TRAINING RESPONSIBLE SCIENTISTS

TEACHING ACTIVITIES FOR UNDERGRADUATE AND POSTGRADUATE STUDENTS TO EMPOWER RESEARCH ETHICAL BEHAVIOUR

OVERVIEW

'Training responsible scientists: Teaching activities for undergraduate and postgraduate students' is a user-friendly sourcebook which consists of case studies relating to a variety of scientific disciplines, role play activities, and scenarios for group discussions. The sourcebook has been developed to complement and enhance research methods tutors' and supervisors' existing course materials in the following areas:

- understanding the subtleties of research ethics
- understanding ethical norms and deception
- developing critical reflection and preparing to conduct decision making on ethical issues in research work
- exploring the historical context of research ethics
- understanding the role of research ethics committees
- obtaining informed consent
- conducting research with potentially vulnerable human participants
- conducting research that might raise risks
- data acquisition and management

The proposed ready-to-use activities encourage active learning and engaging classroom practice to support undergraduate and postgraduate students who are or will be undertaking research with human participants and personal data. This is done by providing teaching instructions that will enhance students' ability to develop well-reasoned responses to the kind of ethical problems that are likely to arise from practising research.

The goal of the proposed activities in this sourcebook is to develop key competencies so that students learn to take an active role in considering and in solving moral problems: competence to identify moral problems; competence of judgement and of

taking an active role in weighting arguments; competence in listening and respecting other people's arguments.

Each of the activities has several advantages especially for teaching research ethics: they engage students in the learning process through collaborative and reflective activities; they provide students with a safe environment to explore examples of research conduct without feeling self-conscious that they will be judged; due to the tutor's limited role, students examine ethical situations without the preaching of an authority figure; the proposed activities allow students to explore the nuances of ethical dilemmas providing a well-round understanding of the complexities surrounding research ethics.

The activities included in this sourcebook are recommended by the literature on teaching research ethics education in the higher education context (reference to these studies is specifically made in the 'Further reading and useful links' sections for the tutors' convenience), and align with the University's Curriculum 2021 pedagogical philosophy. Furthermore, the activities are student-centred and embed research ethics in concrete contexts to facilitate transfer between generalized principles and ethical research conduct in practice.

There is considerable flexibility in the way the sourcebook can be used in a teaching context. Some of the activities could be covered in one or two teaching sessions, and the best configuration (for example a long session including an introduction to the material by the tutor and student discussion of case studies, or separate lecture and seminar sessions) may depend on student numbers and the level of the course.

To support supervisors and research methods tutors in delivering the teaching activities included in this sourcebook, each activity is followed by tutor notes and student handouts.

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ACTIVITY 1: UNDERSTANDING THE SUBTLETIES OF RESEARCH ETHICS

TUTOR NOTES

Learning objectives and outcomes: The purpose of this activity is to support students to develop an appreciation of the subtleties of research ethics using a classroom activity which encourages active learning. By the end of this activity learners will be in a position to recognise that there is more than one vantage point from which the ethical evaluation of a study can be made. A first frame of reference is that of the research discipline itself as represented by professional associations. A second frame of reference is that of the community in which the research is being sanctioned or a research ethics committee. The third is the point of view of the individual investigator (i.e the researcher), who may not have thought much about his or her own ethical biases and assumptions.

Type: Group discussion and role play

Prerequisite activities: read ethics guidelines published by the most relevant professional bodies; read articles from a primary research journal of interest and select an article that reports to a research study; prepare a brief paper that focuses on the ethics of the research study.

Description of the activity:

Prerequisite activities

First familiarise the students with ethics guidelines produced by the most relevant professional bodies. Here can be found some examples. Explain that the ethical standards were developed to check the possible tendency of some researchers to be carried away by the judged importance of doing the research. The class might, therefore, be asked to think about the possibility that there are ethical boundaries that should not be crossed, as put forth in the ethical codes.

Then each student scrutinises the past year's issues of any primary research journal of interest. The assignment is to find an article that reports a research study that the student personally feels used an "unethical" manipulation or procedure. The student is instructed to read the article carefully and thoroughly, to be prepared if called on in class to give a detailed report and be able to answer questions about it, and to turn in a brief paper that focuses on the ethics of the study. The sampling bias in this assignment would seem implicit, inasmuch as the students are reading only studies that supposedly have passed ethical scrutiny.

In the classroom

Have the students give oral reports of the results of their assignment for the entire class. Then pose questions regarding potentially troublesome aspects of the procedure (i.e. invasion of privacy, deception, use of covert observation). The objective of the questions is to draw the group as a "community" into the discussion.

After all the studies have been discussed, ask the students to examine them from a different perspective. Instead of acting as critics, the students role-play the author of the study and defend their study in the face of criticisms by the rest of the group. Taking each study in turn, the students evaluate the moral or ethical cost on a 101 -point scale ranging from no ethical or moral cost (0) to the highest ethical or moral cost (100). Students evaluate the studies individually based not on how they think that others in the group will vote but on their own personal perspective. Next, students evaluate each study's utility on a 101-point scale ranging from no theoretical or practical utility (0) to the highest theoretical or practical utility (100).

Following this, draw two matrices on the blackboard, one for the "cost of doing" and the other for the "utility of doing" ratings. The students' names begin the rows, and one- or two-word descriptors of the studies head the columns. While the group copies down the results, calculate the row and column means and the grand mean and insert this information. The results tell the students at a glance whether they were tough or easy relative to one an-other (row means), to the group as a whole (grand mean), and to the collective perception of each study.

Further reading and useful links:

- Activity resource: L Rosnow, Ralph. (1990). Teaching Research Ethics through Role-Play and Discussion. Teaching of psychology (Columbia, Mo.). 17. 179-81.

- Joyner, B. and Young, L., 2006. Teaching medical students using role play: twelve tips for successful role plays. *Medical teacher*, *28*(3), pp.225-229**.**

- Miller, A. G. (1986). The obedience experiments: A case study of controversy in social science. New York: Praeger.

ACTIVITY 2: UNDERSTANDING ETHICAL NORMS AND DECEPTION

TUTOR NOTES

Learning objectives and outcomes: The first objective of this activity is that students will be able to recognise ethical issues by properly identifying the ethical norms that are being violated. The second objective is that students will be able to recognise when deception is occurring in a study and precisely what happened in the study that constitutes deception. This role-playing exercise will allow the students to achieve a more holistic understanding of ethical concerns and enhance their ability to recognise ethical dilemmas for their piece of research. This activity also challenges students to develop cognitive skills beyond comprehension and application.

Type: Role play group activity; tutor's role is limited as a facilitator

The activity as described here would be more appropriate to use for teaching a small size group of students (approximately 27 students). Using nine principles allows the groups to remain small. Tutors can adapt this activity so that it fits to their own class sizes.

Description of the activity:

Prerequisite activities

Make a list of ethical principles that are core to research ethics and easily conducive to role play, and discuss with students ethical codes that have been produced by the most relevant professional bodies (examples of professional codes on ethics can be found in the 'Further reading and useful links' section' below). Some examples of fundamental ethical principles are listed here: confidentiality; voluntary participation; anonymity; deception; no harm to participants; respect for rights, dignity and diversity; honesty and openness; informed consent.

