

**The Newcastle upon Tyne Hospitals NHS Foundation Trust &
the Faculty of Medical Sciences, Newcastle University**

Policy regarding Participation of Volunteers in Research Projects

1. Background

- 1.1. The purpose of this paper is to clarify the key definitions surrounding the participation of volunteers in research projects in the University.
- 1.2. The main focus of this paper is to consider the ethical review and conduct of such projects, as well as ensuring that appropriate processes are in place to review the overall risk to any participants recruited.
- 1.3. It is intended to provide a consistent approach to research being undertaken in either The Newcastle upon Tyne Hospitals NHS Foundation Trust (the "Trust") or the Faculty of Medical Sciences of Newcastle University (the "Faculty"), providing a clear framework for the conduct of research involving volunteers
- 1.4. Following consideration by the Faculty Research Strategy Committee and the JRE, plus including the advice from the Chair of an NHS Research Ethics Committee, the intention is to extend this policy to the other faculties within Newcastle University where any research includes 'invasive procedures' and/or 'interventions', or more broadly 'clinical research' and research involving volunteers.

2. Definitions

- 2.1. "Invasive" in a medical setting is defined as "requiring the entry of a needle, catheter, or other instrument into a part of the body, especially in a diagnostic procedure, as a biopsy" (taken from Dictionary.com).
- 2.2. "Medical Intervention" is defined as "the act of intervening, interfering or interceding with the intent of modifying the outcome. In medicine, an intervention is usually undertaken to help treat or cure a condition" (taken from MedicineNet.com).
- 2.3. "Physiological Intervention" is defined as any action taken on a human subject which modifies or has the potential to modify the physiology of the human subject.
- 2.4. "Clinical Research" is any project which involves
 - (a) medical intervention **and/or**
 - (b) involves NHS patients, staff (as NHS substantive employees) or premises.

Projects involving physiological interventions which do not involve 2.4 (a) or (b) above require consideration as to whether they are projects which are best handled in a clinical setting or not.

3. Guidance

3.1 Notes of guidance will be available to address such matters as:

- (a) an appropriate setting and appropriately trained staff (see 4.1 below);
- (b) clarification of the definition of "invasive" procedures;
- (c) the capacity to give consent in relation to specific groups of participants (eg adults lacking capacity) (see 6.3 below).

4. Ethical Issues

- 4.1. The involvement of any invasive procedure or physiological intervention in a research project implies a potential medical risk, no matter how small. Consequently, it is recommended that all such projects are undertaken in an 'appropriate setting' supported by appropriately trained staff approved by the Faculty.
- 4.2. Any projects involving a medical intervention must be undertaken in an NHS/trust setting, irrespective of where the participants are drawn from.
- 4.3. Projects involving the NHS (staff, patients or premises) must be reviewed via an NHS Research Ethics Committee, plus the Trust R&D Approvals Committee which considers the overall governance of the project (ref. also 'Review of Risk' in 5 below). Projects where the staff involved in administering the research activity are acting as employees of the University rather than the NHS do not automatically need to be reviewed by an NHS Research Ethics Committee, even if they are University substantive employees holding honorary NHS contracts.
- 4.4. Those projects which do not involve the NHS staff, premises or patients or involve a medical intervention but which do include any invasive procedure(s) or physiological intervention with Volunteers must be reviewed by the Faculty Ethics Committee.
- 4.5. For clarification, if a non-invasive project, with no medical interventions, invites any NHS staff, students or patients to become volunteers then they would be invited on the basis that they were members of the public (and not part of the NHS). Such studies would not normally require REC approval, but ethical review must be sought through the University. For any other types of research (e.g. qualitative studies) that appear to involve significant material ethical issues, then review by an NHS REC might be necessary. However, informal advance may be sought from either the Chair of the Faculty Ethics Committee or the Chair of an NHS REC.
- 4.6. For any studies which involve volunteers who are also children (i.e. under the age of 18) there are potentially different ethical/safety issues to consider. In

terms of the NHS REC system, this is acknowledged by the specific training of certain committees who are then authorised to review such projects. In recognition of the potential risks associated with such projects, specific guidelines are being developed to support both the individual researcher and the members of the Faculty's Ethics Committee both in developing and reviewing these projects. Similar guidelines are also being developed for projects involving participants over the age of 65 or women of child-bearing age, as well as guidance for any research projects involving MR, exercise testing, nutrition or any invasive procedures. For any projects involving a physiological intervention additional considerations also need taken into account

5. Review of Risk

- 5.1. It should be noted that volunteers may meet the inclusion criteria of a particular research project but may also have a completely unrelated and/or undiagnosed medical condition. They may also be more vulnerable as direct result of the project itself – e.g. exercise testing in otherwise healthy participants who do not routinely exercise.
- 5.2. In these circumstances, there are obvious issues which need to be addressed appropriately in relation to the specific research project protocol and ensuring informed consent. For example, very clearly defined exclusion criteria would be needed to rule out (apparently unrelated) medical conditions which may conflict with the main area of the research project; details surrounding how to support participants if underlying conditions are discovered (if appropriate) should be clearly thought through and included in study documentation such as information sheets/consent forms; etc.
- 5.3. The Faculty Ethics Committee should also refer to the guidelines noted in 3.6 above when considering the overall risk to the participants of a project as well as undertaking the required ethical review.
- 5.4. The terms of reference of the Faculty Ethics Committee should be expanded to explicitly refer to the review of risk to the participants of potential projects.

6. Policy Statement

- 6.1. All research projects involving any **medical interventions** as defined in this policy (however minimal) must be undertaken in a Trust setting, supported by appropriately trained staff. This includes any research undertaken solely with volunteers recruited from outside of the NHS.
- 6.2. All research projects involving any **invasive** procedures and/or physiological interventions as defined in this policy (however minimal) must be undertaken in an 'appropriate setting', supported by appropriately trained staff approved by the Faculty. This includes any research undertaken with volunteers recruited outside of the NHS. The projects should be reviewed by the Faculty Ethics Committee (from an ethical viewpoint and also to assess the risk of the project

overall). If researchers are in any doubt as to whether the invasive procedures they propose to undertake would be regarded as simple procedures (e.g. single blood sample in a healthy volunteer) or more complex procedures which would more appropriately be considered under the definition of a medical intervention (e.g. multiple blood samples in a short period of time, biopsies, etc.) then advice should be sought from the Chair of the Faculty Ethics Committee.

6.3. Researchers developing a protocol, consent form and participant information sheet for projects which include any of the following groups should consult the relevant guidelines, available from the Faculty Research Office: older participants or those under the age of 18; women of child-bearing age; procedures involving MR, exercise testing, nutrition or any invasive procedures.

6.4. The Faculty of Medical Sciences Ethics Committee should also refer to the above guidelines when reviewing such projects.

6.5. That all **clinical** research/consultancy projects should be reviewed by and advised upon by the Joint Research Office, irrespective of which area of the University they originate from.

Approved by University Research Committee

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Faculty of Medical Sciences Research Projects Process for ensuring Ethical and Risk/Governance Reviews

