Research tissue banks

Question–specific application form

The following document collates all guidance for the questions in Research tissue banks forms.

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**General guidance on REC application**

- NRES recommends that applications for ethical review of RTBs are booked for review via the Central Allocation System (CAS). (For guidance on booking, see applying for ethical review).
- Applications will normally be allocated by CAS to one of a panel of "flagged" RECs, which have been assigned to review RTB applications.
- Applicants may opt to apply to another committee within their geographical domain if they prefer, but the committee may not be so familiar with policy and procedure for review of RTB applications.
- Under the NRES SOPs an ethical opinion for a RTB will be valid for the whole of the UK.
- Site-specific assessment is not required for ethical review of RTBs.

**Submission date**

- Insert the date on which you intend to submit your application. This will be agreed with the Central Allocation System or the REC when you book the application.

**Question 1 – Title of the tissue bank**

- This will usually be the same title used in the licensing application to the Human Tissue Authority (where applicable).
- In some cases, the Licence may cover a group of tissue banks under the control of the same establishment with a single Designated Individual. If so, it is a matter of discretion for the applicant whether to make a single application for ethical review, embracing all the tissue banks, or to apply for review of each individually. Where a group application is made, the REC will expect to receive details of each bank (either in the application form or in enclosures), indicating the different types of samples, research purposes, etc and to be aware of any material differences in policy for the management of the banks.
Question 2 – Name of the establishment

- This should be the legal entity with custodianship of the tissue samples, e.g. the NHS Trust, commercial company or voluntary organisation. The name should be the same as that cited in the licensing application (where applicable).

- In some cases, the applicant organisation may subcontract storage of samples to another organisation, which will be the licence holder. Where this applies, name the Licence Holder at A2. It would be helpful to give further details of the arrangements in a covering letter.

Question 3 – Contact point

- Give the name of the person responsible for the application, and to whom all correspondence from the REC should be addressed. It need not be the same as the Designated Individual for HTA licensing purposes.

Question 4 – Establishment responsible for tissue storage

- The details given in question 2 will be automatically entered here, but if the establishment responsible for storage of the tissue is different from the establishment responsible for management of the tissue bank, please amend appropriately.

Question 5 – Has a Licence been applied for?

- Under the Human Tissue Act 2004, tissue banks in England, Wales and Northern Ireland storing relevant material for use in as yet unspecified research must obtain a Licence from the Human Tissue Authority (HTA).

- Applicants for ethical review of RTBs will be expected to provide the REC with a copy of the Licence as a condition of ethical approval except where:
  1. The RTB is established in Scotland, or
  2. All biological material to be stored for use in research is outside the definition of "relevant material" under the Human Tissue Act 2004, i.e. it does not consist of or contain human cells.

- The HTA has published guidance on what constitutes "relevant material" at http://www.hta.gov.uk/.../definition_of_relevant_material.cfm.

- If a Licence is not required, please explain why not in answer to this question.

- Detailed guidance on licensing is available from the HTA at http://www.hta.gov.uk/licensing.cfm.
Question 6 – Name of the Designated Individual

- This should be completed for any tissue bank that requires a Licence from the Human Tissue Authority (HTA). If all the biological material to be stored is outside the definition of “relevant material” under the Human Tissue Act 2004, i.e. it does not consist of or contain human cells, and is not licensable, please say "not applicable". The HTA is preparing detailed guidance on what constitutes relevant material.

Question 7 – Previous ethical review

- If the tissue bank has been the subject of previous ethical review, please enclose a copy of the opinion letter from the REC together with any other relevant correspondence.

Question 8 – Types of tissue samples to be collected/stored from the living

- Please describe the following:

**Samples**

- Body sites involved – organ or tissue specific, or wide-ranging (with examples of the range).
- Formats stored or supplied – fresh, processed or preserved. Please indicate if the samples are perishable in nature, their likely deterioration time and the purposes for which they might be useful.
- Estimated number of samples to be stored, accrued annually, and used or distributed or destroyed annually.

