Research Ethics: Planning your Project and Securing Ethical Approval

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Overview

1. Research Governance and Ethics
2. Issues to Address when Planning your Project
3. Ethics Review Process

Research Governance and Ethics

- Research Governance is:
  - the regulation, monitoring and quality assurance of research on human beings
    - and includes appropriate legislation and procedures that impact upon:
      - universities, the Health Services and other bodies

- There are increasing demands from funding bodies and others upon researchers to be able to demonstrate that their research is subjected to appropriate scrutiny and monitoring
  - **So we need to familiarise ourselves with this environment**

Research: Design and Conduct

- Research governance mechanisms are used for managing certain parts of the research process
  - helps to ensure that each research project:
    - has been **well designed** and
    - is **properly conducted** in terms of its:
      - viability
      - science
      - ethics
      - recruitment
      - reporting
- Research governance has already become embedded in many research cultures
  - Particularly the USA, UK and Europe

Why Research Governance?

It's all about people …

Why Research Governance?

- setting standards
- defining mechanisms to deliver standards
- monitoring and assessing arrangements
- improving research quality
- **safeguarding the public**
  - by enhancing ethical and scientific quality
  - promoting good practice
  - reducing adverse incidents
  - ensuring that lessons are learned
  - preventing poor performance and misconduct

"I can't emphasise enough the value we place on sound research, Keith ... I mean Dave, Phil, Nigel ... whatever the heck your name is."

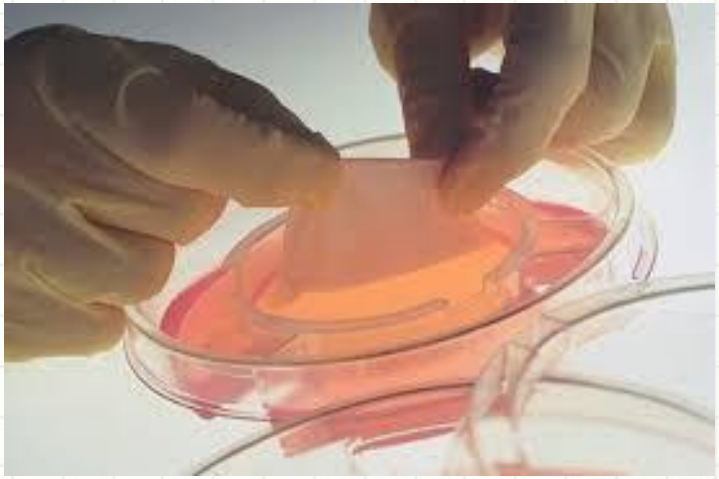
In Practice …

- The climate in human subjects research has become more restrictive
  - eg, recent European legislation places tight controls on the conduct of clinical trials of investigative medicinal products (IMPs)
  - This and similar legislation has effects on research in all areas of health care and, by association, social care

eg, any research involving patients or clients of the Health and Social Care sector must go through detailed and sometimes lengthy review and approval processes

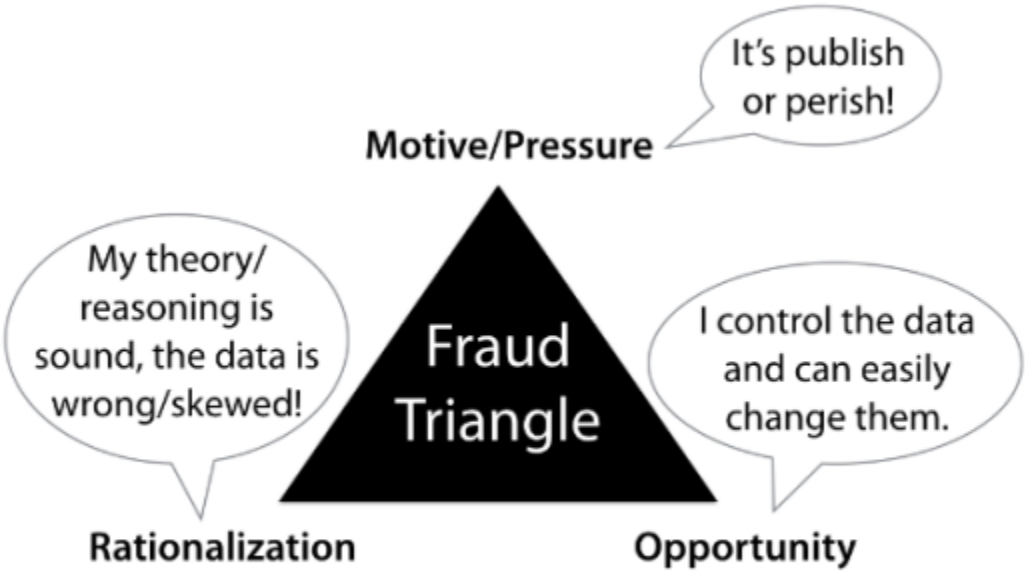
Human Tissue

- any organisation that wishes to store human tissues (including blood or any other body fluid that may contain a human cell) for research purposes must be licensed and comply with strict monitoring and quality assurance measures



