Scope of the Code Of Practice And Exemptions From Further Ethics Approval In Respect Of Research & Teaching Involving Human Participants, Data or Material or of a Socially/Politically Sensitive Nature

November 2021

Scope

- The ethics arrangements for research and teaching:

  All research and teaching 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 or the study/activity is potentially of a socially/politically sensitive nature. Anything that has the potential to affect the reputation of the University must undergo ethical clearance at the UREC 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. For proposals which are essentially teaching arrangements where established procedures, demonstrations or modelling are involved, the focus will be on the ethical compliance of the arrangement as a recurrent teaching practice rather than each specific instance of its delivery.

  Normally, the default for research proposals from undergraduate and taught postgraduate programmes is that they are subject to scrutiny by the Departmental Ethics committee (DREC) or its nominated officer unless there is a specific reason they should not be, while for teaching arrangements that do not include human participants, material or data the default is that they are not subject to the Departmental Ethics Committee unless there is a specific reason why they should be.

- Instances of teaching activities which should be referred to UREC include but are not limited to:

  Teaching activities which deal with *inter alia* human tissue, blood samples, bodily fluids or DNA (both to ensure compliance with relevant University licences and to consider whether the activity is appropriate within context)

  Teaching activities involving private data of individuals (both to ensure compliance with relevant GDPR and other data protection legislation and to consider whether the activity is appropriate within context)

  Teaching activities that may have the potential to be socially or politically sensitive in nature or that have to potential to highlight illegal or harmful activities.

  Teaching activities which raise ethical issues in relation to the safety of students, staff or others, should be scrutinised under the University's Health & Safety policies and risk assessment arrangements. In the event that such activities are deemed to be safe they

may still be subject to review by UREC for any residual ethical issues.

- Referral of teaching activities will normally be from the following sources:

    - The academic or technical member of staff planning to carry out the activity
    - A programme approval panel and relevant officer in relation to a new or reviewed programme of study
    - The line manager of a member of staff developing or planning a teaching activity
    - The Head of the relevant School
    - The Dean of the relevant Faculty
    - A member of the Executive Board.

- Staff and postgraduate researchers:

    All research or teaching activity that is carried out on University of Bolton premises and/or by University of Bolton staff, postgraduate research students or visiting researchers and that involves human participants, human material or data, requires ethics approval. All such research or teaching activities must be submitted for ethics approval via the **EFIT online system** 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. The EFIT system may require an RE2(U) to be completed for further consideration by UREC.

- Undergraduate and taught postgraduate students:

    All such students must complete an RE1 form (research ethics checklist) and conform to the University's Code of Practice for Ethical Standards in Research involving Human Participants as the first stage in seeking ethical clearance. 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.

    In accordance with the following criteria, Department Heads or their Research Ethics Officer have final judgement as to whether a particular activity should be exempt from the requirement for furtherethics approval (via an RE2(D) or RE2(U)). But 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 exceptwhen the investigator(s) do not participate in the activities being observed.

    Exemption from further approval **DOES NOT IMPLY** that the research is also exempt from theUniversity'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 investigator 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 insuch a manner that human participants can be identified AND any disclosure of the human participants' responses outside the research could reasonably place theparticipants 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 foodingredient 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 appropriategovernment regulators.

Notes:

If University of Bolton staff and/or University of Bolton students under the supervision of University of Bolton 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 the University of Bolton.

The University 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 University's Research Ethics Committee.

If the research involves:

- the use of patients and users of the NHS,
- individuals identified as potential research participants because of their status asrelatives 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 humansubjects 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 availablefrom the Central Office for Regional Ethics Committees (http://www.hra.nhs.uk/about-the-hra/our-committees/research-ethics-committees-recs)