The University of Sheffield
Research Ethics Policy Note no. 5

ETHICS REVIEW OF HEALTH AND SOCIAL CARE RESEARCH IN THE UK

The University of Sheffield's Research Ethics Policy is intended to complement the long-established National Health Service (NHS) ethics review system (overseen by the Health Research Authority (HRA) and incorporated into the HRA Approval process), and the procedure established by the national Social Care Research Ethics Committee. The University's Ethics Review Procedure does not duplicate the functions, or overlap with the remit, of the NHS ethics review system or the national Social Care Research Ethics Committee.

It should be noted that, in addition to the requirement for ethical review, health and social care research in the UK is subject to additional research governance requirements. For more details refer to the following webpage: https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance.

It should be noted that in the UK, for clinical trials of Investigational Medicinal Products (IMP-trials) or Medical Devices, and for research involving the use of human tissue, there are specific legal and regulatory requirements which must be considered alongside the requirements for ethical review. Further information relating to the requirements for IMP-trials and Medical Device trials can be found in sections 1.2 and 2 of this Policy Note, and the MHRA's website (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency). Further information relating to the use of human tissue in research is provided in section 2 of this Policy Note and in Research Ethics Policy Note no. 11.

In addition, there is a legal requirement for social care research involving adults in England and Wales who are deemed to be lacking in capacity to be reviewed by a recognised Appropriate Body under the Mental Capacity Act 2005. Appropriate Bodies include certain NHS Research Ethics Committees and the Social Care Research Ethics Committee; for full details see section 3 of this Policy Note and the Specialist Research Ethics Guidance Paper entitled 'Research involving adult participants who lack the capacity to consent'.

1 DEFINITIONS

1.1 Research

The University's Research Ethics Policy defines research as 'a process of investigation leading to new insights, effectively shared'.

The HRA defines research as 'the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods'.

Thus the University's definition of research is broader than that of the HRA. This means that some studies which are not considered research by the HRA, and which therefore do not require ethical review by an NHS Research Ethics Committee, may still require ethical review via the University's Ethics Review Procedure (e.g. studies classed as service evaluation by the HRA, but which are undertaken by a student as the research element of a University degree award).

1.2 Health care research

The '*UK policy framework for health and social care research* (2017) defines health care research as:

> Health and social care research that is within the responsibility of the HRA or the Devolved Administrations' Health Departments. This includes: research concerned with the protection and promotion of public health; research undertaken in or by a UK Health Department, its non-Departmental public bodies and the NHS, and social care providers; and clinical and non-clinical research, research undertaken by NHS or social care staff using the resources of health and social care providers and any research undertaken within the health and social care systems that might have an impact on the quality of those services.

In practice, the University considers research that requires review by an NHS Research Ethics Committee to be health care research (see section 2 of this Policy Note for more details).

Clinical trials of investigational medicinal products (IMP-trials), which are one type of health care research, are defined by the International Conference on Harmonisation Guideline on Good Clinical Practice (ICH-GCP) as:

> Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Research involving human tissue is one type of health care research. The Human Tissue Act (2004) defines human tissue as 'relevant material that has come from a human body and consists of, or includes, human cells'.

1.3 Social care research

Social care research refers to research that is undertaken in or with bodies (either independent or statutory) that provide personal social services.

Local social care providers will have their own research governance requirements, and researchers will need to refer to the relevant provider in order to determine which types of project will be affected. For example, the definition of social care research applied by Sheffield City Council is 'research that involves human participants who have been identified through the social care services of Sheffield City Council with the aid of Council resources'.

It should be noted that not all social care research requires access to human participants via statutory social care services.

2 ETHICS REVIEW PROCEDURE FOR HEALTH CARE RESEARCH

Health care research is reviewed by an NHS Research Ethics Committee (NHS REC). Review by an NHS REC forms part of the HRA Approval process. The remit of NHS RECs is defined by the Department of Health's policy document *Governance arrangements for research ethics committees.*

In general, review by an NHS REC will be required for research that involves participants identified from, or because of, their status as patients of the NHS or other health services of the UK Devolved Administrations, and/or the relatives of such patients. There are also specific types of health care research that will require review by an NHS REC (e.g. a clinical trial of an

Investigational Medicinal Product and research involving human tissue). Research involving only the premises and/or staff of the NHS or other health services does not require review by an NHS REC. Researchers should refer to the HRA's ethics decision tool for full details:

http://www.hra-decisiontools.org.uk/ethics/

The University requires all research involving human participants, their data or their tissue to be ethically reviewed. This means that research that falls outside the remit of NHS RECs, but which involves human participants, their personal data or tissue must be reviewed via either the University's Ethics Approval Procedure or an Alternative Ethics Review Procedure (for further information about the latter, see section 4 of the University's Research Ethics Approval Procedure). It should be noted that this may include studies that the NHS considers to be service evaluation, and those which involve NHS staff or premises.

3 ETHICS REVIEW PROCEDURE FOR SOCIAL CARE RESEARCH

The national Social Care Research Ethics Committee (SCREC) is part of the HRA. The University's Ethics Review Procedure does not duplicate the functions, or overlap with the remit, of SCREC. SCREC generally expects to review particular categories of social care project, including social care studies funded by the Department of Health, and social care research that involves people lacking capacity in England and Wales and requires approval under the Mental Capacity Act 2005; full details can be found on the HRA's website:

http://www.hra.nhs.uk/resources/before-you-apply/non-nhs-recs/national-social-care-research-ethics-committee/.

The SCREC does not review studies involving clinical interventions. Such research should be reviewed by an NHS REC.

If social care research does not require review by an NHS REC or SCREC, but involves human participants, personal data or human tissue, it must be reviewed using the University Ethics Review Procedure, on the proviso that the requirements of the ESRC *Framework for Research Ethics* are met. This means that the ethical scrutiny of social care research projects of this kind will be undertaken by a sub-committee of the UREC, comprising two ethics reviewers from the project's department of origin, one lay member from the UREC, and additional members of the UREC as required on a case-by-case basis in order to meet the requirements of the external body. The departmental Ethics Administrator should be notified of social care research projects, so that they can liaise with the UREC Minute Secretary to arrange appropriate ethical review.

3.1 Mental incapacity

The University's Ethics Review Procedure cannot review research that involves adults in England or Wales who are defined as lacking mental capacity. Only Research Ethics Committees that are recognised as *Appropriate Bodies* for this purpose can do so under the Mental Capacity Act (MCA) 2005 (these are also sometimes known as 'flagged committees' for the purposes of such reviews). SCREC as well as NHS REC established in England and Wales are recognised for this purpose. The MCA applies only to people aged 16 and over.

The MCA does not apply to Scotland. In Scotland medical research which involves people aged 16 or over who lack capacity requires approval from an NHS REC. There is currently no equivalent law on mental capacity in Northern Ireland.

For further information, see the Specialist Research Ethics Guidance Paper dealing with 'Research involving adult participants who lack the capacity to consent'.