University of Dundee

Ethical Approval for Non-Clinical Research Involving Human Participants

CHECKLIST 1: Does your project require ethical approval from a School Research Ethics Committee (SREC)?

Section A: Definition of Research	**YES**	**NO**
A1. Is Your Project Research?	**X**	

If YES please proceed to Section B.

If NO please see guidance on requirements for registering and approval of clinical audit and service evaluation projects with NHS Tayside Clinical Governance.

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)?		X
B2. Does the project involve analysing primary or unpublished data from, or about, living human beings?		X
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 Does the project involve collecting or analysing primary or unpublished data about people who have recently died, other than data that are already publicly available?		X
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 Does the project involve collecting or analysing primary or unpublished data about or from organisations or agencies of any kind, other than data that are already publicly available?		X

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.

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)?		**X**
C2. Does the project involve the investigation of the safety or efficacy of a medicine, foodstuff, medical device or placebo in humans?		**X**
C3. Does the project involve access to collections of patient data?		**X**

[1] For overseas healthcare research please refer to the Checklist 1 Guidance for Researchers

C4. Does the project involve use of any NHS resources including staff time, clinical support services (e.g. biochemistry, haematology) or NHS facilities (e.g. consulting rooms)?		**X**
C5. Does the project involve research within prisons?		**X**
C6. Does the project involve adults (aged 16 or over) with incapacity (i.e. lack of capacity to make decisions for themselves)?		**X**
C7. Does the project involve social care research with NHS patients or a mix of NHS patients and social care users?		**X**
C8. Does the project involve the use of tissue for genetic analysis/diagnosis or a therapeutic purpose (e.g. the use of DNA for analysis or RNA when used to provide information about DNA for research (section 45, Human Tissue Act))?		X
C9. Will the project use anonymised tissue and associated data from NHS patients that is surplus to diagnostic and surgical requirements and will be obtained from a tissue bank (e.g. Tayside Biorepository)?		X

If you answered YES to ANY of the questions C1 – C8 above your project is likely to require NHS REC approval or may fall under other approval schemes (e.g., Caldicott Guardian). You must therefore contact the Tayside Medical Science Centre (TASC) Research Governance Office (TASCgovernance@dundee.ac.uk) for advice. TASC will advise if the project should be designated as healthcare research and which research approvals are required.

If you ONLY answered YES to question C9, you should obtain ethical approval through the Tayside Biorepository (https://www.tissuebank.dundee.ac.uk/?page=contacts).

If you have answered YES to ANY questions in section B and NO to ALL questions in section C please proceed to Checklist 2 as you will require approval from a School SREC.