In the classroom

On the day of the activity explain to the students that they will role-play the violation of ethical principles that you have previously discussed. Explain that they will be grouped in small teams, and that each team will be given an ethical principle. Each team's task will be to devise a skit lasting about 2-3 minutes in which that ethical principle is violated. Give groups between 10-15 minutes to formulate their skit. During this time, assist group with developing their ideas and walk around to each group. If students are confused about the principle and instructions that have been given to them this is an opportunity to clarify what they are expected to do.

After the allocated time for devising their skit has passed, ask each group to come to the front of the room one at a time to perform their skit. Once each skit is performed, ask the class to guess what ethics principle is being violated.

Adaptation of teaching activity

Because students are responsible for devising their skits, they may role-play obvious ethical situations and may not demonstrate grey areas of research ethics. Tutors who wish to draw students' attentions to specific questions may assign students specific situations instead of having groups develop their own skits.

Further reading and useful links:

- Activity resource: Kraus, R., 2008. You must participate: Violating research ethical principles through role-play. *College Teaching*, *56*(3), pp.131-136.
- Joyner, B. and Young, L., 2006. Teaching medical students using role play: twelve tips for successful role plays. *Medical teacher*, *28*(3), pp.225-229.

- Anthropology

  Association of Social Anthropologists of the UK and Commonwealth

- Criminology

  British Society of Criminology: Statement of Ethics for Researchers in the Field of Criminology

- Education

  British Educational Research Association: Ethical Guidelines for Educational Research

- Geography

  Association of American Geographers Statement on Professional Ethics

- History

  Oral History Society of the UK Ethical Guidelines

- Management

Academy of Management's Professional Code of Ethics

- Socio-legal

  Socio-Legal Studies Association: Statement of Principles of Ethical Research

- Sociology

  British Sociological Association

- Psychology

  The British Psychological Society Standards and Guidelines

  The British Psychological Society: Ethics Guidelines for Internet-mediated Research

- Visual Research

  ESRC National Centre for Research Methods Visual Ethics: Ethical Issues in Visual Research

ACTIVITY 3: DEVELOPING CRITICAL REFLECTION AND PREPARING TO CONDUCT DECISION MAKING ON ETHICAL ISSUES IN RESEARCH WORK

TUTOR NOTES

Learning objectives and outcomes:

The Erasmus University of Rotterdam has developed the Dilemma Game: Professionalism and Integrity in Research, which consists of 75 cards reflecting common practical cases of questionable research practices on one side and multiple potential solutions on the other. This Dilemma Game has been designed to help preparing students for decision making on ethical issues, and for students to learn how to practise reflexivity and find solutions to these issues through group discussion.

Equipment/materials: Print off Dilemma Game: Professionalism and Integrity in Research and use this as a student handout.

Type: It is considered useful to aim for a non-hierarchical interaction between students and tutor where the tutor's role is primarily to facilitate or moderate the discussion

Further reading and useful links:

- Activity resource: Dilemma Game: Professionalism and Integrity in Research

ACTIVITY 4: HISTORICAL CONTEXT OF RESEACH ETHICS

TUTOR NOTES

Learning objectives and outcomes: This activity aims at providing a historical context of research ethics, and at engaging students in the moral reasoning process.

Type: 1 hour documentary followed by a 10-15 minute discussion in small groups and then 10-15 minute classroom discussion.

Equipment/materials: Use of projector; flip chart

Description of the activity

Start the session by providing a historical context of research ethics, extending the conversation on the reasons for the development of ethics regulations and committees. Explain that researchers have been required to reconceptualise the rights of human participants and their responsibility for the effects that scientific discoveries might have on society in the early 1940s. Some suggested references include: the Tuskegee Syphilis study 1932-1972; the Nuremberg trials 1946-1949: the Doctors Trial; the Nuremberg Code; the Declaration of Helsinki; Stanley Milgram's infamous experiment; the infamous case of the sociologist as voyeur.

Having provided a historical context for the development of research ethics, explore current events by engaging students with documentaries to bring the importance of

ethical issues in science to the front. The Nova documentary The Deadly Deception is approximately 1 hour and discusses the Tuskegee Syphilis Experiments. The Tuskegee Study, an observational study of over 400 sharecroppers with untreated syphilis, was conducted by the U.S. Public Health Service to document the course of the disease in blacks, and racial differences in the clinical manifestations of syphilis, not given counselling on avoiding spread of the disease, and not given treatment throughout the course of the study. The study became the longest (1932-1972) nontherapeutic experiment on humans in the history of medicine, and has come to represent not only the exploitation of blacks in medical history, but the potential for any exploitation of any population that may be vulnerable because of race, ethnicity, gender, disability, age or social class.

The documentary is useful in engaging students in the moral reasoning process. Invite students to make a list of ethical considerations for protecting study participants that were violated as they watch the documentary, and then ask them to discuss these in small groups using their lists. Put on the board a list of issues gathered from the groups.

Further reading and useful links:

- Activity resource: Eisen, A. and Parker, K.P., 2004. A model for teaching research ethics. *Science and Engineering Ethics*, *10*(4), pp.693-704.

- Bryman, A., 2016. Social research methods. Oxford university press.

- Cohen, L., Manion, L. and Morrison, K., 2002. Research methods in education. Routledge.

- Corbie-Smith, G., 1999. The continuing legacy of the Tuskegee Syphilis Study: considerations for clinical investigation. The American journal of the medical sciences, 317(1), pp.5-8.

- Eisen, A. and Parker, K.P., 2004. A model for teaching research ethics. *Science and Engineering Ethics*, *10*(4), pp.693-704.

- NOVA, 1993. The Deadly Deception. Boston. WGBH Educational Foundation retrieved from http://court.rchp.com/history/us-government-discrimination/

- Reports concerning the treatment of Polish priests and other clergymen, and medical experiments at Dachau.

- Shuster, E., 1997. Fifty years later: the significance of the Nuremberg Code. New England Journal of Medicine, 337(20), pp.1436-1440.

ACTIVITY 5: UNDERSTANDING THE RESEARCH ETHICS COMMITTEE REVIEW PROCEDURE

Activity background

Nuffield Council on Bioethics has developed a set of teaching resources which give an introduction to ethical issues and can be accessed by following this link. Activity 5 has been designed by Nuffield Council on Bioethics and introduces how research is reviewed or approved.

TUTOR NOTES

Purpose: This activity aims to introduce students to the research ethics review procedure.

Type: Scenario; Role play followed by group discussion

Description of the activity:

First, have the students read the research proposal that follows below which shows what a protocol for ethics approval might look like. Students consider the research protocol as if they were a research ethics committee. In groups of six, each student is given a Committee Member role card and asked to discuss the research study proposed in the student handout and decide whether to approve the research as proposed; suggest the researchers make some changes and resubmit the proposal; or refuse to approve the proposal.

Secondly, ask students to watch the second part of the film Processes, Papers and Professor: how clinical research in young people gets approved (from 04:30 until end – about 12 mins). This film shows a mock research ethics committee discussing the research proposal and whether to approve it.

Students are invited to reflect on what they heard in the film clip showing a research ethics committee discussing the proposal. Questions to discuss might include:

- Did the Research Ethics Committee in the film reach new or different conclusions from the students?

- Did they miss any ethical issues that the students thought important?

- Do students agree/disagree on the points made by the committee members in the film, i.e about calling participants 'subjects; incentives –rewarding the children who participate; the researchers' approach to risk?