**Data**

- Describe the types of data collected and stored for linking with the tissue samples – demographic, medical, etc with examples.
- Indicate whether data was derived from direct contact, questioning, interviewing, questionnaires or other contact with donors.
- Indicate any other sources, e.g. health records, other records and means of capture.
- Describe how the data will be stored and who will have access to it.
Question 9 – Types of tissue samples to be collected from the deceased

- This question refers to the collection and storage of samples from persons who were deceased at the time of collection. Samples taken from the living should continue to be regarded as tissue from the living even where the donor may since have died.

**Samples**

- Body sites involved – organ or tissue specific, or wide-ranging (with examples of the range).

- Formats stored or supplied – fresh, processed or preserved. Please indicate if the samples are perishable in nature, their likely deterioration time and the purposes for which they might be useful.

- Estimated number of samples to be stored, accrued annually, and used or distributed or destroyed annually.

**Data**

- Describe the types of data collected and stored for linking with the tissue samples – demographic, medical, etc with examples.

- Indicate whether data was derived from direct contact, questioning, interviewing, questionnaires or other contact with donors before they died or with relatives, etc after their death.

- Indicate any other sources, e.g. health records, other records and means of capture.

- Describe how the data will be stored and who will have access to it.

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**Question 10–1 – Linked data**

- Describe the policy for collection of data and linking of samples or data to donors. It is considered good practice to retain links where possible. This potentially allows for further data to be accrued, further consent sought from donors where appropriate and feedback given on any research findings of clinical significance.

- Where samples or data are linked, say who will have access to the codes and briefly describe the arrangements for maintaining confidentiality.

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**Question 10–2 – Separation of identifiers from clinical data**

- This question applies only to applications to the National Information Governance Board for Health and Social Care to process identifiable patient data without consent.
Question 11 – Use of the samples or data in research

- This is a key question on the form. Samples and data are donated on the basis that they will be used for the benefit of other patients and for society in general. The REC will wish to know how the bank plans to maximise these benefits in order to fulfil the purposes of the donation.

- Say how the existence of the bank will be publicised.

- Outline in broad terms who may use the bank and for what purposes. Indicate and justify any restrictions on who will be regarded as potential "legitimate users" of the samples or on the uses to which samples may be put. Indicate any differences in the access policy between researchers within the establishment responsible for the bank or outside it.

- Indicate if any uses of a particularly sensitive nature are possible using the samples – cellular or therapeutic cloning, stem cells, reproductive research (including contraception), genetic analysis or use in animal models.

- Describe how applications for access to samples will be made and assessed.

- Describe policies for financial dealings related to the supply of samples and/or data.

- Describe policies related to return/publication or other methods of sharing the knowledge or data gained from the use of the samples/data in research.

- Mention any policies for accountability of the bank to donors.

- It is good practice to produce a self-contained "protocol" which brings together in one document the key principles, policies and procedures for management of the tissue bank. A copy of the protocol should be enclosed with the application.

Question 12–1 – Public and patient involvement

- Public involvement includes consultation with or working alongside members of the public, patients, service users or carers in the choice of research topic, and the design, planning, conduct and dissemination of research. The UK health departments are committed to active patient and public involvement in all stages of research. For more information see INVOLVE (http://www.invo.org.uk/) or, in Wales, see Involving People (http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=14773).

- This question does not refer to the involvement of patients, relatives or members of the as donors of tissue.
Question 12–2 – Consulting patients and public on processing data without consent

- This question applies only to applications to the National Information Governance Board for Health and Social Care to process identifiable patient data without consent.

- As NIGB approval involves the setting aside of the common law duty of confidentiality, it is important that applicants make efforts to test with patients the acceptability of the use of confidential patient information for this particular study, both in terms of the purpose, the degree of identifiability and sensitivity of the data required.

- This does not replace patient consent but if done appropriately can provide useful insights for the research and gives an indication of the general acceptability of the use of the data for this purpose. Please see the NIGB advice on user involvement for further details http://www.advisorybodies.doh.gov.uk/PIAG/userinvolvementguide.pdf.

