Consent in Non-Clinical Research

Considerations and processes

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Dictionary: informed consent
'permission granted in full knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with knowledge of the possible risks and benefits.
Applies to any volunteer participants involved in research (not always clinical) from whom data is collected.

Required elements for documentation of the informed consent discussion:
(1) the nature of the procedure
(2) the risks and benefits and the procedure
(3) reasonable alternatives
(4) risks and benefits of alternatives
(5) assessment of the patient's (participant's) understanding of elements 1 through 4.
(https://www.ncbi.nlm.nih.gov/books/NBK430827/)

Lots of good resources that are basis for processes in many institutions:
https://esrc.ukri.org/funding/guidance-for-applicants/research-ethics/

Getting informed consent, aims to ensure :

- Participants understand what they’re signing up to, making participation and research more effective
- Research conducted is ethical
- Compliance with data protection law

https://www.gov.uk/service-manual/user-research/getting-users-consent-for-research

Consent is required from ALL research participants, even if they work for the organisation where research is conducted.

For consent to be informed, participants must understand:

- who is doing the research
- the purpose of the research
- what data you're collecting
- what will happen during the research
- how you will use the results of the research, and who you'll share them with
- that their participation is voluntary, and that they can stop or withdraw their consent at any time
- how long their data will be kept
- what their rights are and how they can complain

Participants also need to know:

- whether session they participate in is being observed (and who's watching)
- whether and how a session is being recorded

How their personal data is being handled, including:

- which organisation is responsible for their data (known as the 'data controller') so the participant knows who to contact if they want to stop taking part in the research or make a complaint
- any other organisations that will be processing the data, for example transcription services, or staff from a design agency working in your team

Non-clinical research ethics

The ethical review and approval of non-clinical research involving human participants proposed by staff and students is overseen by six School Research Ethics Committees (SRECs). Security-sensitive research (whether or not involving human participants) will also require ethical approval and should be referred to the Convener of the University Research Ethics Committee (UREC) in the first instance.

SRECs are responsible for maintaining ethical standards of practice in non-clinical research involving human participants, in order to protect participants and researchers from harm, preserve participants' rights, and ensure public trust in the conduct of research at the University.

SRECs report directly to the University Research Ethics Committee (UREC), which provides oversight, monitoring and guidance to the School Research Ethics Committees. For further details on membership and remit of UREC and the SRECS please see:

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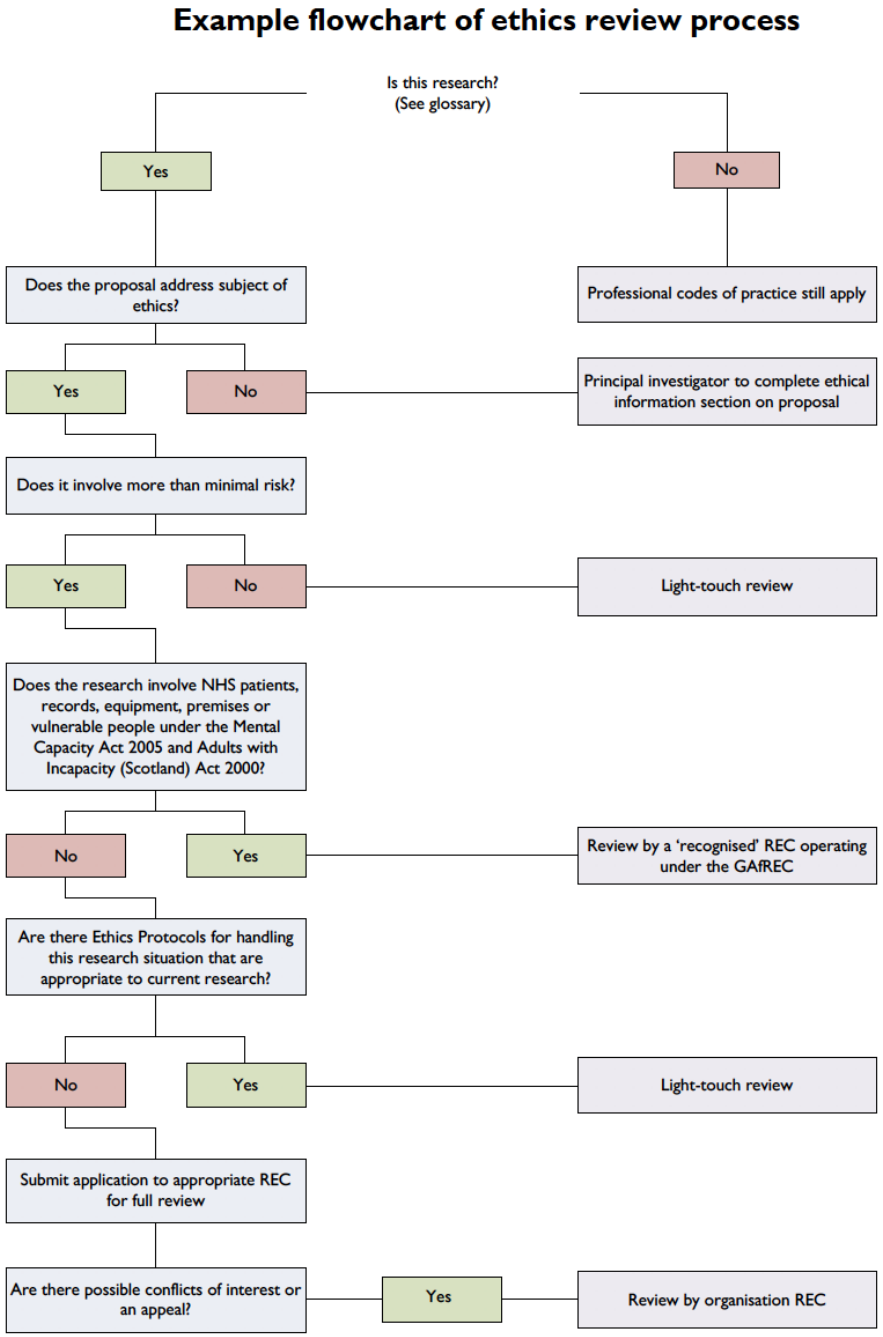
Identify