This document sets out a fictional research study developed for educational purposes. Find out more at www.nuffieldbioethics.org/teaching-resource/REC Research ethics and how health research is reviewed – an educational resource: www.nuffieldbioethics.org/teaching-resource/REC

Improving asthma treatments for children and young people Application for ethics approval

1. **Title of project**

   Asthma treatments for children with the MAS gene: a clinical trial assessing the efficacy of Exhalin vs Verabreath.

2. **Details of researchers**

   The research project will be led by a Professor who is Chair of Paediatrics at the University of Hove and is also a consultant in paediatric asthma at North Brighton NHS Foundation Trust.

   The Professor will be assisted by a medical doctor who is a Reader in Child Health at the General and Adolescent Unit at the University of Hove's Institute of Child Health.

   Further support will be given by another doctor (a Senior House Officer) at North Brighton NHS Foundation Trust. This doctor is currently researching a PhD that focuses on how children with asthma and their parents manage living with the condition.

3. **Type of project**

   Clinical trial

4. Summary of experimental protocol

Background Asthma is a very common illness in children and young people. On average, it affects two children in every classroom in the UK.

Asthma is usually controlled by a 'preventer' inhaler, usually brown in colour. Children with asthma also have a 'reliever' inhaler, usually blue in colour. The blue inhaler is taken on demand to relieve symptoms of breathlessness, while the brown inhaler is taken regularly to prevent symptoms occurring, or reduce their intensity. Where a child's asthma is inadequately controlled with these two forms of inhaler, a third 'line of defence' is needed. Thus the three 'lines of defence' are:

Stage 1 Defence: the use of a blue inhaler only, when necessary to relieve symptoms (e.g. for mild asthma)

Stage 2 Defence: the use of a brown inhaler on a regular basis to control asthma, plus a blue inhaler on demand in response to symptoms Stage 3 Defence: an additional control (in conjunction with the use of the brown and blue inhalers), which includes two drug options:

• Exhalin or
• Verabreath

Aim

The protocol seeks to compare the efficacy of Exhalin and Verabreath, for a particular subgroup of children: children with asthma with a particular gene (MAS). Exhalin and Verabreath are both licensed and used at present as Stage 3 Defences.

Hypothesis

Randomised controlled trials suggest that Exhalin is better at controlling asthma in the child population as a whole. However, clinical practice suggests that some children nevertheless do better on Verabreath.

At present, we are unable to identify which children will do better on Verabreath, so physicians prescribe Exhalin first, and then try Verabreath later if Exhalin does not appear to work well. This means that children and young people may suffer with uncontrolled asthma for a longer period while their medication is modified, particularly since it may take some considerable time to identify longer-term patterns of asthmarelated disability.

We have also observed that children who are have the MAS gene appear to be at increased risk of asthma attacks if they take Exhalin with their brown inhalers.

We suggest that it may be possible to find the children and young people who ought to have Verabreath by testing them for the MAS gene – i.e. that the presence of the MAS gene will be a reliable indicator that Verabreath will be better for this child. We will use ‘quality of life’ outcome measures such as how often a child misses school, and how often they need to use their blue inhaler, to measure the extent to which the Stage 3 Defence medication succeeds in controlling their asthma (see further detail of outcome measures below).

No other studies have yet been published that compare Exhalin with Verabreath for children with the MAS gene.

If our hypothesis is correct, the aggregated outcome measures for the children and young people in Group 1 should be better than the aggregated outcome measures for Group 2. This is because the children and young people in this group will have been allocated to the more appropriate measure straight away through the diagnostic tool of genotyping. We therefore expect there to be fewer absences from school and less use of blue inhalers in Group 1 when compared to Group 2.

Method

Research subjects

We would like to take 200 children with persistent asthma, who require Stage 3 Defence and randomly assign them to two groups. Group 1 would be tested to find out whether they have the MAS gene. If they do, they will receive Verabreath, and if they do not they will receive Exhalin. We suggest that there will be a prevalence of approximately 25% of participants in Group 1 who have the MAS gene. Group 1 is therefore the trial group, as this is the group where genotyping will be used to allocate children to either Exhalin or Verabreath.

The children in Group 2 are our control group and will not be tested to see if they have the MAS gene. They will receive Exhalin, based on existing research. Both of these stipulations (no genetic testing and prescription of Exhalin) mirror existing normal practice. If participants in Group 2 are observed to react poorly to Exhalin, their medication will be changed in accordance with standard medical practice. If such changes are made, the participant will remain in the trial as the purpose of our research is to observe whether aggregated results in the genotype-directed prescribing model (Group 1) are better than those reached by the usual 'trial and error' model (Group 2).

The research subjects will be recruited from asthma clinics in hospitals in the Brighton area. Asthma doctors will be invited to identify children who meet the eligibility criteria (i.e. need a stage 3 line of defence as their asthma is not adequately controlled by blue and brown inhalers) and invite them to participate in the study.

Additional requirements for participation

Participants will need to discontinue their current Stage 3 Defence medication for a period of two weeks before the research begins. The purpose of this requirement is that the research participant must 'wash out' the effects of their previous medication to avoid any compounding factors in the research. For this period, participants must therefore only take their brown and blue inhalers to alleviate their symptoms. Ideally, this wash out period would be four weeks, but this was felt to be likely to be unacceptable to the children. Given the length of the follow up (a full year), two weeks is proposed as an acceptable minimum wash out period.

Outcome measures

There are two outcome measures which we propose to use.

Measure I

The first outcome measure we propose to use in comparing the approach taken to each group's asthma treatment will focus on each child's attendance at school.

Each participant will begin to take Exhalin or Verabreath at the start of the school year (September 2014). For a period of one school year (ending July 2015), we will record and compare the number of absence days recorded by each child's school register. We will seek permission from the child's parents and their schools to obtain these data.

Measure II

The second outcome measure will focus on whether each Group are able to use their blue inhaler less while taking Exhalin or Verabreath. To measure this, we propose to use an online questionnaire, which allows the data to be collected without the need for children to visit clinics, and potentially miss a day of school. These questionnaires will be completed at the start of the research (when the research subject stops taking their current Stage 3 Defence drug), two weeks later (i.e. at the point of randomisation), and then at three-monthly intervals for the remainder of the school year.

Collecting additional data on effectiveness of outcome measures

As part of this research project, we would also like to improve our understanding of the outcome measures used in children's asthma research. Participants will therefore be invited to contribute additional information as part of the study, in order to improve the accuracy of outcome measures in the future. Thus, in addition to the online data collection described above, participants will also be asked to visit their hospital four times during the year's research study, to undertake a number of tests (including lung function tests, and exercise tests). This additional data collection will not directly benefit the children participating in the research, but will contribute to a very valuable

evidence base of the relationship between clinical data of this kind, and the quality of life data collected online, thus improving research methods in the longer term.

We would also like to retain and store the saliva sample that each participant provides. These samples would be used to answer further research questions that are not apparent at this stage.

5. Lay summary

We would like to carry out a research study which involves 200 children between the ages of 7 and 18 years of age. This study is based on the theory that children with a particular gene (MAS) may not react well to asthma medicine currently in use (Exhalin). Our theory is that, for these particular children, Verabreath may in fact work better than Exhalin.

These 200 children – all of whom will have asthma – will be split randomly into two groups. The first group (Group 1) will have their saliva tested to see if they have the MAS gene. If the child does have the MAS gene, they will be given Verabreath as an extra treatment on top of their usual inhalers. If they do not have the MAS gene, they will be given Exhalin on top of their usual inhalers (which is what is likely to happen in hospitals at the moment).

Children in Group 2 will not be subject to a test to see if they have the MAS gene. Instead, they will all receive Exhalin. However, if – during the course of the research period – the child or young person in Group 2 does not do well on Exhalin, their medication will be changed. This mirrors how treatments are managed in standard medical practice.

The outcomes for children in Groups 1 and 2 will then be compared in order to find out if children in Group 1 have better outcomes overall than children in Group 2. We will measure this in two ways:

i. By analysing the school attendance records of each child who takes part. ii. By analysing whether children in each Group use their blue inhaler less frequently while they take Exhalin or Verabreath. We will find this out by using an online survey.

In addition, we would also like each child who takes part in the study to visit the hospital on four occasions during the year that the research takes place. They will be asked to have a number of tests, including ones that test how well their lungs function, and also how they cope with exercise. The reason we would like to do these tests is to see how the results of these tests match up with the effect on the children's day-to-day lives, as described in the online surveys and school attendance records.

We would also like to retain and store the saliva (spit) sample that each participant provides. These samples would be used to for research that takes place in the future, but we are not able to state exactly what this research would be at this stage.

6. Duration of the study

The study will last for one academic (school) year.

7. Location(s) of the study

The study will be undertaken in three locations: the hospital clinic, the child's home, and the child's school.

8. Description and number of volunteers to be studies

200 children between the ages of 7 and 18.

9. Will written consent be obtained from all participants?

Written informed consent will be sought from participants' parents/guardians (see attached information sheets and consent forms). Potential participants will be given an information sheet and also asked for their written to participate in the study.

While the child's assent should be sought, if the child is unsure or says that they do not want to take part, it will still be acceptable to continue, as long as the parents consent.

10. Will any reward, recompense or reimbursement be offered to participants?

The researchers will pay the travel expenses of each child who takes part, and any parent or guardian who accompanies them.

At the end of the project, each participant will receive an Amazon voucher worth £20. They will not be made aware of this 'thank you' until the research project is completed.

11. Will the participants' general practitioners (GPs) be told about the study?

Yes. The research team will write to each GP to make them aware of the drugs that are involved in the research study, and to alert them to the need for the 'wash-out' period of two weeks.

12. Funding

The study is being funded by the UK Institute for Research in Medicine.

The research team will not receive any monetary benefit from taking part in the research.

The doctor who is a Senior House Officer will use the outputs of this research project to complete his PhD.

13. Drugs or other substances to be administered

Exhalin Manufacturer: General Pharmaceuticals Ltd., Long Street, Brighton, UK.

Verabreath Manufacturer: Normal Drugs Ltd., James Town East, Boston, Massachusetts, USA.

14. Will blood samples be required?

No. We will, however, take samples of each child's saliva.

15. How will the subjects be chosen?

This document sets out a fictional research study developed for educational purposes. Find out more at www.nuffieldbioethics.org/teaching-resource/REC
Research ethics and how health research is reviewed – an educational resource: www.nuffieldbioethics.org/teaching-resource/REC

Potential participants will be identified via medical records held at the Professor's hospital clinic.

16. Describe how possible participants will be approached

Where children fit the criteria for the research study, they (and their parents) will be contacted via letter initially. These letters will be signed or co-signed by a doctor that

the child already knows. One week after letters are sent, members of the research team will follow up with a phone call.

Potential research participants will be given an opportunity to visit members of the research team to discuss how the study will be undertaken.

17. What sources of information will be included?

GP and hospital records, questionnaire, school attendance records, results of the lung function/exercise tests undertaken as part of the collection of data on appropriate outcome measures

18. Whose permission will be sought to access this information?

School headteachers, parents, children/young people, GPs and hospital consultants

19. What ethical problems do you foresee for this project?

Informed consent and assent

- Children and their parents may feel pressured to take part in the research because of their prior relationship with the project leader.

Risks to participants

- The ‘washout’ of the participants’ current Stage 3 Defence medication for a period of two weeks before the research begins. This could cause discomfort or distress to the participants. - Opportunity costs to the participants: o Playing sport: during the washout period, they may find taking part in sporting activities very difficult or impossible. o Missing school: we will make every effort to ensure that each of the four

days of follow-up visits to the hospital will take place on either a weekend, in the school holidays, or after school hours.

Confidentiality and anonymity

All data will be secured in line with the Data Protection Act (1998).
This document sets out a fictional research study developed for educational purposes.
Find out more at www.nuffieldbioethics.org/teaching-resource/REC
Research ethics and how health research is reviewed – an educational resource: www.nuffieldbioethics.org/teaching-resource/REC

- Confidentiality and data protection: we will ensure that the data obtained from each child/young person's school (i.e. attendance records) will be stored on an encrypted software programme on the University of Hove's server.

20. Declaration

I understand my obligations as to the rights, welfare and dignity of the subjects to be studies, particularly with regard to the giving of information and the obtaining of consent.

Signature of Lead Investigator:

Date:

Address for correspondence: Department of Paediatrics, Hospital Way, Brighton, B1 2NN.

Further reading and useful links

- University of Liverpool students can find more information on research ethics by visiting the Research and Support Office intranet
- University of Liverpool's policy on research ethics
- Undergraduate and taught postgraduate research ethics application procedure
- Interchange Programme application procedure
- Application procedure for the ethical approval of research projects taking place at a research site outside the United Kingdom
- More information on the submission of a research ethics application for institutional review is available here
- Templates of participant information sheet and consent form are available to download from here
- The research ethics application system can be accessed by following this link
- Ethics Committee Dates

ACTIVITY 6: INFORMED CONSENT

Activity background

The European Textbook on Ethics in Research aims at contributing to the infrastructure for ethics deliberation and ethics review in Europe and beyond by facilitating access to information and education about research ethics. Amongst others, the textbook contains case studies that relate to a variety of scientific disciplines, and facilitate the discussion of key ethical issues. This Activity uses case studies from the textbook that illustrate key ethical issues in relation to informed consent.

TUTOR NOTES
Learning objectives and outcomes: This activity will develop students' understanding of the importance of informed consent in research ethics. **Type:** Case studies group discussion followed by plenary discussion. **Equipment/materials:** student handout (case studies)

Description of the activity

Prerequisite activities

The central part of this teaching activity is the consideration of case studies, but before proceeding into looking into these cases, it would be useful to provide students with some background information about obtaining informed consent. This can include reference to international codes and declarations and to ethics principles that underpin

the informed consent procedure. Further reading and useful links in relation to informed consent is available in the ‘Further reading and useful links’ section below. Background information can be provided prior to the session, or, alternatively in the classroom.

In the classroom

Start the Activity by introducing the learning objectives and why this teaching activity has been selected. To ensure that disagreements during the activity remain productive, it would be useful to set appropriate expectations before beginning to discuss case studies in a group discussion. If the group is ‘too large’ split the class into several smaller groups. Groups of six to eight discussants are large enough so that diverse views will be represented, but small enough so that you can elicit the views of each participant. When splitting the groups, identify a group leader and provide the group leader with guidance, encouraging them to elicit active participation from each group member.

Handout one of the cases that follow next to each group and present participants with a list of reflection questions to help them identify important issues. To encourage active participation ask silent individuals ‘What do you think?’, and ask participants to think about the case and write their own responses to the questions before discussing the case with the rest of the group. In this way, even if the individuals do not share their answers to the questions during the group discussion, they will have actively engaged with the questions.

After the group discussion ends, ask a representative from each group to feedback the points raised in their group to all of the students in the classroom.

