

Scope Of The Code Of Practice And Exemptions From Further Ethics Approval In Respect Of Research Involving Human Participants, Data Or Material

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All research (with the exceptions listed below) that is carried out on University of Bolton premises and/or by University of Bolton staff or by any student under the supervision of University of Bolton staff and that involves intervention or interaction with living human participants or the collection and or study of data or material derived from living human participants, requires ethics approval.

All such research must be submitted for ethics approval at the appropriate level and in accordance with current policy and procedures but, 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.

Researchers Planning Such Studies Must Still Complete A Research Ethics Checklist (Form RE1) And Conform To The University's Code Of Practice For Ethical Standards In Research Involving Human Participants.

In accordance with the following criteria, Department Heads or their nominee have final judgement as to whether a particular activity should be exempt from the requirement for further ethics approval. But note that the exemptions below (apart from exemption (a)) do not apply to research involving vulnerable participants (e.g. mental patients, prisoners, fetuses, pregnant women). Note also that exemption (b) does not apply to research on children except when 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 the University'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 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.

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 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,
- fetal 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. 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>)