:
- data with long term human effects must be retained for at least 20 years (e.g. patient records); and
- data from a clinical trial must be retained for at least 15 years or otherwise in accordance with the requirements of the Therapeutic Goods Administration.

You should consult the University Archives and Records Management Services if you require further advice.

Response B: Incorrect Answer.

Although you have published the results, you are still required to retain records and primary materials in a certain manner and form and for minimum periods. You should check the funding agreement and the Human Research Ethics Approval. You should confirm the relevant retention period and requirements by reference to the University’s Research Code of Conduct and Recordkeeping Policy, Recordkeeping Manual and Privacy Policy.

For example:
- data with long term human effects must be retained for at least 20 years (e.g. patient records); and
- data from a clinical trial must be retained for at least 15 years or otherwise in accordance with the requirements of the Therapeutic Goods Administration.

You should consult the University Archives and Records Management Services if you require further advice.

Response C: Incorrect Answer.

This is not the best course of action. The periods of retention differ depending on the data and type of research. You are required to retain records and primary materials in a certain manner and form and for minimum periods. You should check the funding agreement and the Human Research Ethics Approval. You should confirm the relevant retention period and requirements by reference to the University’s Research Code of Conduct and Recordkeeping Policy, Recordkeeping Manual and Privacy Policy.

For example:
- data with long term human effects must be retained for at least 20 years (for example patient records); and
- data from a clinical trial must be retained for at least 15 years or otherwise in accordance with the requirements of the Therapeutic Goods Administration.

You should consult the University Archives and Records Management Services if you require further advice.
TUTORIAL 3: MANAGEMENT OF RESEARCH DATA AND PRIMARY MATERIALS 2

QUESTION:

You are a senior research fellow who has successfully gained funding to create a large multi-disciplinary research group. The research group will include both internal and external researchers. You are the lead researcher.

What should you do to determine who is responsible for the data?

ANSWERS:

Choice A: Relying on past practice, you should make each researcher responsible for their research data as decisions about retention are best decided at the individual researcher level.

Choice B: You are the lead researcher and have control of the funding, so you should be able to make the final decisions in respect of how the data is managed.

Choice C: You should discuss management of data with the other researchers and take into consideration any requirements under the funding arrangements, related agreements and the requirements of the University’s Research Code.

ANSWER RESPONSES:

Response A: Incorrect Answer.
As the lead researcher, the University’s Research Code advises that you and your department will be responsible for the management and storage of the data unless there is an alternative arrangement in place or you come to a different agreement with the other researchers. You should discuss management of data with the other researchers and take into consideration any requirements under the funding arrangements, related agreements and the requirements of the University’s Research Code.

Response B: Incorrect Answer.
As the lead researcher, the University’s Research Code advises that you and your department will be responsible for the management and storage of the data unless there is an alternative arrangement in place or you come to a different agreement with the other researchers. You should discuss management of data with the other researchers and take into consideration any requirements under the funding arrangements, related agreements and the requirements of the University’s Research Code.

Response C: Correct Answer.
As the lead researcher, the University’s Research Code provides that you and your department will be responsible for the management and storage of the data unless there is an alternative arrangement in place or you come to a different agreement with the other researchers.
TUTORIAL 4: PUBLICATION AND DISSEMINATION OF RESEARCH FINDINGS

QUESTION:
You run a blog which contains information on recent research findings, and tips for dealing with grief and other mental health related topics. On one particular blog, you mistakenly refer to a group of children as displaying symptoms of ADD (Attention Deficit Disorder) where, in fact, that group of children had symptoms of ADHD (Attention-deficit Hyperactivity Disorder). You do not consider this is a material issue as ADD is an out of date term that is commonly used for one of three subsets of what is now known as ADHD.

Is the following statement true or false?

You do not have to correct the reference to ADD as the information is in a blog and not a journal.

ANSWERS:

Choice A: True
Choice B: False

ANSWER RESPONSES:

Response A: Incorrect Answer.
You have a responsibility to:
• report research findings accurately regardless of the form of dissemination; and
• correct any inaccurate statements as soon as possible once you become aware of them. The reference to ADD may be misleading as it only refers to one subset of ADHD.

Response B: Correct Answer.
You have a responsibility to:
• report research findings accurately and regardless of the form of dissemination; and
• correct any inaccurate statements as soon as possible once you become aware of them. The reference to ADD may be misleading as it only refers to one subset of ADHD.
TUTORIAL 5: AUTHORSHIP

QUESTION:
A student approaches you to discuss a research topic and you agree to write a joint paper on the topic with the student.