Case One: Spaceflight simulation study on healthy female volunteers

A proposed International Space Agency (ISA) research project aims to gather preliminary information about how women's bodies would cope with prolonged periods of time in spacecraft. Since most astronauts to date have been men, very little information on this exists and, given the prospect of long-range space missions involving both sexes, the ISA believes that this research is vitally important for the design of future spacecraft and space travel protocols.

In an experiment simulating certain aspects of weightlessness, 50 healthy female volunteers, recruited via advertisements in women's fashion and lifestyle magazines, will be paid EUR 200 per day (plus expenses and free food) to spend up to four months on a specially designed bed which is tilted backwards at a six degree angle. The volunteers will also be awarded a terminal bonus payment of EUR 20 000 provided that they manage to complete the study (i.e. if they stay for the full four months).

During the experiment (and afterwards, in follow up sessions) numerous medical checks will be carried out. Furthermore, subjects' behaviour will be continuously monitored by video feed. Participants will be largely isolated from the outside world and allowed only occasional contact with friends and family via email or telephone. No visits will be permitted. They will, however, be given access to personal entertainment devices.

Physical side-effects of participation are likely to include: swollen face, blocked nose, severe aches, muscle wastage, constipation, sores, and loss of bone mass. Participants are also likely to encounter psychological problems resulting from boredom and lack of exercise. All of the abovementioned restrictions and risks will be fully disclosed in advance to prospective volunteers, who will be provided with written information and individual counselling, and will undergo thorough psychological assessments. Counselling and psychological assessment will also be made available to the women during and after the experiment.

In order to enter the study, the women must be:

(a) competent adults aged between 20 and 40 (because this is the age group most likely to be recruited for space missions); (b) in good general health, mentally and physically – and moderately, but not exceptionally, fit; (c) not significantly over/under weight; (d) non-smokers (because smoking is not possible in space and withdrawal symptoms may contaminate the results of the experiment if addicted smokers were used); (e) childless (because of the welfare of the child, and possible psychological harm to mothers); (f) single (because of the welfare of the partner, and because of possible psychological harm to women who are separated from their partners); (g) not pregnant, and willing to undergo a pregnancy test before the start of the study (because of concerns about foetal damage).

They must also promise to do their best to avoid pregnancy for 3 years after participation in the experiment ends. The experimental design has been subjected to extensive scientific peer review and graded 'excellent' for its methodology.

Case One: Discussion questions

- Is the research important enough to justify subjecting these women to the discomfort, inconvenience, and risk described?

- Do you have any concerns about the quality of the women's consents? If so, what are these?

- Is it possible for a woman validly to consent to be in this study?

- Do you have any other ethical worries about, or objections to, this research (that is, apart from those to do with consent)?

Case Two: Police and rescue research using cadavers

The European Institute of Police and Rescue Research has a long-running, internationally renowned research programme that seeks to discover which police and rescue training methods work best.

One part of this programme aims to discover whether training using real human cadavers is more effective than the alternatives in certain areas of police and rescue work. For instance, there is a growing (although still controversial) body of evidence suggesting that using real corpses (to represent the victims of terrorist bombings or other disasters) is the best way to teach people anti-terrorist and 'catastrophic situation' techniques.

One of the Institute's experiments is as follows. One group of trainees is instructed to search clothed deceased persons for objects such as diaries, mobile phones, jewellery and keys to ensure that they are properly documented. Trainees are then asked to strip the bodies to look for scarring and other distinctive marks that could aid identification. A second group of trainees goes through a similar process, but using realistic mannequins instead of actual bodies. A third receives classroom-based training only. The different groups' performances are later tested and comparatively evaluated using a well-established proprietary assessment tool. (The methodology of this experiment has been subjected to external peer review and accepted.)

Other similar experiments use bodies to assess different search training techniques. These involve, amongst other things, human body parts being buried and then searched for by trainees.

The bodies used by the Institute come from the nearby University Hospital. Prior to their deaths, all of the deceased persons involved gave general consent, in writing, for the use of their bodies for "research, training and education".

Case Two: Discussion questions

- Ethically, does it matter that the consent given by the deceased persons was rather general and that they may not have known that their bodies would, or could, be used in the study described above? Would it have been morally better to give them more detail?

- If valid consent was given by the deceased persons for their bodies to be used in this research would that allay all of your concerns about the research? Or would there be residual worries about using bodies in this way?

- What sort of consent to take part in the trial (if any) ought the researchers to seek from the trainees?

- Ought relatives of the deceased persons to be involved at all and, if so, at what stage and how?

Further reading and useful links:

- Guidance on how to navigate the discussion around Case One is available in the **European Textbook on Ethics in Research (pg 41-43).**
- Guidance on how to navigate the discussion around Case Two is available in the **European Textbook on Ethics in Research (pg 44-45).**
- **World Medical Association Declaration of Helsinki. Ethical principles for Medical Research Involving Human Subjects.**
- **Human Tissue Authority. Code A: Guiding principles and the fundamental principle of consent**
- **International Sociological Association. 2001. Code of Ethics.**
- **Economic and Social Research Council Framework for Research Ethics**
- **Nuffield Council of Bioethics.The ethics of research related to healthcare in developing countries.**
- **Directive 2001/20/ec of the European Parliament and of the Council**
- **NHS Health Research Authority. Last updated on 11 March 2019. Informing participants and seeking consent**

ACTIVITY 7: RESEARCH INVOLVING POTENTIALLY VULNERABLE HUMAN PARTICIPANTS

Activity background

The European Textbook on Ethics in Research aims at contributing to the infrastructure for ethics deliberation and ethics review in Europe and beyond by facilitating access to information and education about research ethics. Amongst others, the textbook contains case studies that relate to a variety of scientific disciplines, and facilitate the discussion of key ethical issues. This Activity uses case studies in the textbook that illustrate key ethical issues in relation to research involving potentially vulnerable groups of people.

TUTOR NOTES
Learning objectives and outcomes: This Activity will help students to develop an understanding of ethical issues that are raised by research involving potentially vulnerable human participants. **Type:** Case studies group discussion followed by plenary discussion. **Equipment/materials:** student handouts (case studies)

Description of the activity

Prerequisite activities

The central part of this Activity is the consideration of case studies which reflect some of the specific ethical issues that are raised by research involving potentially vulnerable human participants. Before proceeding into looking into these cases, it would be useful to provide students with an account of what vulnerability is; its ethical importance; additional factors that might make a research participant vulnerable. A starting point for doing so are ethics codes and guidelines, and established literature. This information can be provided prior to the Activity, or, alternatively in the classroom.

Start the Activity by introducing the learning objectives and why this teaching activity has been selected. To ensure that disagreements during the activity remain productive, it would be useful to set appropriate expectations before beginning to discuss case studies in a group discussion. If the group is 'too large' split the class into several smaller groups. Groups of six to eight discussants are large enough so that diverse views will be represented, but small enough so that you can elicit the views of each participant. When splitting the groups, identify a group leader and provide the group leader with guidance, encouraging them to elicit active participation from each group member.

Handout one of the cases that follow below to each group and present participants with a list of reflection questions to help them identify important issues. To encourage active participation ask silent individuals 'What do you think?', and ask participants to think about the case and write their own responses to the questions before discussing the case with the rest of the group. In this way, even if the individuals do not share their answers to the questions during the group discussion, they will have actively engaged with the questions.

After the group discussion ends, ask a representative from each group to feedback the points raised in their group to all of the students in the classroom.

