

Scope of the Code of Practice and Exemptions from Further Ethics Approval in Respect of Research Involving Human Participants, Data or Material of a Socially/Politically Sensitive Nature

July 2022

Scope

- The ethics arrangements for research:

All research arrangements must be subject to appropriate levels of scrutiny to ensure that no violations of ethical principles occur where human participants, material or data are involved. Anything that has the potential to affect the reputation of the College must undergo ethical clearance at the CEP level.

For proposals which are principally research in nature even if part of a taught programme (including research activities as part of taught programmes eg undergraduate final year projects or projects within masters projects) the assessment will be made in the context of research ethics. Normally, the default for research proposals from staff and students is that they are subject to scrutiny by the College Ethics Panel (CEP) or its nominated officer unless there is a specific reason they should not be.

All research activity that is carried out on Regent College London premises and/or by Regent College London staff, students or visiting researchers and that involves human participants, requires ethics approval. All such research activities must be submitted for ethics approval in accordance with current policy and procedures. This will result in an ethical clearance certificate being issued that defines the scope of the ethical clearance for the project.

- Researchers associated with Regent College London:

All such researchers must complete an RE1 form (research ethics checklist) and conform to the College's Code of Practice for Ethical Research involving Human Participants as the first stage in seeking ethical clearance. This RE1 form must be submitted to the College Ethics Panel. In some instances, an RE2(U) may be required to be completed for further consideration by CEP.

Where the only involvement of human participants in particular research activities will be in one or more of the following categories, the research will normally be EXEMPT from FURTHER ethics approval, unless approval is specifically required by an external funding body or other external body in order to obtain research permission.

Note that the exemptions below (apart from exemption (a)) do not apply to research involving vulnerable participants (e.g. mental patients, prisoners, foetuses, and pregnant women). Note also that exemption (b) does not apply to research on children except when the researcher(s) do not participate in the activities being observed.

Exemption from further approval DOES NOT IMPLY that the research is also exempt from the College's Data Protection Policy.

The following types of human participant research DO NOT normally require further ethics approval:

- a. Research involving the collection or study of EXISTING data, documents or records that are publicly available or where the information is recorded by the researcher in such a manner that participants cannot be identified, directly or indirectly or through identifiers linked to the participants. This exemption is only applicable to data derived from non-NHS sources.
- b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour UNLESS the instruments contain material of a sensitive nature (eg. sexual, financial, or other personal content), OR UNLESS information obtained is recorded in such a manner that human participants can be identified AND any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of: physical or psychological danger or intrusion into their personal lives or affairs; criminal or civil liability; damage to participants' financial standing, employability, or reputation.
- c. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed, OR if a food is consumed that contains a food ingredient at or below the level and for use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the appropriate government regulators.

Notes:

If Regent College London staff and/or Regent College London students under the supervision of Regent College London staff are involved as co-researchers in a project led by a principal researcher from another institution and ethics approval has been granted by that other institution, it is NOT necessary to obtain additional ethics approval from Regent College London.

The College is NOT ultimately responsible for considering the ethics of research which falls under the remit of Department of Health approved ethics committees who abide by governance arrangements for NHS research ethics committees. Such research committees may, however, require that any such research proposals made to them have first been approved by the College Ethics Panel.

If the research involves:

- the use of patients and users of the NHS,
- individuals identified as potential research participants because of their status as relatives or carers or patients and users of the NHS,
- access to data, organs or other bodily material of past and present NHS patients,
- access to or use of pathological specimens, or diagnostic samples from human subjects which are archived on NHS premises,
- the recently dead in NHS premises,
- foetal material and IVF involving NHS patients,
- the use of, or potential access to, NHS premises and facilities,

- NHS staff recruited as research participants by virtue of their professional role,

then the ethics of such human research MUST be referred to the appropriate Department of Health approved ethics committee. Also note that research involving human materials and remains will be within the scope of the Human Tissue Authority and checks need to be made with the local Designated Officer to ensure that the research is compliant with any licence held by the University. Further details and information on how to apply is available from the Central Office for Regional Ethics Committees (<http://www.hra.nhs.uk/about-the-hra/our-committees/research-ethics-committees-recs>)

Acknowledgement

This Scope of the Code of Practice has been adapted from Regent College's partner, the University of Bolton: https://www.bolton.ac.uk/assets/Uploads/Scope-of-Code-of-Practice_Nov_2021_V2.pdf