Notes for Guidance

1. Membership

The Research Ethics Committee was established by the Council on the recommen(n)1.0d(a)5(b14.1(e Ci(n)4( )11(n)4f1.06(h)-1(e Co)(t)-S(ee)( )1(b)-4(ee).hi) In)1(h)-5

risks whic h were not at first apparent.

6. Exceptions

(a) In order to reduce the work of colleagues and of members of the

(i) The subject and/or parent receives an Information Sheet explaining the purposes of the project, how they have been selected a s potential participants and a full and clear accoun t of what will be asked of them;

(ii) The subject and/or parent is invited to sign a Consent Form;

(iii) Copies of the Information Sheet and Consent Form are provided for r etention by the subject/pare nt;

(iv) The Information Sheet and Consent Form include the name and designation of a member of staff with responsibility for the project together with a contact address or telephone number. If any of the project investigators are students, this informat ion must be in cluded and their name provided;

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Sub-Group Meetings

The Research Ethics Committee delegates consideration of project submissions to its Sub-Groups which meet on eleven occasions in each academic year. Dates of meetings and submission deadlines are published on the Committee's webpage at http://www.reading.ac.uk/internal/res/ResearchEthics/reas -REcommitteedeadlines.aspx

Membership of the Sub- Groups shall be

- The Chair of the Research Ethics Committee
  A University member of the Research Ethics Committee
- A medically -qualified member of t he Research Ethics Committee (who may also be the Chair)
- A lay member of the Research Ethics Committee drawn from among those appointed by the Committee

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Checklist

1. This form is signed by my Head of School (or authorised Head of Department)

2. The Consent form includes a statement to the effect that the project has been reviewed by the U niversity Research Ethics Committee and has been given a favourable ethical opinion for conduct

3. I have made, and explained within this application, arrangements for any confidential material generated by the research /Artik7(m)orh6 TD 2(te)16(o)1(r(te)1c(o)1(8 [(re)0(l)y b)1 w(m)1si)16hin hi

Consent Form

1. I have read and had explained to m e by …….. …

   the accompanying Information Sheet relating to the project on :

   …… ...

2. I have had explained to me the purposes of the project and what will be required of me, and any questions I have had have been answered to my satisfaction. I agree to the arrangements described in the Information Sheet in so far as t hey relate to my participation.

3. I understand that participation is entirely voluntary and that I have the right to withdraw from the projec t any time, and that this will be without detriment.

4.

   a) I authorise the Investigator to consult my General Practitioner .

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Research involving the taking of blood samples

Researchers should be aware of the provisions of the Human Tissue Act 2004, which regulates the consents required for the use or storage of "material which consists of, or includes, human cells", and requires that anyone storing such material for the purpose of research must have a licence from the Human Tissue Authority. The Department of Food and Nutritional Sciences has a licence for this purpose.

1. The Health and Safety Committee and the Resea rch Ethics Committee have reviewed procedures relating to the taking of blood samples.

2. The arrangements which the two Committees have agreed are intended to safeguard the position of all those concerned without being unduly cumbersome in their operation.

3. Any person giving a blood sample, or a se(t)-4(h)9(e(sed1(edp)11(sa))10(m)(i)5(s[(w)2(1(saq)3v

Guidelines to assist Heads of School (or authorised Heads of Departments) in defining research and therefore whether projects need to be referred to the University Research Ethics Committee

The purpose of this annexe is to help Schools decide if a project is research, which normally requires review by a School or University Research Ethics Committee (REC), or whether it is some other activity such as audit, or service evaluation . It draws on

The primary aim of researc h is to derive generalizable new knowledge, whereas the aim of audit and service evaluation projects is to measure standards of care. Research is to find out what you should be doing; audit is to find out if you are doing planned activity and assesses whether it is working. Some projects may have more than one intent, in which case a judgement will need to be made on the primary aim of the project.

- Treatment/service

  Neither audit nor service evaluation uses an intervention without a firm basis of support in the

Annex F: University of Reading: Process of Ethical Review