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Question 13 – Generic ethical approval for research conducted within the establishment

- Questions 13–21 apply to uses of the samples by researchers within the establishment holding the storage Licence from the Human Tissue Authority. The assumption is that the samples will continue to be stored, during the research, on the premises specified in the Licence and under the conditions agreed with the HTA. This might apply where, for example, a Licence is held by an academic institute or medical school, and research projects are undertaken by staff or students.

- The applicant may seek generic ethical review for programmes of research to be conducted within the establishment. This would provide ethical approval for individual researchers who undertake future projects within the conditions agreed by the REC.

- Where the applicant opts not to seek generic ethical review, questions 14–21 will be disabled. Individual researchers requiring ethical approval should then apply separately by submitting the normal, project–based version of the REC application form.

- Some tissue banks may not be directly involved in any research programmes, but act as a distributor of samples to external researchers. If so, answer No to this question and move to questions 22–32, which deal with external research.

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Question 14 – Types of research

- Indicate whether the research will be related to a specific disease or group of diseases, or could range more widely across biomedicine generally.

- Will the research be of a basic, translational nature (experimental medicine) or will it be clinical research? Please provide examples.

- Indicate if any of the research is related to the testing or safety of cosmetics or other consumer products (i.e. not related to healthcare).
Question 15 – Types of test or analysis

- In broad terms, describe the ranges of methodologies likely to be applied to the study of the samples.
- Indicate the nature of the research data that will be generated by these methods.
- Highlight the types of analysis you anticipate may raise ethical questions and how the bank deals with such issues.

Question 16 – Analysis or use of genetic material

- Specifically indicate if the analyses may produce information that involves genetic sequence data, single nucleotide polymorphism data, genetic “finger print” data, ploidy data or cytogenetic data, including the detection of mutations or genetic variants.

Question 17 – Findings of clinical significance

- Indicate whether the analyses described in question 16 could have prognostic, predictive or other significance for individual donors/subjects or their relatives.
- If so, please describe the nature of the clinical significance for the individual subjects that might be encountered.

Question 18 – Arrangements to notify individuals of clinically significant findings

- If No, indicate clearly the reasons why data will not be notified to the subjects or their healthcare professionals. For example, the reasons may be based in ethics, practicality or science. Explain how the decision not to provide feedback to subjects is consistent with the terms of their consent.
- If Yes, describe how the feedback will be provided – will it be directly to the subjects or via a healthcare professional? In either case, please explain how the implications of the feedback will be explained to the subjects and how they will be supported or counselled in light of the feedback. If some subjects have indicated that they do not wish to receive feedback of clinical significance, how will the bank deal with this in the light of clinically significant information resulting from the research?
Question 19 – Animal research

- Describe the nature of the animal research, the purpose of using an animal model and the means by which samples will be used.

- Describe if and how the potential use of samples in animal research will be (or has been) explained to the donors prior to consent.

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Question 20 – Research into termination of pregnancy or reproductive cloning

- The REC would wish to know about any potential research into termination of pregnancy or contraception. Describe the potential use of the samples and the potential outcome of such research.

- Please also refer to any potential research involving human embryos or stem cells. This includes research related to therapeutic cloning; or research into the possible scientific development of reproductive cloning (although it would be unlawful to perform such cloning at present).

- Describe if and how the potential use of samples in these types of research will be (or has been) explained to the subjects prior to consent.

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Question 21 – Applications from researchers for tissue and data

- Describe the arrangements made by the bank to receive a scientific critique, either internally or externally, and justify the approach used.

- Describe the measures taken by the bank to ensure the provision of adequate resources and funding.

- Describe how the bank ensures that the proposed research is within the terms of the donor consent.

- Where a committee is in place to review research proposals, outline its composition and procedure. A copy of the membership and terms of reference should be enclosed with the application. Indicate how any potential conflicts of interest for committee members would be addressed.

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Question 22 – Generic ethical approval for research conducted outside the establishment

- Questions 22–32 apply to the supply of samples to external researchers or research organisations. The assumption is that the samples will no longer be stored, during the research, under the terms of the establishment's Licence from the Human Tissue Authority.