- Requirement for ethics approval
- Relative Risk
  –>process accordingly



TASC – Tayside Medical Science Centre

Economic and Social Research Council

All research projects involving human participants must have appropriate ethical approval before they begin. To determine whether your project requires ethical approval from a School Research Ethics Committee (SREC) please complete Checklist 1: Does the Project Require Ethical Approval?.

If after completing Checklist 1: Does the Project Require Ethical Approval? you are still unsure whether your project requires ethical approval, please contact the Convener of the relevant SREC.

Checklist 2: Risk Assessment will be used to determine whether your application is low, medium or high risk. Depending on the risk level you will be required to use one of two forms. Form A is required for low risk applications, Form B needs to be used if the application is medium or high risk.

Section B: Collection and Analysis of Data From or About Human Beings	YES	NO
B1. Does the project involve collecting primary data from, or about, living human beings (this includes data collected via interviews, surveys, social media or any other data containing identifiable information including the completion of consent forms)?		
B2. Does the project involve analysing primary or unpublished data from, or about, living human beings?		
B3. Does the project involve collecting or analysing primary or unpublished data about people who have recently died, other than data that are already publicly available?		
B4. Does the project involve collecting or analysing primary or unpublished data about or from organisations or agencies of any kind, other than data that are already publicly available?		

If you have answered YES to ANY of these questions your project will require ethical approval: please proceed to Section C. If you answered NO to ALL of the questions you will not require formal ethical approval.

If your project does not require ethical approval, and you wish to publish your findings, you may still wish to seek approval from the relevant SREC in order to meet journal requirements. If so, please proceed to Checklist 2.

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Section C: Healthcare or Social Care Research 'In or Through the NHS'?[1]	YES	NO
C1. Does the project involve patients, their carers or volunteers in the NHS (in hospital, General Practitioners, community care)?		
C2. Does the project involve the investigation of the safety or efficacy of a medicine, foodstuff, medical device or placebo in humans?		
C3. Does the project involve access to collections of patient data?		

–> establish if TASC needs to be involved (i.e. which committee and procedure)

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Tayside Medical Sciences Centre (TASC)

Please note that if a proposed project will involve any of the following activities, then you should refer to the website of the Tayside Medical Sciences Centre (TASC) to identify the correct policy to govern the research (http://www.tasc-research.org.uk/tasc/for-researchers) and contact the TASC Research Governance Office (TASCgovernance@dundee.ac.uk) for advice on the appropriate approval route:.

