

UNIVERSITY OF LEEDS

UNIVERSITY RESEARCH ETHICS COMMITTEE

## Guidance for completing the application form for University ethical review

### The form itself

The latest version of the form is available at <http://ris.leeds.ac.uk/uolethicsapplication>. **Please use the latest version as the form is updated on a regular basis.**

If you are unable to select the radio buttons or tick boxes on the form this could be because the macros are disabled in your version of Word. When you open Word a dialogue box asking whether you wish to enable macros should appear. Click yes. If you do not get this box you can change your settings by selecting the office button in the top left-hand corner of the screen, clicking on the 'word options' button, selecting 'trust centre' from the options on the left, clicking on the 'trust centre settings' button and then choosing the option 'enable all macros with notification'. Further information on enabling macros is available via the on-line Word help <https://support.office.com/en-us/article/Enable-or-disable-macros-in-Office-files-12b036fd-d140-4e74-b45e-16fed1a7e5c6>.

### Section A

1. For clarification of the University's requirements for ethical review refer to the Research Ethics Policy (available at [www.leeds.ac.uk/ethics](http://www.leeds.ac.uk/ethics)). In funded research you need only apply for ethical approval at the award stage, though advice is available at the application stage if required. This form should be used for research, or parts of research studies that has not be subject to ethics review by the NHS.
2. There are several [Faculty Research Ethics Committees](#) (FRECs) in the University. In some cases a FREC is responsible for more than one Faculty. Applications should normally be made to the FREC covering the Faculty in which the researcher or student is based, although another FREC could be requested (by negotiation) if the preferred FREC would be more familiar with the projects methodology. Similarly, the FRECs themselves may choose to refer a project to another FREC if they feel that it would be more appropriately reviewed elsewhere. As of September 2013 EdREC and LIHS/LIGHT/LIMM have been replaced by one School of Medicine Research Ethics Committee (SoMREC). EdREC applications are now referred to either SoMREC or DREC. SoMREC will take on the medical education research and DREC will take on dental education research.
3. Wherever possible the title on consent forms, information sheets, other supporting documentation and this application should be consistent. The title should make clear (where appropriate) what the research is about. There may be instances where a different title is desirable on information to participants (for example – in projects which necessarily involve an element of deception or if giving the title might skew the results of the research). It is not imperative that the titles are consistent, or detailed, but where possible then they should be.
4. This is the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study. For externally funded research the main investigator will normally be the grant-holder.
5. What question(s) are you trying to answer? Reviewers pay particular attention to the purpose of the research, asking "What question is the research asking is it worth asking and can it answer it?" Your answers should be succinct and realistic. Your methodology can be explained later in the form.

6. Educational Research and Evaluation: educational studies involving access to staff, students and documentation. The focus of the research is the education of the researcher themselves. (E.g. Masters Student)

7. For the distinction between clinical research, medical audit and health service evaluation see <http://ris.leeds.ac.uk/NHSethicalreview> and <http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research>.

8. Your research may pose a risk that may result in, or contribute to, a detrimental impact upon the physical environment above and beyond that which might be expected to occur during the course of day to day life. Examples of areas of risks can be found at <http://ris.leeds.ac.uk/EnvironmentallImpact>. You may like to structure your answer using the following sections:

- The potential type of impact, including the uniqueness and importance of the resources impacted.
- The magnitude of any potential damage.
- The spatial extent of any potential damage.
- The temporal impact of any potential damage, for example, the time scale that environments will take to return to normal, and the impact during that recovery.
- The recoverability of the environment, or the efforts that would be required to return the environment to normal.
- The likelihood of impacts happening, balanced against the magnitude of impact if they did.
- Prevention or recovery processes.
- Please outline any processes for mitigating against these risks, including any formal processes currently covering the risks. This section can also be used to outline any mechanisms for post-damage recovery, reclamation, or remuneration.
- Justification.