- The applicant may seek generic ethical review on behalf of researchers to which it will be supplying samples. This would provide ethical approval for individual researchers who undertake future projects within the conditions agreed by the REC.
• Where the applicant opts not to seek generic ethical review, questions 23–32 will be disabled. External researchers requiring ethical approval should then apply separately by submitting the normal, project–based version of the REC application form.

• Some tissue banks may not be involved in supplying samples outside the establishment. If so, answer No to this question. Generic ethical review for research programmes conducted within the establishment is covered in questions 13–21.

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Question 23 – Types of research

• Indicate whether the research will be related to a specific disease or group of diseases, or could range more widely across biomedicine generally.

• Will the research be of a basic, translational nature (experimental medicine) or will it be clinical research? Please provide examples.

• Indicate if any of the research is related to the testing or safety of cosmetics or other consumer products.

• If you have specific plans for collaboration, please provide details including the name of the collaborating research unit or organisation and the nature of the organisation (e.g. academic research department, pharmaceutical or biotechnology company).

• It is recognised that the bank may not know with any certainty at this stage the names of future research organisations that may use the samples and data. If so, please outline the types of research organisations expected to use the bank.

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Question 24 – Restrictions on supply to types of research or research organisation

• Where restrictions apply, please outline the terms of the policy and justify it.

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Question 25 – Animal research

• Describe the nature of the animal research, the purpose of using an animal model and the means by which samples will be used.

• Describe if and how the potential use of samples in animal research will be (or has been) explained to the donors prior to consent.
Question 26 – Research into termination of pregnancy or reproductive cloning

- The REC would wish to know about any potential research into termination of pregnancy or contraception. Describe the potential use of the samples and the potential outcome of such research.

- Please also refer to any potential research involving human embryos or stem cells. This includes research related to therapeutic cloning; or research into the possible scientific development of reproductive cloning (although it would be unlawful to perform such cloning at present).

- Describe if and how the potential use of samples in these types of research will be (or has been) explained to the subjects prior to consent.

Question 27 – Applications from researchers for tissue and data

- Describe the arrangements made by the bank to receive a scientific critique, either internally or externally, and justify the approach used.

- Describe the measures taken by the bank to assess the capability of the research organisation to conduct the project, including the provision of adequate resources and funding.

- Describe how the bank ensures that the proposed research is within the terms of the donor consent.

- Where a committee is in place to review research proposals, outline its composition and procedure. A copy of the membership and terms of reference should be enclosed with the application. Indicate how any potential conflicts of interest for committee members would be addressed.

Question 28 – Anonymisation of tissue or data

- Tissue or data will normally not be identifiable where obvious identifiers (e.g. name, address, date of birth) are removed at the point of release. However, consideration should be given to whether donors could be identifiable if viewed in conjunction with other publicly available information. This will depend on the information in the dataset and its rarity. For example, incidence of a rare disease in a woman aged 85 in a known postcode region might be identifiable to anyone with knowledge of the community or access to census data.

Question 29 – Supply of tissue or data outside the UK

- If Yes, indicate the likely geographical locations of the research organisations and in particular whether or not they will be within the European Economic Area.

- Indicate how the bank proposes to ensure that the research to be conducted will be considered legal and ethical in the jurisdiction to which the samples will be exported.
• Say if and how the plans to export samples will be (or has been) explained to the subjects prior to consent.

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Question 30 – Policy for feedback of research data

• Outline the policy of the bank for the return of research data by researchers following the completion of final analysis, how the policy is operated and if compliance with the policy is enforced.

• Indicate if the research data is returned as "raw data" or in synoptic form.

• Describe how the policy enhances the utility of the stored tissue or data within the bank.

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Question 31 – Arrangements to notify individuals of clinically significant findings

• If No, indicate clearly the reasons why data will not be notified to the subjects or their healthcare professionals. For example, the reasons may be based in ethics, practicality or science. Explain how the decision not to provide feedback to subjects is consistent with the donor consent.