- patients, their carers, or volunteers in the NHS (in hospital, General Practitioners, community care)
- the investigation of the safety or efficacy of a medicine, foodstuff, medical device or placebo in humans
- access to collections of patient data
- use of any NHS resources including staff time, clinical support services or NHS facilities
- research within prisons
- research involving adults (aged 16 or over) with incapacity
- social care research with NHS patients or a mix of NHS patients and social care users
- use of tissue for genetic analysis/diagnosis or a therapeutic purpose
- the collection or use of donor identifiable human biological samples
- human biological samples obtained from a tissue bank

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Application

- Checklist 1: Guidance
- Checklist 1: Does the Project Require Ethical Approva
- Checklist 2: Risk Assessment
- Forms A & B: Data Management Guidance
- Form A: Low Risk Application
- Form B: Medium/High Risk Application
- Research Projects Involving the Use of Human Tissue from Healthy Volunteers
- Guidance for Module Level and Group Applications

Review

- Reviewer Checklist: Form A
- Reviewer Checklist: Form B

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Appeals

- SREC Appeals Procedure
- SREC Appeals Form
- UREC Appeals Procedure
- UREC Appeals Form

Participant Information Sheet and Consent Form Templates

- Participant Information Sheet Template
- Consent Form Template

Amendment/Extension

- Post-Approval Request for Amendment
- Post-Approval Request for an Extension

Revised CODE OF PRACTICE/ POLICY FOR NON-CLINICAL RESEARCH INVOLVING HUMAN PARTICIPANTS

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Fundamental principles underpinning research
Rights of participants
Responsibilities of researchers
Definition of research
Research Governance
Ethical approval for research project
Research conducted overseas
Research involving secondary data
Research involving social media and other data available on internet
Research involving human tissue
Insurance
Safety and wellbeing of researcher
Reporting criminal activity and/or risk of harm
Security-sensitive research
Other relevant policy documents and codes of practice

What to do when samples or data that involved human volunteers to be used are generated in countries other than UK?

Ideally obtain all ethics approval documents and confirm that ethical standards used in generating data/samples were/are on par with UK (BEFORE receiving samples)
If in doubt consult experts locally/nationally
Issues that can arise:

- Language not able to be translated
- Consent forms not complete or do not comply with our standards
- Provenance of samples not clear
- Documents not available or only partial

Remember if ethical approval cannot be demonstrated to UK standards publication of data may be difficult or impossible!

Social media/ secondary data

Research involving secondary data including social media data and other data available on the internet

Secondary data are data that have already been collected for some other purpose. Some secondary data are publicly available, e.g. from social networking services. Data available on the internet are likely to have been collected and made available using **consent** processes based on a lower ethical standard than that appropriate for research. **It cannot be assumed that secondary data will have the appropriate consent for new uses of the data for research purposes.** As such research based on secondary data should consider the possibility of harm to data subjects and whether steps to mitigate risk are required, even where these data are anonymous. Where data are combined or added to by the researcher, the risk of re-identification should be carefully evaluated.

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A different type of project:

Public engagement projects:

- UG honours students learn about scientific principal or idea and design a public engagement project to educate a specific (non-scientific) group about it
- They design an activity to achieve this education
- To measure the effectiveness of their activity they conduct a survey before and after their activity
- Often, they collect feedback/information from **participants** (usually personal data is not collected)
- They assess the effectiveness of their activity by evaluating the 'data' collected form the participants

Requires ethical approval and involves consent forms from participants.
There are lots of them each year!

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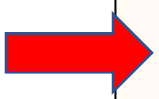

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Criteria

In order to be considered for **module/group** level approval, the application must meet the following criteria:

- Be low risk as determined by checklist 2
- Not collect any personal data
- The various projects within the application must be substantially similar
- There must be a named single point of contact overseeing all the projects (such as module lead, project supervisor, PI etc)

Procedure

Same as for individual ethical applications. If recurrent yearly, i.e. rolling applications, i.e. a module that occurs every year), approval will be given for a **maximum of three years**, assuming no substantial changes, after which it must be reviewed. The project end date will therefore be three years from the first ethical approval.

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Additional Requirements

Ethical approval may not be a sufficient precondition for carrying out the research. For example, researchers working with children and/or protected adults in Scotland will need to apply to Disclosure Scotland for membership of the Protecting Vulnerable Groups (PVG) scheme. Any necessary risk assessment needs to be carried out before the research begins and researchers must abide by all appropriate health and safety regulations (contact Safety Services for advice). Research must also comply with all relevant data protection legislation (contact dataprotection@dundee.ac.uk for advice).

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