When things go wrong …

- Litigation and damages claims have a higher profile than ever before
  - impacts on reputation
  - and future insurance provision



Fraud Triangle (by Donald R. Cressey) adapted to Scientific Misconduct

- Research misconduct may result
  - ❖ **we need to follow policies on good research conduct and integrity**

Your Legacy …

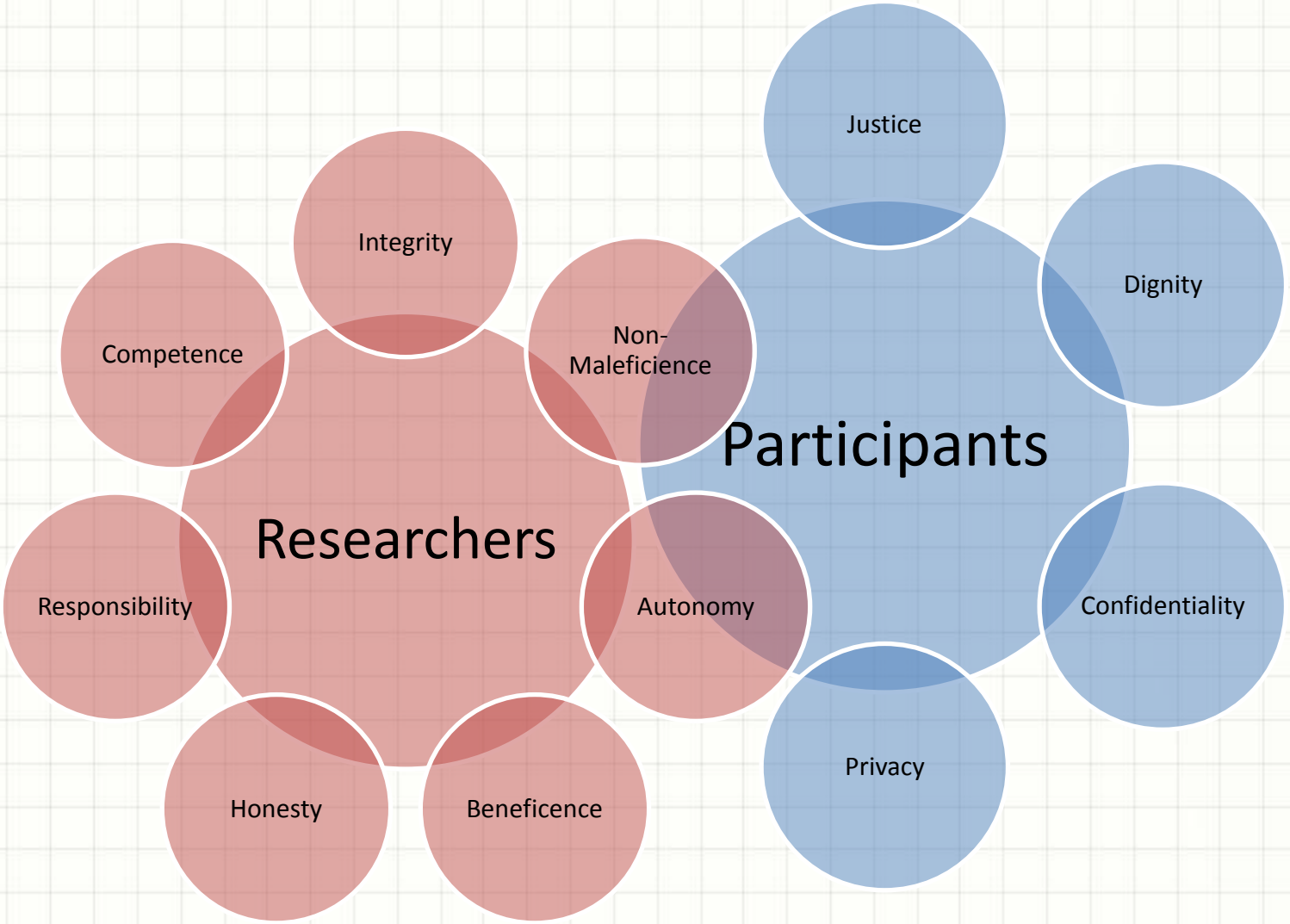
Research Ethics – Issues to Address

Research ethics is about ensuring that research – especially research involving human participants – is conducted **appropriately**

Some basic general principles normally apply:

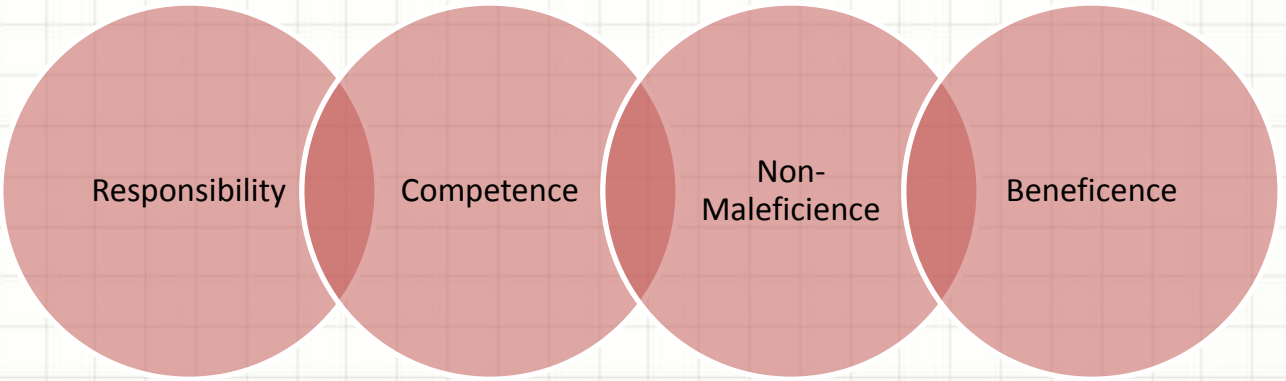
- the research should not have the intent or obvious capacity to cause injury or other (psychological, emotional) harm
- people should not be coerced or falsely led into taking part
- consent or appropriate permission must be obtained before using individuals' personal details or tissues
- all relevant information – including any risks or disadvantages – should be made clear in advance to potential participants

Principles and Considerations for Ethics



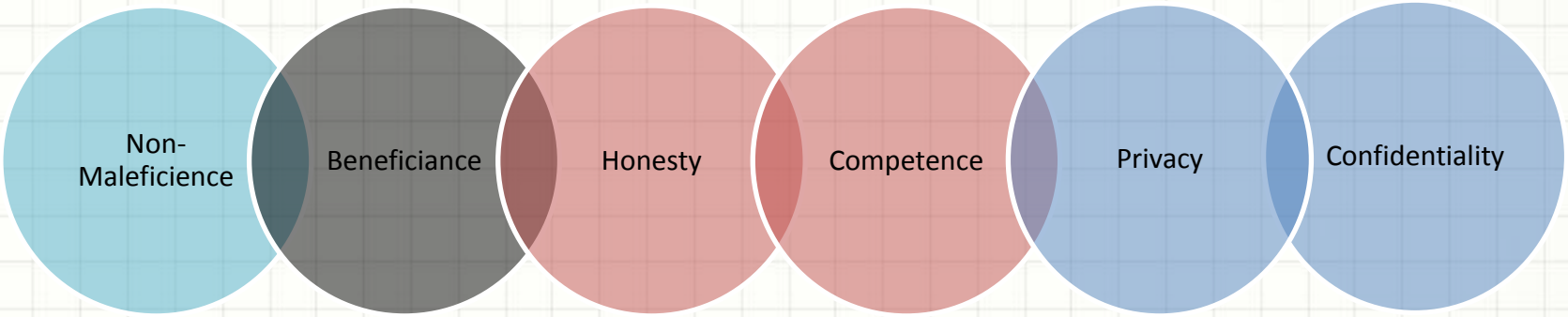
Planning your Project - Background & Rationale

- Is your research aimed at addressing a significant problem where the investigation will benefit others?
- Is it worth spending public/funder's money?
- Have you completed a thorough literature review to ensure that the work has not been done already by other studies?
- Is it ethical to carry out a study if very similar work has been done before?
  - *you may be confirming, extending ,or refuting previous findings*



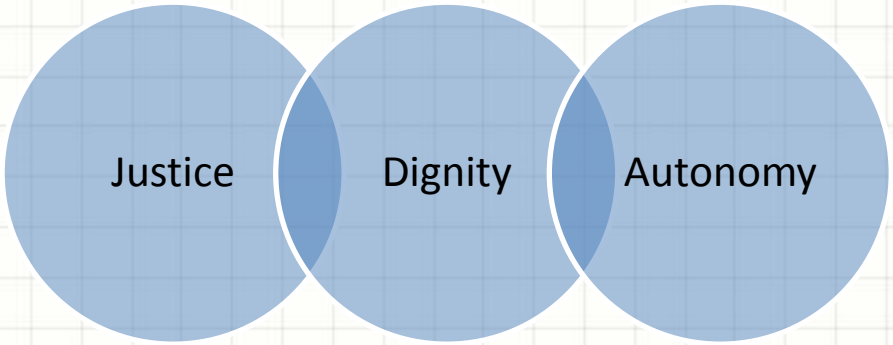
Planning your Project – Risks & Purpose

- Could your project expose the participants to an unacceptable risk, invasion of privacy, or loss of dignity?
  - harm could be physical, psychological, social, economic, legal
- Can you identify clearly the purpose of the study and explain it to participants?
- Do you have the expertise to conduct your project?
- Would a pilot study be advisable?