• If Yes, describe how the feedback will be provided – will it be directly to the subject or via a healthcare professional? In either case, please explain how the implications of the feedback will be explained to the subjects and how they will be supported or counselled in light of the feedback. If some subjects have indicated that they do not wish to receive feedback of clinical significance, how will the bank deal with this in the light of clinically significant information resulting from the research?

• Explain the mechanisms to ensure that any clinical feedback is linked to the right donor. It is good practice for samples to be linked to more than one identifier (e.g. bank accession number, date of birth, pathology number) to ensure correct identification by the bank.

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Question 32 – Return or disposal of samples

• If samples are not to be returned, justify this policy.

• Explain the conditions made by the bank for the restriction of unauthorised further uses by the researcher or research organisation beyond the proposed study.

• Explain the nature of any disposal required or conducted by the bank.

• If samples are to be returned, describe how sample quality is to be assured.
Questions 33–34 – Existing collections

• It is always best practice where possible to have consent for the use of tissue samples in research. The REC would find it helpful to know whether or not consent has been given previously and for what purposes. Say whether the consent was project-specific or "broad" consent for storage and use in future research.

• It is recognised that it may not be feasible to seek further consent in the case of established collections, which were not obtained for the primary purpose of research. It may not be possible to identify or re-contact donors. This could also cause distress in some cases, for example if it reminded patients or their relatives of a serious illness or injury.

• In some cases it may be advisable to re-contact donors, in particular if identifiable samples are to be used and the results could have clinical significance for the donors or their relatives.

• In addition to the interests of donors, ethical review will take into account the potential benefits to future patients and society of allowing such material to be used in research. The Human Tissue Authority’s Code of Practice of Consent states that "some of these collections may be irreplaceable and of national and international importance…. the fact that there is no evidence of consent to their storage and use should not be a reason for destroying existing collections”.

• The REC will weigh these issues in a proportionate way having regard to the particular circumstances of each collection.

• Under the Human Tissue Act 2004, where tissue was collected and stored prior to 1 September 2006 there is no legal requirement for consent to store or use the samples in research. These samples are referred to in the Act as "existing holdings". (A Licence to store existing holdings for use in research is still needed.)

• Although there is no legal requirement to have consent in place to use existing holdings in research, the Code of Practice on Consent states that “this does not mean that all such human tissue can be used freely and without regard to issues of consent or other ethical considerations” (paragraph 114). The Code gives detailed guidance, to which both researchers and RECs should have regard. It is available at http://www.hta.gov.uk.

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Question 35 – Collections from the deceased

Requirements for appropriate consent

• Under the Human Tissue Act 2004, "appropriate consent“ is required to store or use tissue obtained from the deceased after 1 September 2006, unless the person died more than 100 years ago.

• In the case of a deceased adult, appropriate consent means:

  (i)  The consent of the deceased person given before death.

  (ii) If there is no prior consent by the deceased person, the consent of a nominated representative.
(iii) If no representative was appointed by the deceased person, a person in a qualifying relationship (see below).

- In the case of a deceased child, appropriate consent means:
  
  (i) A person who had parental responsibility immediately before the child's death.
  
  (ii) If no person had parental responsibility, another person in a qualifying relationship.

**Qualifying relationship**

- Persons in a *qualifying relationship* are ranked in the following order:
  
  (a) Spouse or partner (including civil partners)
  
  (b) Parent or child
  
  (c) Brother or sister
  
  (d) Grandparent or grandchild
  
  (e) Child of a brother or sister
  
  (f) Stepfather or stepmother
  
  (g) Half brother or half sister
  
  (h) Friend of long standing.

- Where there is more than one person in the same rank in the hierarchy, the consent of any one of them will constitute appropriate consent.

- In the case of consent to analyse DNA or use the results of the analysis for research purposes, the consent of any person in the list above is enough – the list is unranked in this case.

**Seeking consent**

- Detailed guidance on consent to store and use tissue from the deceased is given in the Human Tissue Authority Code of Practice on Consent (available at [http://www.hta.gov.uk](http://www.hta.gov.uk)).