If risks cannot be mitigated in a full manner, or some risk or damage is essential to the project, please detail why this is, and how the project will contribute to the greater good. In general the committee recognises that significant large-scale benefits to the environment or lesser, but more locally important benefits, may justify limited environmental damage or risks. The applicant may also find it useful to discuss community and public engagement plans in this section.

9. The use of tissue is covered by the Human Tissue Act 2004, regardless of whether it has come from healthy volunteers or NHS patients. The definition of tissue in the Act is any human biological material that could contain a cell. This includes urine, bone, teeth, blood, faeces, nasal lavages, pus, skin, stomach contents, sputum or spit and tissue cells. If you are unsure as to the status of your material please see further advice from [governance-ethics@leeds.ac.uk](mailto:governance-ethics@leeds.ac.uk) in the first instance. Applications for collection of relevant material under the Act usually need to be approved by an NHS Research Ethics committee. See [www.hta.gov.uk](http://www.hta.gov.uk) and <http://ris.leeds.ac.uk/HTA> for further information on the Human Tissue Act, or contact [Debbie.gibson@leedsth.nhs.uk](mailto:Debbie.gibson@leedsth.nhs.uk).

For further information on NHS Research Ethics Review please visit <http://www.hra.nhs.uk/research-community/applying-for-approvals> or <http://ris.leeds.ac.uk/NHSethicalreview>.

10. These questions are designed to establish whether your project requires approval by an NHS Research Ethics Committee, in which case a different form must be completed, and you must go through a different process of ethical review. For help determining the type of ethical approval required you can use the HRA decision tool: <http://www.hra-decisiontools.org.uk/ethics>.

If your project includes any of the elements in this question then NHS Research Ethics Committee approval is required, regardless of whether you are based in the Faculty of Medicine & Health, or whether your project would not normally be considered "health research". It is advisable to liaise with

## Guidance for completion of the University Ethical Review Form

the local NHS Ethics Committee and Jean Uniacke/ Clare Skinner in the Faculty of Medicine and Health (for all Faculties) before making an application. Please email [governance-ethics@leeds.ac.uk](mailto:governance-ethics@leeds.ac.uk). For further information visit: <http://www.hra.nhs.uk/research-community/applying-for-approvals>. For an NHS application form visit: [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk).

11. Members of the public will likely be NHS patients. *However* please only select this option if you are identifying participants **THROUGH NHS means** (e.g. by recruitment from clinics or GP surgeries). The following are NOT to be included in this option:

- Recruitment of participants through voluntary sector organisations or patient support groups.
- Participants who have been stopped in the street to answer health related questions.
- Students recruited to answer health related questions.

If you require further guidance please contact [governance-ethics@leeds.ac.uk](mailto:governance-ethics@leeds.ac.uk) for clarification.

12. The research provisions of the Mental Capacity Act 2005 apply to the inclusion of both children and adults in research, and specifically to those people who would not be able to consent for themselves to participate in the research. **A DBS (formerly known as CRB) check will be needed for researchers working with children or vulnerable adults (see <http://www.homeoffice.gov.uk/agencies-public-bodies/dbs>).**

This option should be selected if it is possible that the research could *at any stage* include adults (aged 16 or over) who are unable to consent for themselves due to physical or mental incapacity (including temporary incapacity). You should still answer **yes** if participants will be able to give consent initially but you plan to undertake further research procedures on or in relation to such participants (including collection of new samples or data) following loss of capacity to consent during the study. If participants would be withdrawn from the study following loss of capacity, you may answer **no**.

If you will be including **children under the age of 16**, who would be considered able to consent for themselves according to the Gillick principles and they do not suffer from an impairing condition, they should be regarded as adults able to consent for themselves for the purposes of your application. Detailed guidance on ethical review of applications involving adults unable to consent for themselves is available on the NRES website.