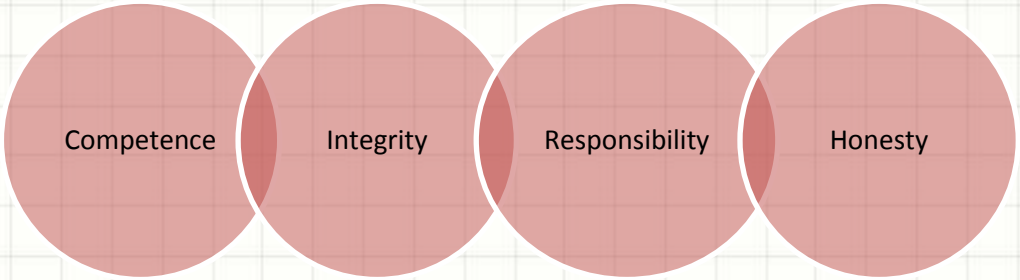
Planning your Project – Recruitment

- Will any of your participants be from a vulnerable group?
  - Children / Adolescents
  - The elderly
  - People in a subordinate position to the researchers
  - People with impairments
  - Dependents



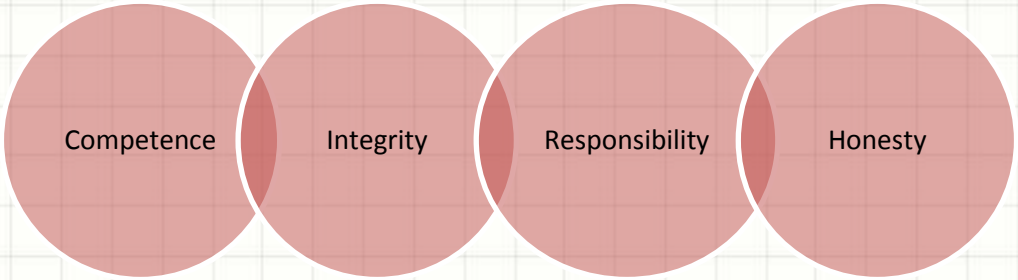
Planning your Project – Informed Consent

- Who are the researchers? (also provide their contact information)
- Who is sponsoring the research?
  - Is there a commercial interest/beneficiary?
- What is the purpose of the research?
- How were the participants selected?
- Can you give assurance that heir participation is voluntary?
- Can they withdraw from the study at any time?
- What are the benefits and risks for the participants?
  - What is the extent and nature of their involvement?
- How will you ensure participant confidentiality?

