Guidance for Researchers

Checklist 1: Does Your Project Require Ethical Approval from a School Research Ethics Committee (SREC)

All research projects involving human participants, including those conducted overseas, must undergo ethical review and approval before the research begins. The first step in determining whether your project requires ethical approval is to determine whether it is or is not research.

**Question A1: Is Your Project Research?**

**i) Definition of Research**

The key source of reference for determining whether an activity is or is not research is the Frascati Manual. The University is required to use the Frascati definition of research and development to report income from externally funded research to the UK Higher Education Statistical Agency (HESA) and to record research activity for the Transparent Approach to Costing (TRAC) methodology, which determines indirect cost rates for grant applications.

The Frascati definition of research and development is summarised in the extracts below:

“Research and experimental development (R&D) comprise creative and systematic work undertaken in order to increase the stock of knowledge - including knowledge of humankind, culture and society - and to devise new applications of available knowledge.”

“The term R&D covers three types of activity: basic research, applied research and experimental development. **Basic research** is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view. **Applied research** is original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective. **Experimental development** is systematic work, drawing on knowledge gained from research, practical experience, and producing additional knowledge, which is directed to producing new products or processes or to improving existing products or processes.”

The creation/acquisition of new knowledge and uncertainty about the final outcome are key elements of the definition. Further details can be found in chapter 2 of the Frascati Manual.

If your project meets the definition of research and you have answered YES to any of the questions in Section B of Checklist 1 your project will require ethical approval before you start the research. You should then complete Section C of Checklist 1 to determine whether your project requires review by an SREC or another ethics committee (such as an NHS Research Ethics Committee (NHS REC) or the Tayside Biorepository).

**ii) Healthcare Research Conducted Overseas**

Healthcare research conducted overseas cannot be reviewed by an NHS REC. Projects must be reviewed by the relevant SREC at the University of Dundee and the local REC in the country where the research is taking place. The formal opinion of the local REC must be shared with the SREC. The local and SREC opinions must then be shared with Tayside Medical Science Centre (TASC) Research.

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Governance (TASCgovernance@dundee.ac.uk) for confirmation of sponsorship. Projects must not start before sponsorship is confirmed.

iii) Activities Not Requiring Ethical Approval

Activities that do not meet the definition of research will not require ethical approval. These include:

1. Performance reviews.
2. Testing within normal education requirements.
3. Literary or artistic criticism.
4. Quality Assurance studies/Audits of standard practice (not involving identifiable records) – designed to find out whether a service meets pre-determined standards. Examples include assessment of teaching practices and clinical audit.
5. Service Evaluation – designed solely (i.e. not as part of a research project) to assess what standard the service achieves.

The Health Research Authority (HRA) has produced a leaflet (Defining Research) to help healthcare researchers differentiate between research, clinical audit, service evaluation, public health surveillance and usual practice. The Medical Research Council (MRC) and HRA have developed an online decision tool, ‘Is my study research’, based on this leaflet to help researchers determine whether their project would be considered research as defined by the UK Policy Framework for Health and Social Care Research. A second decision tool, ‘Do I need NHS REC approval?’, has been developed to help researchers determine whether their research requires approval by an NHS REC. Further advice can be obtained from TASC (TASCgovernance@dundee.ac.uk).

Note that health and social care research involving human participants that does not require NHS REC approval but is in or through the NHS (e.g research involving NHS staff as participants) will still require SREC approval if it meets the definition of research in i) above. It will also require a Sponsor\(^2\) and NHS R&D permission. Please contact TASC for further information and advice (TASCgovernance@dundee.ac.uk).

Requirements for registering and approval of clinical audit and service evaluation projects.

Clinical audit and service evaluation projects must be registered with the appropriate Board/Trust; please contact TASC (TASCgovernance@dundee.ac.uk) for advice on how and where to register such projects. If you do not usually have access to the required patient data (patient-identifiable information) you should apply for Caldicott Guardian approval through NHST or the appropriate Board/Trust to access the data. Please contact TASC for further information and advice (TASCgovernance@dundee.ac.uk).

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\(^2\) An individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, management and financing (or arranging the financing) of the research. Usually the University of Dundee via the Tayside Medical Science Centre (TASC) Research Governance Office.
Research Involving Publicly Available Information

Research on publicly available information, documents or data (e.g. published minutes of a meeting) will not require ethical approval unless it involves sensitive information, access to, and use of, which could reasonably be perceived as unethical or immoral or is subject to intellectual property or copyright restrictions. In this respect, postings on social media or newspaper web pages may be the intellectual property and copyright of the author or platform or both and therefore require appropriate permissions to be obtained to use the information for research.

Information on the internet or social media should be scrutinised carefully to ensure anonymity of individuals. Where there is the potential to identify individuals in online sources, advice must be sought on data protection requirements (dataprotection@dundee.ac.uk) and whether the research requires ethical approval.

iv) Security-sensitive research

Processes are currently being developed for approval of security-sensitive research. If your research falls within this category please contact the Convener of UREC for advice.

v) What if I’m not sure?

If you are unsure whether or not your project falls within the definition of research please contact the Convener of your School Research Ethics Committee for advice.