Case One: Research involving adults with terminal illness

Dr Abbott, an oncologist at a major teaching hospital, has been asked to put forward a number of her patients for participation in a clinical trial of a new cancer treatment. Mr Day is a terminally ill patient with a type of cancer suitable for participation in this trial. Mr Day is incredibly keen to participate and volunteers at the first opportunity. When asked to explain his eagerness during the recruitment process, he says that God has sent him this opportunity, that the treatment (which he's "read all about on the internet") is a "wonder drug", that it will save his life, and that (if entered into the trial) he expects to be "completely cured" in time for Christmas (less than 6 months away). Mr Day's health carers all think that his views of the trial are extremely over-optimistic. What's more, his views persist in spite of the fact that he's been told on a number of occasions that: (a) the experimental treatment isn't expected to prolong his life by more than a few months (although it may have quality of life benefits too); (b) this expected benefit can't be predicted with any certainty; (c) the chances of his being "completely cured" by it, or anything else, are close to zero. When confronted with this information, Mr Day just says things like "you're just being cautious and covering your backs" or "you lack faith". Dr Abbott thinks that participation in the trial might benefit Mr Day psychologically, alongside any direct clinical benefits, by sustaining his hopes and expectations, and (conversely) that not permitting him to take part would be psychologically damaging. She also thinks that the fact that he's very keen to take part should be taken seriously and that not to do so would be a failure to respect his autonomy. But, on the other hand, Dr Abbott is not sure whether Mr Day is capable of supplying valid consent, since he appears unable or unwilling to grasp the true nature of his situation and of the trial.

Case One: Discussion questions

- What are the main ethical issues that this research raises?

- Is Mr Day in a position to give valid consent to take part in the trial?

- Would denying Mr Day a chance to participate in the trial be a failure to respect his autonomy?

- What is the relationship between irrational beliefs and autonomous decision-making?

- Should the fact that Mr Day's seemingly irrational beliefs have a religious basis be a matter for special attention in assessing his vulnerability?

- Would entering Mr Day into the trial be exploiting his vulnerability?

- Are there any alternatives to Mr Day offering consent or any additional safeguards that should be in place to protect his welfare?

Case Two: Research into treatments for behavioural disorders in children

Professor Helsinki, a world famous psychiatrist specialising in the treatment of children, wants to comparatively evaluate four different treatments for a rare behavioural disorder called RBDC. RBDC, which involves occasional bouts of abusive and violent behaviour and episodes of severe paranoia, is most prevalent in children aged between 11 and 15, but 14 % of cases occur in young adults, and a further 6 % of cases are in people aged over 25.

All of the treatments that Professor Helsinki wants to test are 'standard' insofar as each has been used in clinical practice in the recent past. However, the evidential basis for each one is minimal (at least specifically in relation to RBDC) and none is proven to work. In general terms, the options for trial are:(a) a widely used pharmaceutical product; (b) a programme of anger management and relaxation exercises; (c) group therapy; (d) cognitive behavioural therapy.

Professor Helsinki wants to enter almost all of his patients with RBDC (all of whom are younger than 16) into the study and to randomly allocate them into one of the above options. He proposes to do this without telling them or their parents/guardians and, hence, without prior consent for participation in the research (although the parents/guardians will be informed after the trial). Consent for the particular therapies offered will be obtained as normal, but the patients and their parents will not be told about the existence of the study or about the randomisation process.

Professor Helsinki's grounds for the non-disclosure policy include:(i) that disclosure to patients or parents would undermine the scientific validity of the study by affecting the behaviour and mental states of the research subjects; (ii) that disclosure would harm the research subjects by upsetting them and/or exacerbating their paranoia (e.g. the idea of being 'experimented on' and 'watched' would be highly disturbing to many of these young people); (iii) that disclosure would make it impossible to recruit research subjects; (iv) that most people with RBDC lack the capacity to validly consent owing to the nature of the illness; (v) that this important research will benefit sufferers from RBDC and may even benefit the research subjects themselves; (vi) that his

patients could have ('randomly') received any of the treatment options in ordinary clinical practice depending on, for example, where they happen to live and that Helsinki's research is just a more systematic and scientifically valuable version of what would have happened anyway.

Case Two: Discussion questions

- What are the possible benefits that this research proposal raises?

- What are the ethical problems with this research proposal? In particular, is it ethical to conduct the research without obtaining the consent of either the children participating in the trial or that of their parents/guardians?

- Do Professor Helsinki's grounds for non-disclosure justify him carrying out the trial without consent?

Further reading and useful links:

- Guidance on how to navigate the discussion around Case One is available in the **European Textbook on Ethics in Research (pg 54-59).**
- Guidance on how to navigate the discussion around Case Two is available in the **European Textbook on Ethics in Research (pg 68-74).**
- **Economic and Social Research Council. Research with potentially vulnerable people**
- **Economic and Social Research Council. 2015. Framework for Research Ethics**
- **European Commission. 2018. Ethics in Social Science and Humanities**
- **World Medical Association DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS**

ACTIVITY 8: CONDUCTING RESEARCH THAT MIGHT RAISE RISKS

TUTOR NOTES

Learning objectives and outcomes: This activity will help students develop their understanding of the risks for the participants involved when conducting research, and relate this with their own research projects.

Type: Brainstorm; scenario development for class discussion

Equipment/materials: flipchart

Description of the activity:

Prerequisite activities

Start the Activity by holding a 10 minute brainstorm session where students are asked to reflect on what is meant by research involving risks. Then record the identified risks on a flip chart without providing judgements or reflections.

Once the brainstorm session is completed, group students in small teams, and ask them to develop a scenario in their team about a researcher who intends to conduct research that might raise risks for the participants. The students will need to think about the research topic, the type of people who are to participate in the study. The students will also need to think about the research methods that are to be used. It would be useful to also say a little more about the researcher: who the researcher works for; the position within the organisation; how much experience and training they

have in conducting research. The students may want to add further information as to who is funding the research or the intended purpose and impact of the research. Once the students have developed the scenario, ask them to think about potential risks for the participants and ethical dilemmas that could be faced by the researcher. Ask students to develop these risks and dilemmas in a series of bullet points and to present their scenario and points to their classmates. This activity will enable the students to choose research topics and methods that are of interest to them, and that are related to their level of knowledge and experience in a supportive environment.

At the end of the session provide students with access to support network (information about the support the students can receive from the University's central research ethics team or experts in the University and their contact details; information about relevant research ethics training opportunities offered by the University).

Further reading and useful links:

ACTIVITY 9: DATA ACQUISITION AND MANAGEMENT

Activity background

This Activity presents common scenarios that occur at various stages of data acquisition and management: i.e. acquiring sensitive data; sharing data with colleagues; managing data collection processes.

The cases and role play in this part are taken from the Office of Research Integrity (ORI) website. Please click **here** for more information.

The ORI has developed an instructor's manual which would be beneficial for tutors and supervisors to read and use as it provides material for case discussion, class debates, and role plays. The content in the manual will assist you in developing strategies to foster ethical problem-solving skills and to increase ethical sensitivity.

To access the Introduction to the Instructor's Manual please follow this **link.**

The role-play in this Activity has been designed by Bradley et al. (2010). The authors have developed, tested and performed formative evaluation of nine role-play scenarios for teaching central topics in the responsible conduct of research to graduate students. In part E an example of a scenario that focuses on data management can be found accompanied by suggestions to the tutors and supervisors for conducting the role-play session. Should tutors and supervisors wish to evaluate this teaching activity, they can use the formative evaluation survey which has been developed by Bradley et al. (2010), and which can also be found below.

TUTOR NOTES
Learning objectives and outcomes: **Type:** case study group discussion followed by plenary discussion; role play followed by plenary discussion **Equipment/materials:** copies of student handouts (case studies and role play scenario)

Description of activity

Prerequisite activities

Managing data is a central aspect of research ethics, regardless of whether researchers are collecting new data, or if they are performing secondary analysis to already existing data. Data acquisition and management is highlighted by the University's research ethics committees and the Data Officers as a key facet of research. The importance of data management is reflected in the General Data Protection Act as well as the University's policies.

Ask students to familiarise themselves ahead of the session with guidance on data management. Some useful links are provided below. Data acquisition and management awareness will help to facilitate the cases and role play discussion in the classroom.

- Economic and Social Data Service Data Management Guides
- UK Data Archive Managing and Sharing Data
- UK Research and Innovation Common principles on data policy

- The Research Ethics Guidebook: a resource for social scientists. Data and Consent
- UK Data Archive. Managing and Sharing Data
- University of Liverpool's Research Data Management Policy

In the classroom

Start by explaining the learning objectives of the session and the teaching activity that will follow next, and that your role will be to facilitate the discussion rather than to lecture. If the group is 'too large' split the class into several smaller groups. Groups of six to eight discussants are large enough so that diverse views will be represented, but small enough so that you can elicit the views of each participant. When splitting the groups, identify a group leader and provide the group leader with guidance, encouraging them to elicit active participation from each group member.

Handout one of the cases that follow next to each group and present participants with a list of reflection questions to help them identify important issues. To encourage active participation ask silent individuals 'What do you think?', and ask participants to think about the case and write their own responses to the questions before discussing the case with the rest of the group. In this way, even if the individuals do not share their answers to the questions during the group discussion, they will have actively engaged the questions.

After the group discussion ends, ask a representative from each group to feedback the points raised in their group to all of the students in the classroom.

Start the role play by introducing this teaching method and the reason for deciding to use this, organise the students into triads and distribute instructions. In each small group, two students play the speaking roles and the third student serves as an observer. The instructions for the two speaking roles provide divergent perspectives on the same problem.

Each speaker prepares for 5–10 min, writing questions that he or she would ask in that situation, and anticipating questions that the other speaker might ask. The observers read through the instructions for both speaking roles, and they review the observer questionnaire to prepare for taking notes on the interaction. Then the speakers role-play their characters, improvising the dialogue. As the role-play runs, observers record the issues and solutions raised by the speakers, note their communication behaviours (direct, attentive, etc.), identify aspects of the interaction that might be effective in a real situation, and suggest questions that could have been asked but were not.

After the role-play runs for 5–10 min, facilitate a discussion among all participants about the scenario and the underlying issues. First, ask speakers playing each role to describe their initial perspectives, and then ask observers to identify the constructive steps that they saw the speakers take. Invite participants to suggest possible next steps for the characters and the resources that the characters might seek, such as the advice of the campus's research integrity officer. Summarize the key research ethics issues and relevant guidelines. Finally, to close the session, provide further useful resources and links to the students.

Case One: Creating a Public Archive of Sensitive Data

Frances is a researcher studying the molecular basis of cancer. She plans to sequence the genomes of children with cancer. Frances also intends to make such sequencing data publicly available on line. Internet-based DNA sequence databases would allow other scientists to analyze the data and ideally come up with important findings more quickly. This may lead to rapid identification of targets for new pediatric cancer treatments.

If a large amount of sequence data is made available, it may be possible for individuals to eventually be re-identified, which could have negative consequences. For example, participants in childhood cancer studies could become known to future employers or insurers based on their genetic information (their history of cancer and their publicly archived data). Further, data obtained for one study might later reveal other information such as susceptibility to other diseases or previously unknown family relationships. If a subject in a genome-wide sequencing study later released a small set of genetic information to another party for a different purpose, that information might be matched to the more extensive sequence data on the internet, revealing more about the subject to that party than the subject intended. This is a risk that subjects of such research should be made aware of during the informed consent process.

However, children, unlike adults, cannot legally consent. Publishing their personal DNA sequence would be based on parental permission. Since publication of such data is irreversible, parents would have to agree to this on their children's behalf.

Federal regulations permit pediatric research that has no direct benefit to the child only when risks are minimal. The determination that a study involves only minimal risk requires the evaluation of the magnitude of possible harms as well as the probability of such harms.

How should Frances proceed?

Case One: Discussion questions

- Can you describe scenarios in which the data could be re-identified?
- What are some possible harms of re-identification?
- What are ways in which publicly available DNA sequencing data are used by others?
- How might a subject learn about actual occurrence of breaches of confidentiality?
- Do you think that children should have an opportunity to refuse requests to assent to the public use of their genetic information?

Case Two: Data Sharing Fever

Mary admires the NIH-funded work of her postdoctoral advisor, Henryk, who pioneers research on alternative treatments for fever due to infectious diseases. Mary is one of many co-workers who has assisted Henryk in compiling the most comprehensive database ever assembled, tracking many different infectious agents, species of animals, and different interventions and their outcomes. Henryk's interpretation of this rich dataset suggests that some "alternative medicines" are highly effective in certain species, but have no therapeutic value in others. He is completing his analysis and interpretation, and is preparing a manuscript for submission. Mary will be a co-author because of her part in collecting data for the study.

Mary is preparing to seek an Assistant Professor position and wants to build on her postdoctoral work. She asks Henryk for permission to use the dataset to develop her own project. However, she plans to use a different methodology for analysis and interpretation of the dataset to address a different aspect of the outcomes of treatment. At that point, she will develop a career development proposal to submit to the NIH.

Henryk is unwilling to share the entire dataset prior to publishing his interpretation of these data. However, Mary has access to the database as part of her current project, and therefore she decides that it is ethical for her to look more closely at the data. Mary spends quite a lot of time looking at the data and Henryk's analysis, and realizes that he has excluded specific datapoints that impact his interpretation. Henryk's draft manuscript carefully justifies the exclusion of these data in the methods section so that there is no issue with data falsification.

Mary realizes that if she includes these datapoints, an entirely new understanding of therapies to treat fever could emerge. Mary is excited about her impending grant proposal, but is concerned about how to broach the discussion of her use of the data with Henryk.

How should Mary proceed?

Case 2: Discussion questions

- Must Henryk share his database with Mary before publication? After publication? Must he share it with others, outside his lab, and if so, when?

- Who owns the database at this point: Henryk? The institution? NIH? The public?

- Why is sharing a dataset beneficial to the person who collected it? How is it potentially risky?

- Is Henryk obligated to document how datapoints were included or excluded in the methods section of his paper?

Case Three: I Really Can't Acquire Important Data?

John is a research professor in sociology. He knows from past experience how hard it is to get data on sensitive research topics. Nevertheless he wants to evaluate the effectiveness of registry websites for convicted sex offenders. Understanding the lives of sex offenders after release from prison is important to developing programs that stand the best chance of rehabilitating them and safeguarding society. Therefore, he plans to survey the sex offender population listed on websites to advance understanding of the experience of being listed on such a registry. John reasons that the study will be useful only if he obtains a representative sample and open and honest responses from participants. To obtain a representative sample, he plans to mail a survey to a group of 100 individuals listed on his state sex offender registry. To obtain open and honest data, he proposes to offer the strictest of confidentiality protections. The consent form he submits to his IRB mentions that he will obtain a Certificate of Confidentiality from NIH and that under no condition will he share identifiable data gathered during the study.