13. Sometimes there can be confusion when University facilities are co-located within or next to NHS premises. NHS premises would typically be:

- An NHS Trust (in England or Wales)
- An NHS Health Board (in Scotland)
- A Health and Social Care Trust (in Northern Ireland)
- A GP practice
- A Strategic Health Authority in England (for public health, epidemiology or needs assessment studies)
- A prison establishment in England or Wales.

14. A prisoner or young offender is defined as any inmate of the prison systems of England and Wales, Scotland or Northern Ireland. It does not include patients detained under the Mental Health Act at special hospitals or other psychiatric secure units, or juvenile offenders detained in local authority secure accommodation or secure training centres. Health research involving prisoners or young offenders should relate directly to their health care and be of such a nature that it could only be conducted in this population. The Prison Health Research Network (PHRN) publishes guidance on

the various approvals and permissions required to conduct research involving prisoners in England and Wales, and may be able to assist with specific queries. Further information is at <http://www.ohrn.nhs.uk>.

15. A clinical trial is an investigation in human subjects which is intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products; identify any adverse reactions or study the absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/ or efficacy of those products. This definition includes pharmacokinetic studies. It is a **criminal offence** to conduct a clinical trial of an investigational medicinal product (CTIMP) anywhere in the UK without clinical trial authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA). This applies both to commercial and non-commercial research, and both to phase 1 drug development and later phase research. More detailed guidance is available at [http://www.mhra.gov.uk/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodeId=723](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=723). Section 1 of the guidance links to an algorithm to help you decide whether or not your research is a clinical trial of an investigational medicinal product (CTIMP). **If you remain unsure after checking the algorithm, please contact the University of Leeds/ Leeds Teaching Hospitals NHS Trust Quality Assurance Team on 0113 392 6473 ([governance-ethics@leeds.ac.uk](mailto:governance-ethics@leeds.ac.uk))**

16. Please answer **yes** if the research will include participants aged under 16, or use of their data. You should still answer **yes** if some or all of the participants will be able to consent for themselves under the Gillick principles. In the more detailed segments of the application for you should outline the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group. You will need to describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding. **A DBS (formerly known as CRB) check will be needed for researchers working with children or vulnerable adults (see <http://www.homeoffice.gov.uk/agencies-public-bodies/dbs>).**

17. Recruitment of staff and students is often a cost effective and relatively accessible source of research participants, especially in low risk studies. Staff, who are managed by or are students of an academic involved with the research, may feel an undue obligation to agree to participate in the research. Thus there may be coercion, even if this was unintended by the researcher. Care should therefore be taken to ensure that this does not happen and you should describe those steps here. The Committee will consider the risks of participation and the steps taken to ensure participants are not coerced, and may decide that it is entirely appropriate to include such participants in the study.

18. This should be a short summary of the proposed research (maximum 300 words) written in plain English. It should be easily understood by someone who is not experienced in the field you are researching, (E.g. a member of the public.) Where technical terms are used they should be explained. All acronyms should be described in full. The summary should briefly describe the background to the research, why it is important, the questions it will answer and potential benefits, the study design and what is involved for participants, who is funding the research and where it will be recruiting. All acronyms need to be explained. **If your answer is not comprehensible to a lay person your application will be returned to you.**

19. This should be a discussion of the main ethical issues arising in the research, how you have addressed them and who you have consulted in developing the proposal. For example, think about purpose and design, recruitment, inclusion/exclusion criteria, consent, risks, burdens and benefits, confidentiality, health and safety, environmental impact, fees and expenses payments, conflicts of interest, dissemination and exploitation of results. Explain the options you considered and the reasons for and against these, summarising why you finally settled on one. *The reasons are as important as*

*the final choice itself.* Indicate any important information not covered elsewhere in the application, and any specific issues on which you would welcome advice from the REC. If you would like assistance with this, please contact the Senior Research Ethics Administrator, Jennifer Blaikie, tel 0113 3434873, email [ResearchEthics@leeds.ac.uk](mailto:ResearchEthics@leeds.ac.uk).

## Section B

20. **(Only applicable for student studies).** If this is a student project, the student (or a nominated student in the case of a group student project) should be listed as the main contact person. However, an academic or other appropriate individual should be listed here as the Supervisor who takes responsibility for the conduct of the research. Details of additional supervisors may be listed in section B2.

21. Give names of any other key Co-Investigators or key members of the PI's research team. This should also include any international collaborators.

## Section C

22. What question(s) are you trying to answer? Reviewers pay particular attention to the purpose of research, asking "What question is the research asking; is it worth asking and can it answer it?" Your answers should be succinct, excluding methodology, and realistic. If your question / aims will not be answerable by the project you describe in the application then there may be an ethical issue in placing participants at risk, or burdening them needlessly.

23. You should describe here what participants will be expected to do when participating in the study. (E.g. tests, questionnaires). Include information on:

- How long any tests, visits, interviews will take
- Number of visits to the research centre, number of interviews, tests etc.

This information should also be contained in the participant information sheet, which should be given to participants before they enrol on the study. Template information sheets are available on the RIS website at <http://ris.leeds.ac.uk/InvolvingResearchParticipants>.

24. It is important that research conducted outside the UK complies with any requirements for ethics review or obtains necessary approvals in the country where the research is to be performed. Ethics review should also be conducted within the University of Leeds. The University Research Ethics Committee will need to be satisfied that procedures in the other country have been followed, and also that the usual ethics standards expected within the UK are met. However, if the recommendations or requirements of ethics review in the University and the local country are in conflict, then further consideration will be required. The opinion of the University of Leeds REC should not automatically take precedence. If you are not the Lead Institution for the research and approval has been sought overseas, then please contact your Research Ethics Committee (via [ResearchEthics@leeds.ac.uk](mailto:ResearchEthics@leeds.ac.uk)) to ascertain whether University of Leeds review is required.

25. For example, whether the research is being conducted within the University, in a research subject's home, on the street, in a shopping centre. Say whether research is being performed in Leeds, another town or city in the UK, another country etc.

26. Please ensure that you describe ALL aspects to be addressed in this question (identifying, approaching and recruiting participants).

(i) Identifying participants

## Guidance for completion of the University Ethical Review Form

- Will you need to access sources of identifiable personal information to identify potential participants?
- Will you use a “gatekeeper” to access this information? (i.e. someone outside the research team) If so, who would that person be?
- If any of the above is applicable, did the person originally consent for their personal information to be shared?

### (ii) Approaching participants

- How will potential participants be approached? E.g. in the street, in lectures, by letter or telephone?
- Who will make that initial approach?

### (iii) Recruiting participants

- Will you use emails or posters to recruit new participants?
- Has the appropriate permission been sought to send mass emails or to display posters?

Your ethics approval reference and date of approval must be included on any recruitment material.

Include copies of any emails/ posters/ other recruitment materials used to approach potential participants with your ethics application.

All advertising material used in recruitment should be submitted for review by the Ethics Committee. This includes posters, television and radio broadcasts and web pages. It is suggested that the tone of recruitment material is restrained and care should be taken not to overemphasise the benefits of participation. Recruitment materials should be in lay language.

27. Research should not be unnecessarily exclusive of groups of people. No-one should be unfairly excluded from research. Inclusion exposes participants to potential risk and burden, while exclusion may deny them benefit from research. Both inclusion and exclusion criteria require justification. You should state clearly any criteria for including and/or excluding potential participants based on the following:

- Age
- Disability (including learning disability, physical disability, sensory impairment and mental health problems)
- Gender (including gender identity)
- Race, ethnic origin (including Gypsies and Travellers) or nationality
- Religion or belief
- Sexual orientation (including lesbian, gay and bi-sexual people).

However, in some cases it will be necessary to deliberately exclude groups of people, if this is the case please highlight and justify this here.

28. The number of participants should be sufficient to achieve worthwhile results but should not be so high as to involve unnecessary recruitment and burdens for participants. This is especially pertinent in research which involves an element of risk. Describe here how many participants will be recruited, and whether this will be enough to answer the research question. If you have received formal statistical advice then please indicate so here, and describe that advice.

29. Some research may necessarily involve deception of participants (e.g. where knowledge of the purpose of the research may skew the results of the study, or research which involves integration into a group). Generally it is not desirable to deceive participants, but it is recognised that it is necessary in some projects. Please describe here the nature of that deception, justify why it is necessary and describe whether you will inform participants of the true nature of the research once completed. It may not be possible to inform participants after the research is finished, and this should be explained also.

30. For most types of research, it is an ethical requirement for participants able to consent for themselves. There are exceptions however. Examples might include:

- Data that has been completely and irrevocably anonymised and is no longer personal data within the meaning of the Data Protection Act.
- Personal medical data where approval has been given by the Confidentiality Advisory Group (<http://www.hra.nhs.uk/research-community/applying-for-approvals/confidentiality-advisory-group-cag>).
- Observational research where consent might not be able to be taken
- Use of information in the public domain.

If you propose *not* to seek consent, please explain why. There are some circumstances where consent cannot reasonably be obtained, either because it is not feasible to do so e.g. where there is population observation, or because altering subjects to the fact that they are being observed can alter their behaviour and hence affect the validity of the research. In some studies, there is partial disclosure and consent, with some of the aims of the research being concealed. Participant-observer research and other ethnographic research are legitimate research, but the REC will give particular attention to justifications given for not requesting consent or may require that disclosure about the research is given as soon after data collection is complete as is practicable.

For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. A capable person will:

- Understand the purpose and nature of the research, what the research involves, its benefits (or lack of benefits), risks and burdens.
- Understand the alternatives to taking part.
- Be able to retain the information long enough to make an effective decision.
- Be able to make a free choice.
- Be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity).

Where the research team will be recruiting participants whose capacity is likely to be borderline or to fluctuate, please say how capacity will be assessed and by whom, and what relevant expertise this person will have. Where adults unable to consent for themselves are to be included, separate information about recruitment should be provided.

Other key points about consent

- Informed consent should be obtained from the research participant(s) involved for audio/video recording.
- Exclusive reliance on handing out the participant information sheet should be avoided. Researchers should be able to explain the study clearly to potential participants.

- Consent is not something that only needs to be obtained once; it is an ongoing process covering the entire time that a person is participating in the research (including via continued retention of identifiable data or tissue). Thus consent can be withdrawn at any time without repercussion for the participant. If appropriate, participants should be reminded that they are part of a research study and of their right to withdraw.

Advice on writing the participant information sheet and a pro-forma can be found at <http://ris.leeds.ac.uk/InvolvingResearchParticipants>. Participant information sheets should be regarded as setting out the basic minimum information, which can be supplemented if required. Information should explain the study clearly, and the language used should be suitable for a lay person. All technical words must be explained. The tone of the information sheet should be invitational and not coercive. Consent must always be voluntary. Where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected. Particular consideration should be given to informed consent arrangements where participants are in a dependent relationship with the research team e.g. members of University staff or Students participating in research by their tutors. In such cases, participants may feel under obligation to participate. It is important that every effort is made to avoid coercion and ensure consent is voluntary. The consent to take part in a study should be recorded in the study records.

If you do propose not to obtain consent in writing, you should justify this. The REC usually requires that written consent be obtained for all but the most minor procedures. In studies involving postal questionnaires where the burdens are insignificant and sensitive topics are not involved, the REC will normally regard the return of the questionnaire as adequate evidence of consent. This is sometimes called "implicit consent". Where a participant is unable to sign or mark a document to indicate their consent, arrangements should be made for their consent to be witnessed and this should be documented. Refer to the verbal consent protocol which is available at <http://ris.leeds.ac.uk/InvolvingResearchParticipants>.

**Copies of any written consent form, written information and all other explanatory material should accompany this application.**

31. Potential participants need time to consider fully the implications of taking part in research. They should be able to ask questions and reflect. Participants should not be rushed into decisions. There are no fixed guidelines for the time to be allowed to participants. It has been common practice to suggest a minimum of 24 hours, but this is not an absolute rule. Each study should be considered on its own merits and for lower risk studies a shorter time period might be acceptable. If you feel that a shorter period is reasonable in the circumstances and taking into account the nature of the study, please justify this in your answer.

32. The inclusion or exclusion of potential participants who may have difficulties in adequately understanding written or verbal information in English raises ethical issues. If they are to be included, you should explain what measures will be taken to provide necessary translation of written information and interpretation. Any proposal to exclude such participants should be clearly justified in the application.

33. If interviews touch on sensitive areas, reviewers will consider the experience of interviewees and how they will handle these aspects, so please detail any experience you have here. The REC would expect the applicant to provide participants with access to an appropriately trained person (or, if appropriate, informed about how to access further informative and support) should they become upset, agitated, angry, etc during any interviews/ group discussions/ completion of questionnaires. Where the research might lead to unexpected disclosure of information by participants that could require notification or other follow-up action by the researcher (e.g. disclosure of illegal activity),

## Guidance for completion of the University Ethical Review Form

please describe how this would be handled. The participant information sheet should make it clear under what circumstances action may be taken by the researcher.

There are of course legal positions on disclosure of child abuse, serious and immediate threat of harm to another person, abuse of vulnerable people, money laundering, terrorism and related activities and, slightly bizarrely, some traffic offences. There are no laws compelling the pro-active disclosure of most other potentially criminal activity. That said, it may well be an offence to conceal or to lie about potential criminal activity if directly asked by the authorities (obstructing the police in an enquiry, for example) - but this is different from pro-active disclosure. The question then becomes a moral one, which the applicant will have to balance against any risk to the research design that might be raised if confidentiality were not assured. . There should be something in the consent form about reporting of potential criminal activity, or, if it arises during the course of research, the researcher should, ideally, seek consent for disclosure or, at least, inform the participant in advance of an intention to disclose.

34. Payment of participants should be ethically justified. The FREC will wish to be reassured that research participants are not being paid for taking risks or that payments are set at a level which would unduly influence participants. Incentives for participation in low risk studies may be ethically justifiable. You should here describe the level of payment so that the Ethics committee can consider whether the participant might be encouraged to take undue risks for the incentive. Information on any payments or benefits must be included in the participant information sheet. Consideration should be given to any expense involved in returning postal questionnaires. If it is not possible to reimburse such expenses this should be explained before the research participant is recruited. A clear statement should be included in the participant information sheet setting out the position on reimbursement of any expense incurred.

35. Please outline any potential risks involved for participants by taking part in the study. This might include physical, emotional and financial risks. You should also describe potential benefits in a similar way. Include any potential for distress, discomfort and/or inconvenience which might be experienced by a research participant, with an explanation of why it is necessary and what has been done to minimise the effects. Most research has potential to cause some distress even if this is felt to be minimal, e.g. breach of confidentiality, upsetting participants in interviews. Where the research only involves the use of data, consideration should still be given to the risks for patients associated with any breach of confidence or failure to maintain data security. The joint BBSRC, MRC and Wellcome Trust policy statement on managing risks of research misuse requires researchers to consider short and medium-term risks of misuse associated with their research: <http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/wtx026594.htm>. Potential risks and burdens should be described in the participant information sheet in such a way that potential participants can clearly understand what is involved if they consent to take part. It may be that no risks or benefits are anticipated, in which case please indicate so. Has a risk assessment been carried out?

36. For example will the project involve researchers working alone in people's homes, and if so does your Department have a lone worker policy? You should here consider your own safety in carrying out the research.