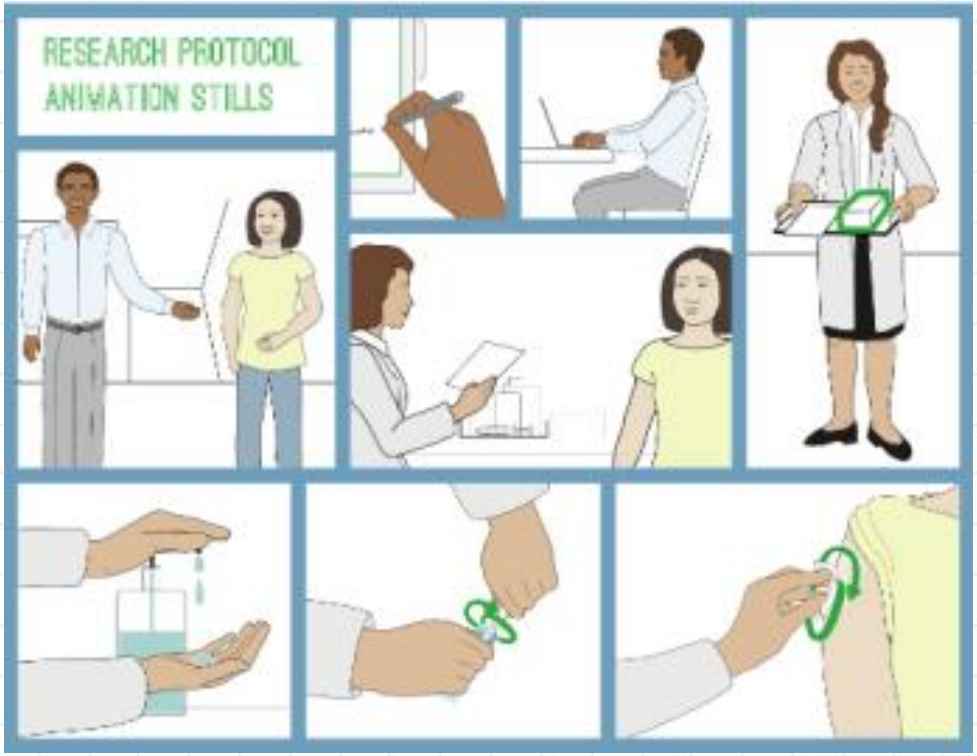


Planning your Project – Data Collection, Analysis and Dissemination

- How will you ensure that participants' privacy and confidentiality are respected?
- How will you monitor the collection of data and management of information?
- How will you protect the anonymity of participants?
- How will you analyse the data?
  - Do you have the experience/expertise?
- For how long will you keep the data once analysed?
- Where and how will you store the data securely?
- When and where will you publish your research findings?



Providing a Research Protocol



- **Title of study**
- **Applicants**
- **Main Research Question**
- **Project Background**
- **Aim & Objectives**
- **Design**
- **Methods**

- ❖ Sample size
- ❖ Recruitment and Consent
- ❖ Selection of Participants (inclusion / exclusion)
- ❖ Randomisation
- ❖ Intervention (what, where, when)
- ❖ Data Collection
- ❖ Data Protection & Security
- ❖ Data Analysis

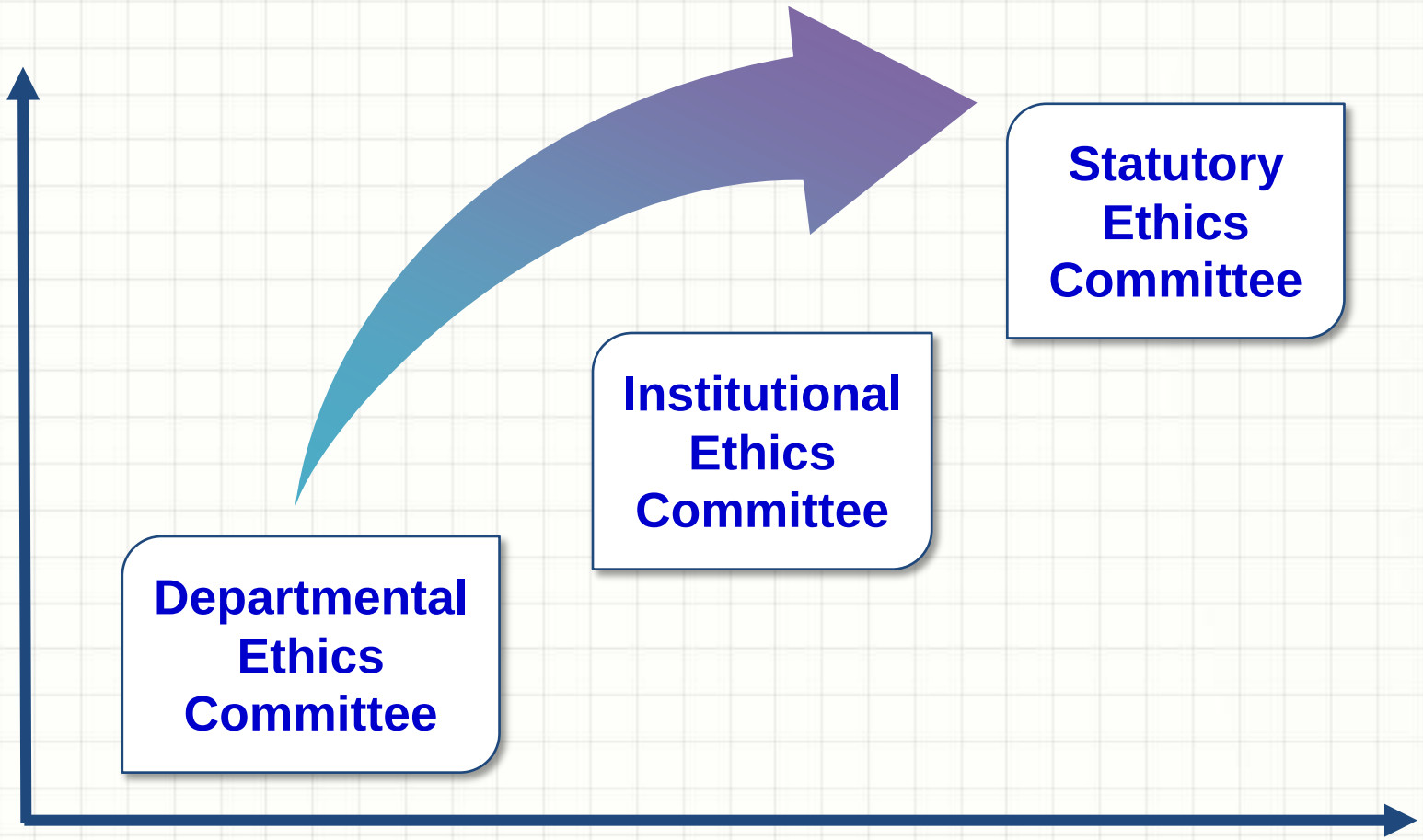
Ethical Review

- Ethical review is a central part of research governance structures in national health services, the health and social care sector, and universities and research institutions
- Ethical review is usually conducted initially by the institution carrying out the research
  - this usually involves research ethics committees (eg, at departmental and institutional levels)
- Further assessment may be needed by a statutory ethics committee outside the institution
  - eg, the research involves patients of a national health service