John's institutional review board (IRB) refuses to approve the study as designed. Their letter requires many modifications, but two pose a particular challenge to John's ability to acquire the data he wants. First, they state that the public registry is designed to protect the public not to facilitate an invasion of privacy. They propose that he recruit by advertising his study. Second, they insist that his consent form detail conditions under which he will, in fact, be required to breach confidentiality, e.g., if participants mention ongoing or planned abuse of children or the elderly.

After spending an hour on the phone, John is exasperated. The IRB is unmoved by his observation that sociologists are not mandatory reporters in his state. He also tells the IRB coordinator that he finds the IRBs decision ironic: He wants to gather data to prevent recidivism among sex offenders to protect people from becoming victims; yet the IRB is preventing this in the name of defending potential victims through mandatory reporting. They are worried about the right to privacy of the sex offenders, yet they also want to weaken their protections by requiring him to breach confidentiality.

What should John do?

Case 3: Discussion questions

- Is there a way John can get honest data from a representative sample?
- Are there some data that simply cannot be acquired?
- Are human subjects protections the only reason why we might not acquire some knowledge, or is there “forbidden knowledge”—things we’re best off not knowing?
- How should society prioritize protection of research subject confidentiality relative to reporting of crimes?

Role-Play Scenario

Professor Role

What follows is an outline of your role. You will need to improvise to some extent – be creative but try to stay within the bounds of what seems realistic.

You are a professor who just received tenure: you have conducted successful research projects, written influential papers and received awards for your work. When you started, your research group was very small, and it has grown rapidly since then. Now that you lead a large group with ten graduate students and two post-docs, you do not have the time to check everyone's work on every project. You have good students who are well trained and conscientious.

You are about to meet with a student in whom you are very disappointed. You asked the student to reproduce some preliminary results produced by your star post-doc that your lab has already published. Reproducing results is important because it confirms previous work. This helps students improve their lab skills, even if these students are unlikely to be named as authors on this series of papers. Until recently, you had a good opinion of this student's skills and work ethic.

This student seems unwilling to put in the time and effort to complete the task promptly. You assume that the unwillingness to work hard is because the student thinks the task you have assigned is boring and unnecessary. It may even stem from jealousy or from a fundamental misunderstanding of how research is conducted. Students earn the right to have others help them in the future by doing non-glamorous supporting work for you and the post-doc now. Because this student has been so lazy and slow, you had to assign a second student to work on this routine confirmation. So far, neither student has finished the task. You are frustrated and impatient.

You don't want to be too hard on the student, but the student must start working harder immediately. In your meeting, you need to balance several goals: advancing the

student's education; ending an unproductive attitude; and motivating the student to complete the task soon and well.

Prepare for your meeting with your student.

Professor Role-Play Notes

You believe the student is not trying hard enough to replicate the post-doc's results
You want to make it clear you are disappointed
You want to set clear expectations: the student must contribute to the work of the lab
You have not had time to check everyone's work on every project

Plan for your meeting:

Write questions that you will ask the student
Follow-up questions that you might ask
Questions that the student might ask you, and your answers

Student Role

What follows is an outline of your role. You will need to improvise to some extent – be creative but try to stay within the bounds of what seems realistic.

You are a second-year graduate student in a large research group. You like and respect your adviser and have been very happy in this group. Your research adviser just received tenure last year. Your adviser published an early paper in a major scientific journal and then received an award from an important federal agency. The group has grown rapidly with your adviser's success.

For months you have been trying to reproduce experimental results obtained by a post-doc in your group. Your lab has already published the post-doc's results as preliminary findings in a journal article that is getting a lot of attention. You have worked very hard to replicate the work: you have run the experiments many times, and you

have watched the post-doc to see his techniques. You are sure you are doing the work correctly and still you are getting nowhere. Your adviser keeps asking you to finish and seems angry about the amount of time you are taking. You have never had anyone angry with you like this before. Your adviser recently assigned another student in the group to do the same work, and that student is also mad at you for diverting her work. You are now sure that it is not possible to obtain the results reported by the post-doc. You do not feel comfortable confronting the post-doc yourself. The stress is keeping you from sleeping. You have an appointment with your adviser to discuss this mess. You have reviewed your notebooks to make sure that it is in good order and that you have properly documented everything you have done. You are sure you haven't missed anything.

Additionally, you don't think it would ever have been possible to do the work in your lab: your lab never had enough of the materials to complete the work that was reported in the journal article. You even checked with the department's business manager, and according to the university's electronic purchasing records, no one either inside or outside your group has ordered these materials in a few years—except for you when you started this project. Furthermore, you have found out that the equipment necessary for at least one part of the experiment was not working in the month when the post-doc said he did the work.

You don't know what to do. You do not want to believe the post-doc made up the results but you don't know what else to think. That would be horrible for your adviser and your lab. Your adviser is not very strict in reviewing notebooks and supervising the lab, so you hope that there is some mistake that will explain the inconsistencies. Prepare for your meeting with your adviser.

Student Role-Play Notes

Your professor and this lab have an excellent reputation
You are sure you ran the experiments correctly
You documented everything you did while running the experiments

You're confused about the lack of research materials and broken equipment and afraid the confront the post-doc

Plan for your meeting:

Write questions that you will ask the student
Follow-up questions that you might ask
Questions that the student might ask you, and your answers

Discussion Starter

Professor: Hello … Please come in …
Grad Student: Thanks … You wanted to talk about the experiments that I have been running…
Professor: Yes … I'm curious as to why it is taking so long to reproduce the results that our post-doc has found … All you have to do is repeat the same procedures …
Grad Student: I don't really understand why they aren't working either … I documented everything I did in my notebook, and I know I didn't miss anything …
Professor: I'll look at your notebook after our meeting … but have you considered the time and effort that is required of graduate students working for a large research lab? … It involves doing a lot of work that may seem unimportant to you now, but it will benefit you in your future …
Grad Student: I really do understand … I've been trying very hard to reproduce the results, and I do not understand what's wrong … so I have investigated a number of reasons as to why the experiments have not been working …
Professor: Have you fixed the problem yet?
Grad Student: I don't think the lab had enough materials to run the original experiments …
Professor: What? That's very strange … Have you talked to the post-doc about this?

Formative evaluation survey

1. Which role did you have in the role-play?

( ) student ( ) professor ( ) observer

2. How would you rate your experience in participating in the role-play?

( ) very good ( ) good ( ) neutral ( ) bad ( ) very bad

3. Do you think the role-play was a worthwhile use of time for learning research ethics?

( ) Yes ( ) No

4. Specifically, what is the most important thing that you learned?

5. What do you see as the advantages and disadvantages of the role-play over a lecture or written case study?

6. Did you find the role-playing notes helpful?

( ) Yes ( ) No

7. Did you find the discussion starter helpful?

( ) Yes ( ) No

8. Is there anything that could be changed to improve the role-play for you?

9. Other comments?

Further reading and useful links

- Information Commissioner's Office Guide to Data Protection
- University of Liverpool Research Data Management Policy
- University of Liverpool Data Protection Policy
- University of Liverpool Policy on ethical approval for research involving human participants, tissues or personal data
- University of Liverpool template of participant information sheet

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