37. Please describe where all personal data of participants will be stored. Explain if filing cabinets, cupboards and/ or rooms will be locked and who has access. Give details of security arrangements for personal data held on computer, especially where laptop computers are used. Explain the arrangements for ensuring confidentiality of personal data during transfer of data. It's important to include details of any plans to export data outside the UK.

Activity	Guidance
Electronic transfer of data by magnetic or optical media,	Where personal data is transferred electronically, data should be encrypted during transfer.

Guidance for completion of the University Ethical Review Form

email or computer networks	
Sharing of data with other organizations	Where data has been effectively pseudonymised it should only be shared on the basis that the recipient cannot disclose pseudonymised data to third parties and is not permitted to link the data with other data which might render the participants more identifiable.
Export of data outside the EEA	In general, personal data should not be transferred outside of the European Economic Area (EEA). This is because other countries do not have the same legal framework or protections for patient data. Even where this is the case, it is difficult to manage and monitor the use of data to ensure it is safeguarded appropriately and is not misused.
Use of personal addresses, postcodes, faxes, emails or telephone numbers	It should be remembered that such personal contact details can be sensitive information, either because individuals are concerned about identity theft or because of domestic violence etc.
Publication of direct quotations from respondents	Should be anonymised. Publication of data should not allow identification of participants. In general, publication of case histories should be effectively anonymised. Where identification is possible individuals it is essential that this is only undertaken with consent.
Storage of personal data on manual files (including X-rays)	Paper and other manual files should be appropriately filed and stored securely.
Storage on home or other personal computers	Under no circumstances should participants' personal data be stored on a home or other personal computer. You should upload research data (identifiable or anonymised) to the University N: or M: drive, via remote access where necessary.
Storage on university computers	Appropriate access controls need to be in place to ensure that access to confidential research information is restricted to those who need access.
Storage on laptop computers	Use of laptops and other portable devices is to be avoided. Where it is necessary for them to be used, data must be encrypted and the data uploaded onto a secure server or desktop as soon as possible and the data removed from the portable device as soon as possible and using appropriate data destruction software.

Monitors and auditors from funding bodies, University auditors (internal and external), and regulatory inspectors may require access to participant notes to verify or cross check data. Review bodies are likely to accept protocols that incorporate such arrangements provided that the following guidelines are observed.

Further information on data protection and storage is available on the RIS website at <http://ris.leeds.ac.uk/ResearchDataManagement>.

38. For externally funded research refer to your funder's guidelines. Where valid consent is in place, identifiable data may be retained, but consideration should be given to anonymisation. Explain how and when data will be destroyed. It would be reasonable to retain data for at least 2 years after publication or three years after the end of data collection, whichever is the longer. This time period would allow for investigation of any allegation of academic fraud or for any negligence or compensation claims to be made by research participants. The participant information sheet should specify the uses to which the material might be put, how the material will be stored and how and when it will be destroyed. It should be noted that videos should not be used for commercial purposes.

## Guidance for completion of the University Ethical Review Form

Consideration should be given to whether it is necessary to retain audio recordings as well as transcripts of qualitative interviews or focus groups.

Guidance on managing, storing and sharing research data is also available at <http://ris.leeds.ac.uk/ResearchDataManagement>. For advice on publishing and disseminating results see <http://ris.leeds.ac.uk/Publication> and <http://ris.leeds.ac.uk/ResearchDissemination>.

39. This question relates to “in pocket” financial payments or additional benefits made directly to researchers, over and above the costs of conducting the research. Such payments could include, for example, contributions to a library, additional equipment not actually required for the research, social events etc. Personal payments or benefits to researchers should not be set at a level to cause undue influence. You should record the fact that researchers are receiving personal payments or benefits in the participant information sheet.

40. Information should be given about any potential conflict of interest for the PI or any other investigator/ collaborator in undertaking the proposed research. An example might be the research funder having control over publication of the results of the research. Or a conflict of roles held by the Investigator.