- **Research Ethics Committees** are convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for research studies comply with recognised ethical standards

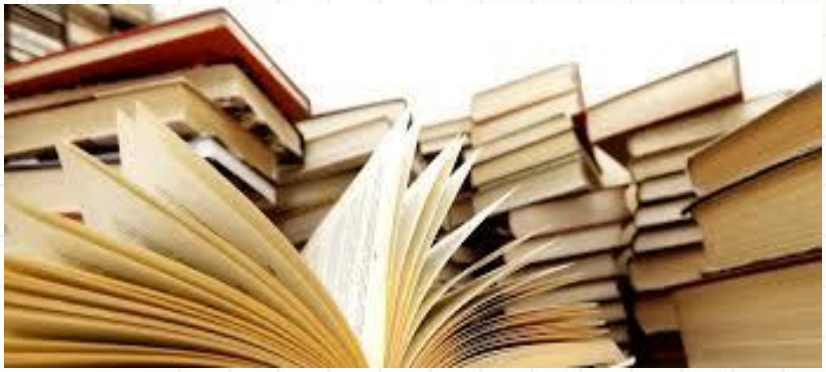
  (Central Office for Research Ethics Committees (COREC) - www.corec.ac.uk)

Ethics Committee Hierarchy



Operational Considerations

- Increasingly, journals will accept papers in areas of human research only if evidence can be shown that the research has been assessed by an ethics committee or equivalent



- Many funding organisations have also implemented policies on research ethics

Research Categories

Category A

No HSC/NHS involvement
Conducted by staff or students
Excludes clinical trials of IMPs*
Excludes new methodologies
Excludes vulnerable populations
Excludes therapeutic interventions
No significant risk to volunteers or researchers

Category B

No HSC/NHS involvement
Conducted by staff or students
Excludes clinical trials of IMPs*
Might use new methodologies
Might include vulnerable populations
Might include therapeutic interventions
Might pose significant risk to volunteers or researchers

Research Categories

Category C

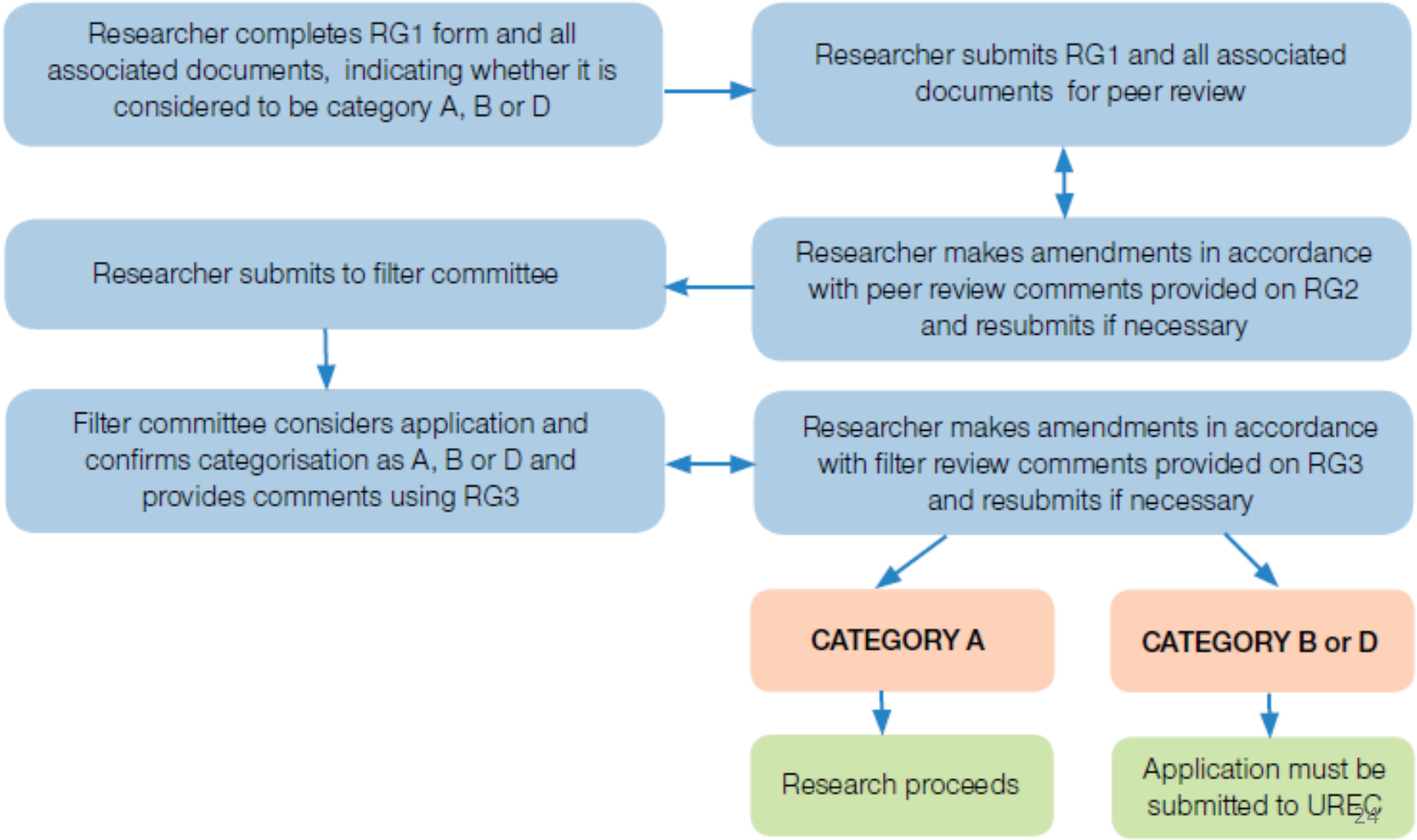
HSC/NHS involvement
Conducted by staff or students
Excludes clinical trials of IMPs*