- A copy of the information sheet and consent form to be used to seek appropriate consent should be enclosed with the application.

**Licensing**

- A licence is required from the HTA to remove relevant material from the body of a deceased person for research purposes. Advice about licensing issues should be sought from the HTA where necessary.

**Scotland**

- Under the Human Tissue (Scotland) Act 2006, which was implemented on 1 September 2006, authorisation is required to use tissue from a deceased person for research purposes. Detailed guidance on the Act has been issued by the Scottish Executive in HDL(2006)46, which is available on

- Under Section 3 of the Act, part of the body of a deceased person may be removed from the body and used for certain purposes (including research) where the removal and use for this purpose is "authorised". Sections 6–10 of the Act make detailed provisions for such authorisation:
  1. Section 6 provides for authorisation by an adult of the removal and use of part of the adult’s own body after death.
  2. Section 7 provides for authorisation by the nearest relative of a deceased adult.
  3. Section 8 provides for authorisation by a child aged 12 or over of the removal and use of part of the child’s body after death.
  4. Section 9 provides for authorisation by a person with parental rights and responsibilities in respect of a child who has died aged 12 or over.
  5. Section 10 provides for authorisation by a person with parental rights and responsibilities in respect of a child who has died under the age of 12.

- The above provisions do not apply in relation to tissue samples and organs removed during post-mortem examinations. Nor do they apply to the body of a deceased person who died before 1 September 2006 and at least 100 years have elapsed since their death.

- Under Section 38 of the Act, a tissue sample removed from the body of a deceased person (or from an organ removed from the body) during a post-mortem examination and no longer required by the Procurator Fiscal becomes part of the medical records of the deceased persons. Section 39 allows such samples to be used for certain purposes (including research) where use for this purpose is authorised. Sections 42–46 contain provisions for authorisation similar to those in Sections 6–10.

- Under Section 40 of the Act, an organ removed from the body of a deceased person during a post-mortem examination and no longer required by the Procurator Fiscal may be retained and used for certain purposes (including research) provided that:
  1. The subsequent use of the organ for this purpose is authorised in accordance with Sections 42–46, and
  2. The research is approved in writing by a research ethics committee.

- Under Scottish law a child is defined as a person aged under 16.

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**Question A36–1 – Identifying potential donors**

- The arrangements for identification of donors should be clearly described here. Details of NHS tissue collection centres should be given in Part C of IRAS.

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Questions A36–2 and A36–3 – Screening of identifiable personal information

- Identifiable personal information is information that relates to an individual, which enables them to be uniquely identified from that information on its own or from that and/or other information available to that organisation.

- Only methods for identifying and contacting potential donors that have been approved by the main REC may be used.

- Please give details of the sources of identifiable personal information that will be used to identify potential donors, who will access that information, and the extent of identifiable patient information that will be accessed. For example, will searches be run on electronic records for specific diagnostic fields or will full medical records be accessed to search for a variety of eligibility criteria?

- Normally only a member of the patient's existing clinical care team should have access to patient records without explicit consent in order to identify potential donors, check whether they meet the inclusion criteria or make the initial approach to patients. The "direct healthcare team" are clinicians directly responsible for providing routine care and treatment to individual patients together with their administrative support staff. Normally such clinical staff will have direct contact with the patients. However, laboratory and other support staff may also directly support the care provided to patients and they would also be included within the boundaries of the healthcare care team. Social Workers are not usually part of the healthcare team and disclosures of confidential information to social services staff should be undertaken with explicit patient consent, at least initially, in order to provide a basis for further disclosures based on implied consent.

- If the research proposes to use someone outside the clinical team to identify suitable donors using identifiable personal information, or as first contact with the participant, please seek advice from the National Information Governance Board for Health and Social Care (NIGB) (see http://www.nigb.nhs.uk) as you may need to get approval to access the information. The necessity for this use of identifiable information should be justified. Give details of the arrangements that will be put in place to inform patients and service users of the potential use of their records for this purpose and any safeguards to restrict or prevent access in accordance with the wishes of patients or service users. Describe how the extent of identifiable patient information that will be accessed will be limited to the minimum necessary for the purpose. Please also provide information about the arrangements that will place a duty of confidentiality on those accessing identifiable patient information.