The student writes the introduction to the paper. You review the introduction and rewrite parts of it because it is not of an appropriate standard. You write the remainder of the article over several months.

You now want to publish the paper however you have not been in contact with the student for several months. What should you do?

ANSWERS:

Choice A: Not name the student as an author and submit the paper to the journal without telling the student.

Choice B: You can submit the paper for publication listing yourself and the student as authors on the paper without telling the student.

Choice C: You should consider whether the student qualifies as an author or only as a contributor. You should try to contact the student, preferably in writing, requesting consent to name the student as an author or, if this is the appropriate option, to acknowledge the student as a contributor.

ANSWER RESPONSES:

Response A: Incorrect Answer.
You must first consider whether the student’s contribution to the paper meets the criteria for authorship. If the student qualifies as an author, the Codes require you to:
• offer authorship to the student; and
• not exclude the student as an author without the student’s written permission. You should try to contact the student (preferably in writing) but if you can’t, you may include the student as an author if there are no grounds to believe that the student would object to being named as an author.
If the student does not meet the criteria of authorship, you should acknowledge the student’s contribution if there are no grounds to believe the student would object.
You can contact a Research Integrity Adviser for further advice.

Response B: Incorrect Answer.
You must first consider whether the student’s contribution to the paper meets the criteria for authorship. If the student qualifies as an author, the Codes require you to:
• offer authorship to the student; and
• not exclude the student as an author without the student’s written permission. You should try to contact the student (preferably in writing) but if you can’t, you may include the student as an author if there are no grounds to believe that the student would object to being named as an author.
If the student does not meet the criteria of authorship, you should acknowledge the student’s contribution if there are no grounds to believe the student would object.
You can contact a Research Integrity Adviser for further advice.

Response C: Correct Answer.
You must first consider whether the student’s contribution to the paper meets the criteria for authorship. If the student qualifies as an author, the Codes require you to:
• offer authorship to the student; and
• not include or exclude the student as an author without the student’s written permission. You should try to contact the student (preferably in writing) but if you can’t, you may include the student as an author if there are no grounds to believe that the student would object to being named as an author.
If the student does not meet the criteria of authorship, you must acknowledge the student’s contribution if there are no grounds to believe the student would object.
You can contact a Research Integrity Adviser from any Faculty for further advice.
TUTORIAL 6: CONFLICTS OF INTEREST

QUESTION:

You are a researcher and a cardiologist with a successful clinical practice. You are conducting research which has the potential for ground breaking results for you as a researcher. You expect it will also benefit you patients. On the days you do consultations in your clinical practice you see around 20 patients. You consider this would be the perfect opportunity to recruit them for your potentially ground breaking research study.

What would be the best way to go about recruiting them as participants for your research study?

ANSWERS:

Choice A: You believe that your patients may directly benefit from your research and you attempt to recruit them into the study when they come to see you. You disclose your interest in the study and discuss the benefits and possible risks of participation.

Choice B: You make an appointment with your patients to discuss their participation in the study outside of their usual clinical appointments.

Choice C: You inform the patient about the existence of the study, and refer them to another person (ideally a cardiologist not involved in the study) to discuss their potential participation.

ANSWER RESPONSE:

Response A: Incorrect Answer.

Even if you do not believe that you are actually conflicted, other parties may perceive that there is a conflict of interest. For example, other parties might think your patients might assume that the quality of their clinical care is dependent upon their participation in the study.

You should:

• never be involved in the direct recruitment of your own patients to your research study;
• inform the patient about the existence of the study, and refer them to an independent party, such as another cardiologist who is not involved in the research or their GP, to discuss their potential participation;
• allow the patient time to consider whether they would like to participate; and
• provide the patient with a Patient Information Sheet, declaring your interest in the study, during the clinical appointment.

Response B: Incorrect Answer.

Even if you do not believe that you are actually conflicted, other parties may perceive that there is a conflict of interest. For example, other parties might think your patients might assume that the quality of their clinical care is dependent upon their participation in the study.

You should:

• never be involved in the direct recruitment of your own patients to your research study;
• inform the patient about the existence of the study, and refer them to an independent party, such as another cardiologist who is not involved in the research or their GP, to discuss their potential participation;
• allow the patient time to consider whether they would like to participate; and
• provide the patient with a Patient Information Sheet, declaring your interest in the study, during the clinical appointment.

Response C: Correct Answer.