Category D

No HSC/NHS involvement
University research regulated by the Human Tissue Act 2004
Conducted by staff or students
Excludes clinical trials of IMPs*

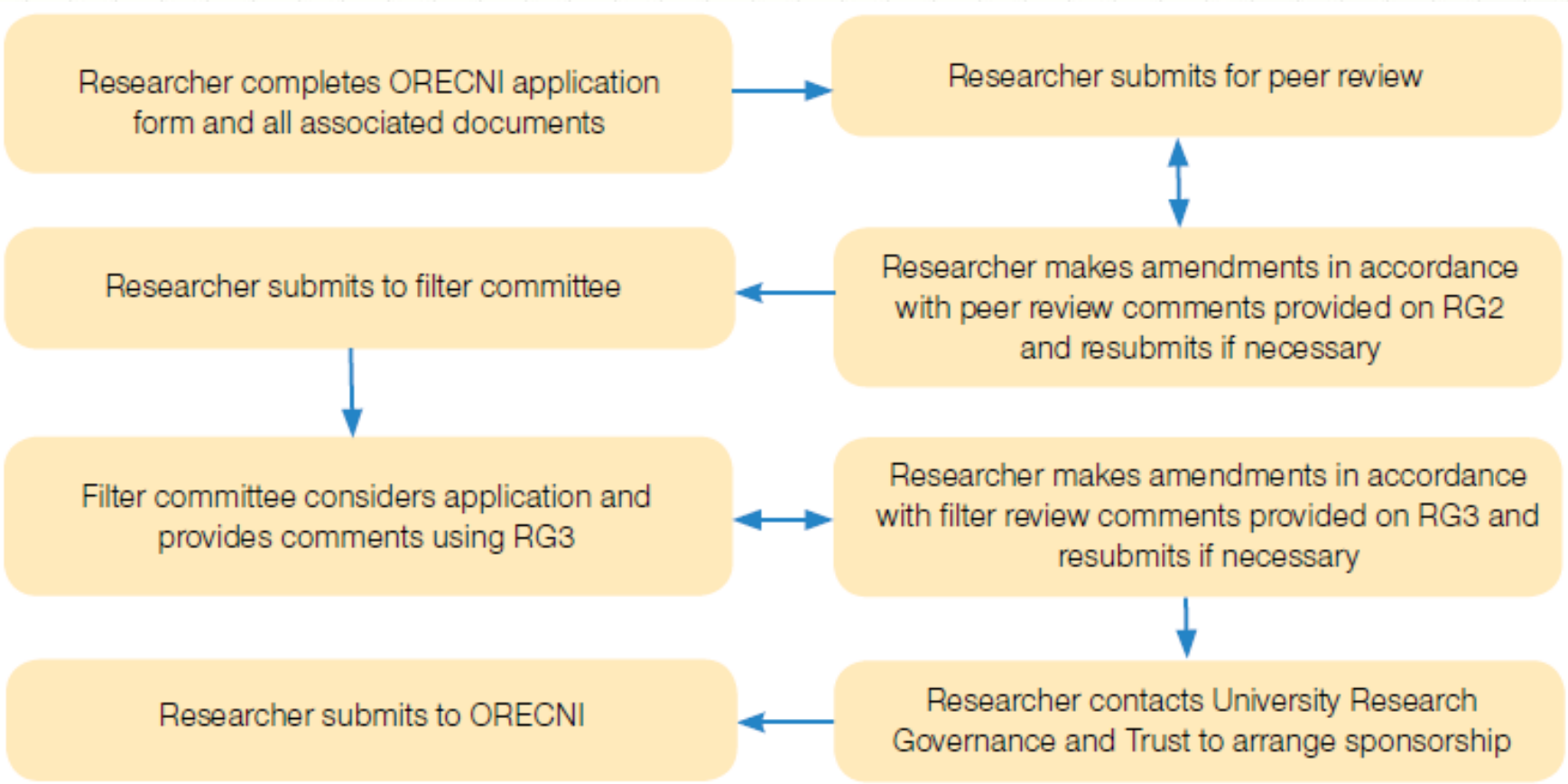
Ethical Review Processes

Category A, B and D research:



Ethical Review Processes

Category C research:



When is Ethical Approval Not Required?

- Market research
- Low impact questionnaire surveys
  - eg, opinion polls
- Management studies or organisational surveys
  - eg, in a retail environment
- Analysis of some types of existing anonymised data
  - eg, audit
- Analysis of certain information for which consent has already been given
  - eg, edited electoral roll

Case Studies

- Research Ethics **Application Forms**

UNIVERSITY OF ULSTER RESEARCH GOVERNANCE

RG1a APPLICATION TO UNDERTAKE RESEARCH ON HUMAN SUBJECTS

PLEASE REFER TO THE NOTES OF GUIDANCE BEFORE COMPLETING THIS FORM. (Available from the Research Governance website at http://www.ulster.ac.uk/research/rg/)

All sections of this form must be completed (use minimum font size 11). If the form is altered in any way it will be returned unconsidered by the Committee.

This form should be used for research in categories A, B and D

Do not use this form for research being conducted in collaboration with the NHS/HPSS (category C).

SECTION A

Chief Investigator	
Title of Project	
Student and course (if applicable)	
Additional Investigators	

Declaration - Chief Investigator:

I confirm that

- this project meets the definition for research in category* *(please insert)* ☐
- this project is viable and is of research or educational merit;
- all risks and ethical and procedural implications have been considered;
- the project will be conducted at all times in compliance with the research description/protocol and in accordance with the University's requirements on recording and reporting;
- this application has not been submitted to and rejected by another committee; and
- Permission has been granted to use all copyright materials including questionnaires and similar instruments

Signed: Date:

Once complete, this application and all associated materials must be submitted for peer review

*In addition, you should complete form RG1d for all category D research and form RG1e for both category B and D research

Version 4 (10/07) 1

Case Studies

- Research Ethics **Participant Information Sheets**

Participant information sheet

Title of Project