- Where patient or disease registers are used to identify potential participants give brief details of the consent and confidentiality arrangements of the register.

Questions 37–38 – Approaching donors

- The REC will wish to know if the collection of tissue or data will involve additional procedures beyond routine clinical care. For example, will an additional visit or venepuncture be required? Will further data be sought through a questionnaire or interview? Will these procedures involve any additional risk or burden for participants? If so, these need to be weighed against the potential benefits and should be described in the information sheet.
Consent requirements

- Under the common law, consent is always required to remove tissue from the living.

- Where tissue is removed primarily for research purposes, consent to store and use the tissue for research is always required. This applies also to the removal of extra tissue in excess of that required for diagnostic or therapeutic purposes, i.e. it is not a by-product of normal clinical care.

- Where tissue is removed with consent for diagnostic or therapeutic purposes (e.g. for a blood test or biopsy, or in the course of surgery) and any material is left over from these procedures, section 1(8) and 1(9) of the Human Tissue Act allow this material to be stored and used for research without consent for research provided that:
  1. The research is ethically approved by a research ethics authority (i.e. a REC), and
  2. The research is to be carried out in circumstances such that the researcher is not in possession, and not likely to come into possession, of information from which the donor can be identified.

- If consent is not to be sought for research, this should be ethically justified. Where no consent for research exists, the bank must ensure that samples are effectively anonymised before being released to researchers so that donors cannot be identified.

- However, it is best practice to seek consent prospectively for use in research where possible. Consent for use in research may be added to the established consent procedure for routine diagnosis or surgical treatment. Where samples are being collected both for a specific research project and for future storage and use in research, consent for both purposes may be sought at the same time. It is good practice for participants to receive a separate information sheet describing the arrangements for longer term storage and use of samples following the end of the initial project.

Arrangements for seeking consent

- For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. A capable person will:
  1. Understand the purpose of tissue donation
  2. Understand what is involved in tissue donation and any risks and burdens.
  3. Be able to retain the information long enough to make an effective decision.
  4. Be able to make a free choice.
  5. 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).

- Say who will undertake the consent process. Where consent will be sought in a number of centres, indicate the type of health care professional who will be involved. RECs will seek reassurance that collaborators understand the ethical principles underpinning informed consent and are able to assess
capacity.

- Where the tissue bank 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 knowledge and/or expertise this person will have. Where adults unable to consent for themselves are to be included, separate information about recruitment should be provided in Part B Section 6 – detailed guidance is available in this section.

Information sheets

- Advice on writing information sheets and a pro–forma can be found on the NRES web site at http://www.nres.npsa.nhs.uk/applicants/guidance/. Reviewers will generally expect applicants to follow the NRES guidelines. They should be regarded as setting out the basic minimum information, which can be supplemented if required.

- 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.

- A copy of the information sheet and consent form should be enclosed with the application. The documentation should be standardised as far as possible across the collaborating centres.

- If recruiting healthy volunteers, a copy of any advertising material should also be enclosed.

Broad consent

- For a tissue bank to function effectively, it is accepted as good practice to seek "broad consent" to store and use tissue/data prospectively in a number of future projects, potentially in a range of research fields. The principle of broad consent has been endorsed in Parliamentary debates during the passage of the Human Tissue Act 2004 and in the HTA Code of Practice on Consent. It may not be possible to give donors specific information about the projects that will be carried out, but information sheets should give an indication of the types of research that might be conducted and the potential benefits.

- Donors should be given specific information about the following potential uses of samples or data:
  1. Export for use in research outside the UK
  2. Animal research
  3. Research involving human embryos and stem cells
  4. Research into termination of pregnancy or contraception
  5. Research involving genetic analysis
  6. Commercial research
  7. Commercial distribution of samples, i.e. any plans by the bank to charge in excess of cost recovery for release of samples to researchers.

- The informed consent process should also deal with:
1. Confidentiality of personal data

2. Potential withdrawal of consent (see question 44)

3. The rights of donors in the event of financial gain from the results of research, and the "gifting" of samples.

Question 40 – Justification for not seeking consent to process identifiable data

- This question applies only to applications to the National Information Governance Board for Health and Social Care (NIGB) to process identifiable patient data without consent.

- Explain why it is not practicable for either your organisation or the current holder(s) of the information you require to obtain consent from patients to use their information. Robust arguments are sought here. For example, the data may be very historical and people would be difficult to trace and/or deceased.

- Often it is argued that 100% coverage of patients is needed and therefore that consent is inappropriate. While NIGB understands that this is desirable, it is often neither possible nor necessary to have 100% coverage to produce valid results. If it is required to support a particular research programme, you should provide a detailed explanation of why and what the consequences of lesser coverage might be, giving evidence to support any assertions.

- As a general principle, the process of seeking consent should be undertaken by the original holder of the data. NIGB occasionally gives approval for a research body to act as data processor for the Trust(s) responsible for the data and to write to patients direct in order to seek consent but the letter should appear to come from the relevant Trust/GP practice.

Question 41 – Recording consent in writing

- Where consent is to be obtained from donors, it should normally be recorded in writing. Consent from patients should be recorded in their medical records as well as in the records held by the bank.

- Please enclose a copy of the proposed consent form when submitting your application. Advice on the consent form and a pro-forma can be found on the NRES web site at http://www.nres.npsa.nhs.uk.

- Where a donor 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.

Question 42–1 – Research participants who may have difficulties in adequate understanding of English

- 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. In a multi-site study, the CI is responsible for ensuring that Principal Investigators and collaborators will make the necessary arrangements at each research site. There are strong arguments in terms of cost and consistency for translation of the documents to be commissioned centrally and then made available to each site as necessary.

• Any proposal to exclude such participants should be clearly justified in the application

• The acceptability of the plan to implement these arrangements in a particular locality falls within the scope of site-specific assessment by the NHS R&D office or the local REC for the site

• If you have concerns about how these issues relate to your research you should seek specific guidance from the REC in your application.

Question 42–2 – Provision of information in Welsh

• If you are approaching potential donors in Welsh centres you should note that provision of information for patients is governed by the Welsh Language Act (1993). The Act established the principle that in the conduct of public business and administration of justice in Wales, the English and Welsh languages should be treated on the basis of equality. This principle of equality offers the public the right to choose which language to use in their dealings with public organisations (including the National Health Service) and recognises that members of the public can express their views and needs better in their preferred language. In research, this presents particular ethical issues relating to informed consent.

• There is considerable geographical variation in the use of the Welsh language within Wales. Before submitting your application it is recommended that you seek advice from local NHS R&D office(s) about the language requirements of local populations and the Welsh language policies in place.

• Please indicate in your answer to this question whose advice you have sought on this issue, as this will provide assurance to the main REC that the local issues have been appropriately addressed. This will be especially helpful where the main REC is in another UK country. The main REC may seek its own advice from local RECs in Wales if necessary.

• If Welsh translations of patient information and consent forms are required, a list of translators can be obtained from the Welsh Language Board (0129 20 224744).

Question 43 – Incentives

• Any financial or other incentives offered should not be set at a level that may induce donors to give samples. The significance of any incentive may vary depending on the nature of the donor population and this should be taken into consideration.
Question 44 – Withdrawal of consent

- Where samples or data are stored with linking information, describe the bank’s policy where donors (or relatives) subsequently withdraw consent. Say what measures will be taken to trace the samples, prevent any further research use and dispose of the samples or data. Outline the approach to research findings from projects that are already in progress or have been completed.

- Where samples are fully anonymised (all links broken), it will clearly not be possible to identify samples and withdraw the data.

- Information sheets for donors should explain whether or not donors will be able to withdraw consent in future and what the effect would be.