Even if you feel you are not conflicted, other parties may perceive that a conflict exists. For example, other parties might think your patients might assume that the quality of their clinical care is dependent upon their participation in the study.
You should:

• never be involved in the direct recruitment of your own patients to your research study;
• inform the patient about the existence of the study, and refer them to an independent party, such as another cardiologist who is not involved in the research or their GP, to discuss their potential participation;
• allow the patient time to consider whether they would like to participate; and
• provide the patient with a Patient Information Sheet, declaring your interest in the study, during the clinical appointment.
TUTORIAL 7: CONFLICTS OF INTEREST 2

QUESTION:

You receive ARC funding for marine research you are conducting. You intend to use a small portion of these ARC funds to hire your daughter as a research assistant to accompany you on a two week expedition to the Great Barrier Reef as part of your research. You need a junior assistant and you feel this would be a wonderful opportunity for your daughter, who you consider has come relevant knowledge and experience and has expressed an interest in studying marine biology at university.

What should you do?

ANSWERS:

Choice A: Go ahead and hire your daughter.

Choice B: Your daughter should not be hired for the position in any circumstance.

Choice C: You should disclose your intention to hire your daughter to the relevant executive supervisor, who would make a decision about whether the conflict can be managed.

ANSWER RESPONSES:

Response A: Incorrect Answer.
Even if you believe there is no actual conflict, it is likely that others would perceive a conflict, due to the close personal relationship between you and your potential research assistant. You should follow the University’s External Interests Policy and disclose the potential conflict in writing to the relevant executive supervisor. Your executive supervisor will determine whether a conflict exists and decide whether to hire your daughter. You should agree to advertise the position if the conflict cannot be appropriately managed in that way. Your daughter could apply for the position. If she did, you should still not make the hiring decision.

Response B: Incorrect Answer.
Even if you believe there is no actual conflict, it is likely that others would perceive a conflict, due to the close personal relationship between you and your potential research assistant. You should follow the University’s External Interests Policy and disclose the potential conflict in writing to the relevant executive supervisor. Your executive supervisor will determine whether a conflict exists and decide whether to hire your daughter. You should agree to advertise the position if the conflict cannot be appropriately managed in that way. Your daughter could apply for the position. If she did, you should still not make the hiring decision.

Response C: Correct Answer.
Even if you believe there is no actual conflict, it is likely that others would perceive a conflict, due to the close personal relationship between you and your potential research assistant. You should follow the University’s External Interests Policy and disclose the potential conflict in writing to the relevant executive supervisor. Your executive supervisor will determine whether a conflict exists, and decide whether to hire your daughter. You should agree to advertise the position if the conflict cannot be appropriately managed in that way. Your daughter could apply for the position. If she did, you should still not make the hiring decision.
TUTORIAL 8: CONFLICTS OF INTEREST 3

QUESTION:

You are a member of academic staff of the School of Languages and Culture. You are responsible for the supervision of a number of PhD students. Your role as supervisor includes approving attendances at conferences. You recently commenced an intimate personal relationship with one of your PhD students. This student asks you to approve attendance at a conference. The student is a promising student in the School, and is widely respected among peers.

Which statement is most correct?

ANSWERS:

Choice A: You give approval for the student to attend the conference because, as supervisor, it is your responsibility to approve the request to attend the conference. It is not relevant that you are intimately involved, as the student is one of our brightest students and you would approve it regardless.

Choice B: Your other PhD students might think it is unfair that you seem to be favouring a student with whom you have an intimate relationship. You disclose your relationship to the relevant executive supervisor who can then make the decision. The executive supervisor can manage any potential conflict going forward.

Choice C: You should not be involved in the decision to approve attendance at the conference, and in any event, it is not appropriate for you to continue as the student’s supervisor.

ANSWER RESPONSES:

Response A: Incorrect Answer.
Although you feel that there is no actual conflict of interest because you would approve the request even if you were not intimately involved, others may perceive there is a conflict due to your relationship. You should disclose your relationship to the relevant executive supervisor who should decide whether the student attends the conference. It is also not appropriate for you to continue as the student’s supervisor.

Response B: Incorrect Answer.
As you have identified, you should disclose your relationship to the relevant executive supervisor and let that person make the decision. Although you feel that there is no actual conflict of interest because you would approve the request even if you were not intimately involved, others may perceive there is a conflict due to your relationship. It is also not appropriate for you to continue as the student’s supervisor.

Response C: Correct Answer.
Although you feel that there is no actual conflict of interest because you would approve the request even if you were not intimately involved, others may perceive there is a conflict due to your relationship. As you have identified, you should:  
• disclose your relationship to the relevant executive supervisor who will decide whether the student attends the conference; and  
• not continue as the student’s supervisor.
TUTORIAL 9: CONFLICTS OF INTEREST 4

QUESTION:
You have been nominated to review a student’s thesis. Shortly before the thesis is submitted, both you and the student’s supervisor attend a conference and strike up a close friendship.

What should you do? Choose the best answer.

ANSWERS:

Choice A: Decline to examine the Thesis immediately.

Choice B: Examine the thesis anyway, as your friendship is with the supervisor (not the student) and pulling out now would negatively impact the student by delaying examination of the thesis.

Choice C: Declare the potential conflict of interest to the relevant executive supervisor.

ANSWER RESPONSES:

Response A: Incorrect Answer.
Your friendship with the student’s supervisor may lead to a conflict of interest in your ability to examine the thesis. If you consider that this is the case, you must declare the conflict of interest and decline to examine the thesis. Even if you do not think you have an actual conflict of interest it may appear as though there is a conflict of interest. Before declining to examine the thesis, you should declare the perceived conflict of interest to the relevant executive supervisor. The executive supervisor will determine whether you should continue as an examiner for the thesis and, if so, any associated conditions.

Response B: Incorrect Answer.
Your friendship with the student’s supervisor may lead to a conflict of interest in your examination of the thesis. If you consider that this is the case, you must declare the conflict of interest and decline to examine the thesis. Even if you think you do not have an actual conflict of interest, it may appear to others that there is a conflict of interest. Before deciding to examine the thesis, you should declare the perceived conflict of interest to the relevant executive supervisor. The executive supervisor will then determine whether you should continue as an examiner for the thesis and, if so, any associated conditions.

Response C: Correct Answer.
Your friendship with the student’s supervisor may lead to a conflict of interest in your examination of the thesis. If you consider that this is the case, you must declare the conflict of interest. Even if you think you do not have an actual conflict of interest, it may appear to others that there is a conflict of interest. Before deciding to examine the thesis, you should declare the perceived conflict of interest to the relevant executive supervisor. The executive supervisor will then determine whether you should continue as an examiner for the thesis and, if so, any associated conditions.
TUTORIAL 10: COLLABORATIVE RESEARCH ACROSS INSTITUTIONS

QUESTION:

Under a written Collaboration Agreement between the University and a research institute, you are involved in a research project exploring the role of Vitamin D in the placenta and pregnancy. You have subsequently agreed to collaborate with the lead researcher at the research institute on preliminary research into the significance of Vitamin B-6 deficiencies in pregnancy. The lead researcher at the research institute suggests that you do not need a written research collaboration agreement for this further portion of work.

What should you do?

ANSWERS:

Choice A: You should contact the Research Contracts Team for legal advice.

Choice B: Given the preliminary nature of the research, you don't need to seek legal advice.

Choice C: As you already have a research collaboration agreement for similar research, this further research will be covered under that agreement, so there is no need to seek legal advice.

ANSWER RESPONSES:

Response A: Correct Answer.
You may not be aware of the terms of the Collaboration Agreement. It is possible that the research collaboration agreement in place relates only to the project (exploring the role of Vitamin D in pregnancy) and does not cover any research concerning the role of other micronutrients in pregnancy. When research is conducted across different institutions, it is important that a written collaboration agreement is in place. The agreement will deal with the complexities of collaborative research. These complexities include the ownership and management of intellectual property, confidentiality and management of research materials and data.

Response B: Incorrect Answer.
It is possible that the research collaboration agreement in place relates only to the project (exploring the role of Vitamin D in pregnancy) and does not cover any research concerning the role of other micronutrients in pregnancy. When research is conducted across different institutions, it is important that a written collaboration agreement is in place. The agreement will deal with the complexities of collaborative research. These complexities include the ownership and management of intellectual property, confidentiality and management of research materials and data.
You should contact the Research Contracts Team, to determine whether you need a further written collaboration agreement.

Response C: Incorrect Answer.
You may not be aware of the terms of the Collaboration Agreement. It is possible that the research collaboration agreement in place only relates to the original project (exploring the role of Vitamin D in pregnancy) and does not cover any research concerning the role of Vitamin B-6 deficiencies.
You should contact the Research Contracts Team, to determine whether you need a further written collaboration agreement. When research is conducted across different institutions, it is important that a written collaboration agreement is in place. The agreement will deal with the complexities of collaborative research. These complexities include the ownership and management of intellectual property, confidentiality and management of research materials and data.
TUTORIAL 11: BREACHES OF THE RESEARCH CODE 2013

QUESTION:
You are the lead researcher in a study. As part of your study, you will be collecting samples of blood from research participants. Under the Human Tissue Act 1983 (NSW), you are required to obtain the consent from each research participant to collect the blood sample. During the study, you realise you have collected blood from a small number of participants without their consent. You retrospectively obtain the appropriate consents from these participants as soon as possible.

Do you need to notify anybody about this breach?

ANSWERS:

Choice A: Yes, you should notify the Office of Research Integrity.

Choice B: No. You now have the appropriate consents, and the breach only related to a handful of research participants.

ANSWER RESPONSES:

Response A: Correct Answer.
As the lead researcher of the project, you must notify the Office of Research Integrity in writing that there has been a breach of a law relating to the conduct of your research (Human Tissue Act 1983 (NSW)).

Response B: Incorrect Answer.
As the lead researcher of the project, you must notify the Office of Research Integrity in writing that there has been a breach of a law relating to the conduct of your research (Human Tissue Act 1983 (NSW)). It is irrelevant that only a handful of participants were involved, or that you have now obtained the appropriate consents.
TUTORIAL 12: RESEARCH MISCONDUCT - OVERVIEW

QUESTION:

You are a researcher in the University’s Business School. You recently published a paper and attributed authorship of the paper solely to yourself. After the paper’s publication you are advised that an allegation of research misconduct has been made against you. The allegation is that you failed to attribute authorship to a number of other researchers who claim to have made a substantial scholarly contribution to the paper. Is the following statement true or false? The research misconduct framework under the Codes is designed to:

- establish the facts and whether research misconduct has occurred; and
- address disciplinary issues

ANSWERS:

Choice A: True

Choice B: False

ANSWER RESPONSES:

Response A: Incorrect Answer. The framework does not address disciplinary issues. The research misconduct framework is only designed to establish the facts and whether research misconduct has occurred. Disciplinary issues for research misconduct are dealt with as follows:

- for staff: as misconduct or serious misconduct and a breach of the Code of Conduct – Staff and Affiliates (Code for Staff and Affiliates);
- for students: as misconduct and a breach of the Code of Conduct for Students; and
- for affiliates: as a breach of the Code for Staff and Affiliates.

Response B: Correct Answer. The research misconduct framework is only designed to establish the facts and whether research misconduct has occurred. The framework does not address disciplinary issues. Disciplinary issues for research misconduct are dealt with as follows:

- for staff: as misconduct or serious misconduct and a breach of the Code of Conduct – Staff and Affiliates (Code for Staff and Affiliates);
- for students: as misconduct and a breach of the Code of Conduct for Students; and
- for affiliates: as a breach of the Code for Staff and Affiliates.
TUTORIAL 13: WHAT IS RESEARCH MISCONDUCT?

QUESTION:

You are currently completing your honours in drug development and you work in a laboratory. Only male mice are required for your tests and the animal ethics committee has given approval to euthanase the female mice from the breeding program. Your supervisor discusses with you using the female mice to conduct a side research project rather than euthanasing them. Your supervisor does not believe that this requires the approval of the animal ethics committee 'because the female mice were going to be euthanased anyway'.

What should you do?

ANSWERS:

Choice A: You are concerned by your supervisor’s disregard for ethics approval and you should discuss the matter with a Research Integrity Adviser.

Choice B: Nothing. Your supervisor already has approval to euthanase the female mice.

Choice C: You should raise your concerns with your supervisor, but if your supervisor continues to insist that ethics committee approval is not required, take the issue no further.

ANSWER RESPONSES:

Response A: Correct Answer.
You should discuss the matter with a Research Integrity Adviser. Your supervisor is proposing to conduct research involving female mice without the required animal ethics committee approval. Your supervisor’s conduct could be considered research misconduct.

Response B: Incorrect Answer.
You should discuss the matter with a Research Integrity Adviser. Your supervisor is proposing to conduct research involving female mice without the required animal ethics committee approval. It is irrelevant that your supervisor already has the approval of the animal ethics committee to euthanase the female mice. Your supervisor’s conduct could be considered research misconduct.

Response C: Incorrect Answer.
You should discuss the matter with a Research Integrity Adviser even if your supervisor insists approval is not needed because there is already approval of the animal ethics committee to euthanase the female mice. Your supervisor is proposing to conduct research involving female mice without the required animal ethics committee approval. Your supervisor’s conduct could be considered research misconduct.
TUTORIAL 14: RESEARCH MISCONDUCT FRAMEWORK 1

QUESTION:

You are a PhD student in the Medical School, and are currently part of a research team investigating the efficacy of a drug. The drug is currently registered on the Australian Register of Therapeutic Goods. The drug has other uses outside the conditions of its marketing approval. The lead researcher, intends to conduct a trial to test the efficacy of the drug for an unregistered purpose. The lead researcher does not intend to notify the Therapeutic Goods Administration (TGA) or apply to the TGA for approval, because the drug is already registered, and is commonly used ‘off-label’ for this purpose. You suspect that the clinical trial may need to be notified to the TGA.

What should you do?

ANSWERS:

Choice A: You should raise your concerns with the lead researcher. If the lead researcher insists the TGA doesn’t need to be notified, you don’t have to take the matter any further.

Choice B: You should do nothing, as the lead researcher doesn’t believe it’s necessary to notify the TGA, and the lead researcher makes these decisions.

Choice C: You should raise your concerns with the lead researcher. If the lead researcher insists you don’t need to notify the TGA, discuss the matter with your Research Integrity Adviser, Head of your department or the Chair of the Medical School’s research committee.

ANSWER RESPONSES:

Response A: Incorrect Answer.
The lead researcher’s failure to notify the TGA may breach the Therapeutic Goods Act 1989 (Cth) and amount to research misconduct. This may have serious consequences for the lead researcher, the Medical School and the University. You should raise your concerns directly with the lead researcher. If the lead researcher insists you don’t need to notify the TGA, you should raise your concerns with:
• your Research Integrity Adviser;
• the Head of your department; or
• the Chair of the Medical School’s research committee.

After discussing your concerns with one of these people, it may be appropriate to make a written allegation of research misconduct to the Director of Research Integrity.

Response B: Incorrect Answer.
The lead researcher’s failure to notify the TGA may breach the Therapeutic Goods Act 1989 (Cth) and amount to research misconduct. This may have serious consequences for the lead researcher, the Medical School and the University. You should raise your concerns with the lead researcher. If the lead researcher insists you don’t need to notify the TGA, you should raise your concerns with:
• your Research Integrity Adviser;
• the Head of your department; or
• the Chair of the Medical School’s research committee.

After discussing your concerns with one of these people, it may be appropriate to make a written allegation of research misconduct to the Director of Research Integrity.

Response C: Correct Answer.
The lead researcher’s failure to notify the TGA may breach the Therapeutic Goods Act 1989 (Cth) and amount to research misconduct. This may have serious consequences for the lead researcher, the Medical School and the University. After discussing your concerns, it may be appropriate to make a written allegation of research misconduct to the Director of Research Integrity.
TUTORIAL 15: RESEARCH MISCONDUCT FRAMEWORK 2

QUESTION:
You are an honours student within the Faculty of Arts and Social Sciences. During your weekly meeting with your supervisor, you mention that you are unsure whether you need ethics approval for one aspect of your project that involves observing people on the beach but not interacting with them in any other way. Your supervisor tells you that you don’t need ethics approval. You are unsure whether your supervisor is correct.

What is the appropriate course of action?

ANSWERS:

Choice A: You should follow your supervisor’s advice, even though you think it may be incorrect. Where there is doubt, it is appropriate to follow your supervisor’s judgment and advice.

Choice B: You should discuss whether you need ethics approval with another senior member of the University’s staff if you think your supervisor’s advice may be incorrect.

ANSWER RESPONSES:

Response A: Incorrect Answer.
If it is not clear and you think that your supervisor may be incorrect, you should discuss whether you need ethics approval with another senior member of the University’s staff. Deliberately conducting research without the required human ethics committee approval is a clear example of research misconduct. You may be found to have committed research misconduct even though your supervisor advised you that you don’t need to obtain ethics approval. If you commit research misconduct, this could have serious consequences for your further study.

Response B: Correct Answer.
If it is not clear and you think that your supervisor may be incorrect, you should discuss whether you need ethics approval with another senior member of the University’s staff. Deliberately conducting research without the required human ethics committee approval is a clear example of research misconduct. You may be found to have committed research misconduct even though your supervisor advised you that you do not need to obtain ethics approval. If you commit research misconduct, this could have serious consequences for your further study.