KT App: Knowledge Transfer in musculoskeletal medicine

Subtitle
Testing the content and design of a Computer App for rehabilitation after lower limb injury

Name of Chief Investigator

Co- Investigators

Invitation
You are being invited to take part in a research study. Before you decide whether or not to take part, it is important that you understand what the research is for and what you will be asked to do. Please read the following information and do not hesitate to ask any questions about anything that might not be clear to you. Make sure that you are happy before you decide what to do. Thank you for taking the time to consider this invitation.

Why is this study taking place?
Lower limb injuries such as ankle sprains commonly occur, particularly during sports and other physical activities. Rehabilitation exercises, such as stretching and strengthening exercises, are commonly used to treat lower limb injuries. These exercises are normally given to patients in the form of a written program with pictures.

We have recently developed an App (computer application) for a smart phone which contains a library of effective rehabilitation exercises suitable for use after an injury. People working in health care (eg. doctors or physiotherapists) and patients could use this App to help recovery after an injury.

We are currently undertaking research to make sure that our App contains the best exercise information and is easy for people to use. As part of the research, we are looking for volunteers to use the App for a short period of time and then give us their opinion. We are seeking volunteers from the following groups:

1). Expert technical developers
2). General Practitioners or Chartered Physiotherapists who have a clinical case load that includes patients with musculoskeletal injury
3). People who have a recent history of ankle sprain

Sources of Information on Research Ethics

U.S. Department of Health & Human Services

- **The Common Rule, governing studies with Human Subjects:**
  - http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

National Science Foundation (NSF)

- **Responsible Conduct of Research :**
  - http://www.nsf.gov/bfa/dias/policy/rcr.jsp

World Health Organisation (WHO)

- **Ethical standards and procedures for research with human beings:**
  - http://www.who.int/ethics/research/en/

British Psychological Society

- **Code of Human Research Ethics:**
  http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf