Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Royal Devon & Exeter Tissue Bank - 5 year extension

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

(●) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the bank be established within a NHS / HSC diagnostic archive?

( ) Yes (●) No

2b. As well as biological samples and data, will the bank also collect and store radiological images from sample donors?

(●) Yes ( ) No

Will donors be invited to undertake any ionising radiation exposures (e.g. X-Rays, CT scans) additional to those authorised as part of normal clinical management?

( ) Yes (●) No

3. In which country of the United Kingdom is the bank established?

- (●) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland

3a. In which countries of the United Kingdom will centres collecting and/or supplying tissue and data to the bank be located? *(tick all that apply)*

- [x] England
- [ ] Wales
- [ ] Scotland
- [ ] Northern Ireland

4. Which applications do you require?

- [ ] IRAS Form
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

6. Do you plan to include any participants who are children?

(●) Yes ( ) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

(●) Yes ( ) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

( ) Yes (●) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (●) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

RESEARCH TISSUE BANK / BIOBANK

NHS Health Research Authority

Application to NHS / HSC Research Ethics Committee

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Royal Devon & Exeter Tissue Bank - 5 year extension

Please complete these details after you have booked the REC application for review.

REC Name:
North Somerset and South Bristol

REC Reference Number:
16/SW/0056

Submission date:
11/02/2016

Preliminary checklist:

Please tick all activities to be undertaken by or within the establishment *(i.e. the legal entity with control of the tissue/data):*

- [x] Existing holding of stored tissue (any "relevant material" as defined by the Human Tissue Act and held prior to 1 September 2006)
- [x] Removal, collection and storage of new tissue from the living for research
- [x] Collection and storage of existing/residual tissue from the living (includes samples held in diagnostic archives)
- [ ] Removal of organs or tissue from the deceased
- [x] Collection and storage of organs or tissue from the deceased
- [x] Collection and storage of DNA
- [x] Collection and storage of other biological material
- [x] Arranging the collection of new tissue samples or other biological material by collaborator(s)
- [x] Collection of new data from the living
- [x] Collection of clinical data from patient records
- [x] Other research procedures involving contact with participants (e.g. questionnaires, imaging)
- [x] Conducting research projects using the samples or data
- [x] Releasing samples or data to other researchers with no involvement of the establishment in conducting the research
- [ ] Releasing samples or data to commercial suppliers
- [x] Export of samples or data outside the UK
- [x] Collection and storage of identifiable samples or data relating to adults unable to consent for themselves due to physical or mental incapacity

Part A: Core Information

Administrative information

1. Title of the bank.

Royal Devon & Exeter Tissue Bank (Five Year Extension)

2. Name and address of the establishment responsible for management of the bank.

Organisation	NIHR Exeter Clinical Research Facility
Address	RILD Building
	Barrack Road
	Exeter
PostCode	EX2 5DW
Telephone	01392408187
Fax	01392406767

Please give details of the locations at which tissue will be stored:
NIHR Exeter Clinical Research Facilities at Royal Devon & Exeter Foundation Trust Sites.

3. Name of the tissue bank manager within this organisation.
This person will be the main contact point with the REC for purposes of the application.

Title	Forename/Initials	Surname
Mr	Malcolm	Crundwell

Address	Royal Devon & Exeter NHS FT
	Barrack Road
	Exeter
PostCode	EX2 5DW
E-mail	Malcolm.Crundwell@nhs.net
Telephone	01392402498
Mobile	
Fax	

A copy of a current CV (maximum two pages of A4) must be submitted with the application.

Questions 4-6 should be answered in relation to each establishment. Please open a separate set of the questions for each establishment.

Storage establishment 1

4. Name and address of the establishment responsible for storage of any relevant material under the Human Tissue Act. *Where relevant material will be held in more than one establishment, please give details of each establishment.*

Organisation	NIHR Exeter Clinical Research Facility @ Royal Devon & Exeter NHS Trust
Address	RILD Building
	Barrack Road
	Exeter
PostCode	EX2 5DW
Telephone	01392408187
Fax	01392406767

5. Does this establishment hold a licence from the Human Tissue Authority to store tissue for use for a scheduled purpose? *Please enclose copy of licence if available.*

◉ Yes ○ No ○ Licence application pending

Licence No.: 12276

6. Please give the name of the "designated individual" for purposes of licensing by the Human Tissue Authority:

	Title	Forename/Initials	Surname
	Dr	Gillian C	Baker
Address	RILD Building		
	Barrack Road		
	Exeter		
PostCode	EX2 5DW		
E-mail	G.C.Baker@exeter.ac.uk		
Telephone	01392408187		
Mobile			
Fax	01392406767		

7. Has this bank (or any part of the bank) previously been the subject of an application for ethical review?

◉ Yes ○ No

If Yes, was the application approved?

◉ Yes ○ No

Name of Research Ethics Committee:	Central Bristol
Date of decision:	08/04/2011
REC reference number:	11/SW/0018

Purpose of the Bank

8. Please summarise the types of tissue sample or other biological material to be collected/stored from the living.
Please state the selection criteria for inclusion of samples in the bank. Indicate what samples are already held and summarise plans for further collection.

Any sample removed during routine clinical care at the Royal Devon & Exeter Foundation Trust that is not required for diagnostic purposes. This may include any residual samples sent for pathological analysis and any tissues or fluids removed during routine procedures. eg. operations. In some cases, extra consent will be asked to take samples specifically for research procedures. The samples are not strictly residual but will be taken at the time of the routine procedure and in quantities in line with standard care. For example, if up to 8 biopsies can be safely removed during a procedure, but only two are needed on this occasion for clinical diagnosis, then the clinician may take two biopies for research purposes if they feel it appropriate. Approval by both the clinician and relevant pathologist is a requirement of any sample being eligible for transfer into the tissue bank.

9. Please summarise the types of organ, tissue sample or other biological material to be collected from the deceased.
Please state the selection criteria for inclusion of samples. Indicate what samples are already held and summarise plans for further collection. If the establishment will be removing organs or tissues from the deceased in England, Wales or Northern Ireland, please provide a copy of the pathology licence.

The bank does not plan to proactively collect tissue from the deceased, but would consider providing the governance oversight for storage and distribution of such tissue if there is evidence of consent for research is available and there is a request to gift such tissue to the bank.

10. Please summarise the types of data to be collected and linked with the samples.
Indicate whether any personal identifiers will be held and explain why this is necessary. Say whether any particularly sensitive data will be held.

Samples will be labelled with a code only. The tissue bank management team will hold a database comprising two tables each linked to this code. One table will contain relevant unidentifiable data taken at time of the donation (e.g. current medication, age of donor, ethnicity, nature of current pathology etc). A second table will contain name, date of birth and NHS/Hospital number. This table will only be available to the tissue bank management team in order to facilitate retrospective addition of data that may be relevant to the sample such as clinical outcome or gleason score of a tumour saved.

Please enclose a list of all data items to be stored.

11. How is it intended to make beneficial use of the samples or data in research?
Please summarise the overall policy of the bank/establishment for use of the samples or data, including release to other researchers or research organisations

Anonymised samples and anonymised data will be available for any medical research with the exception of the following:
a)to be sold for profit
b)to be used in animal research
c)to be used in research into termination of pregnancy or reproductive cloning
providing that is approved by the Research Bank steering committee. The committee will include a clinician, scientist, statistician and lay member to ensure samples are provided for studies that are both scientifically rigourous and considered a properly justified and worthwhile use.

Priority use will be given to staff and collaborators of the NIHR Exeter Clinical Research Facility for research into the mechanisms of common disease. Applications to use samples are however welcomed from any respected research teams.

12-1. How have you actively involved, or will you involve, patients, service users, or members of the public in establishing the bank and its policies?

Members of the public have will be represented on the steering committee and have been invited to comment on the protocol, PIS and consent. The NIHR Exeter Clinical Research Facility is currently managing a steering committee and have developed a lay group of 20-30 people who are involved in helping us make decisions and proof-read documentation.

13. How will you inform donors and other patients, service users and members of the public of the results of research?

Participants will be given a web address where they can see results of studies utilising the tissue bank. As contact details are not taken from donors for tissue bank studies we are not in a position to send results directly to donors.

14. How will the bank be managed and financed?

The governance of the bank is supported through NIHR Exeter Clinical Research Facility Infrastructure funding. Individual studies requesting collection, storage and use of samples contribute funding for consumables, sample handling and additional staffing.

Information governance

15. What personal identifiers will be held with the data records? *Please tick all that apply.*

- [x] Initials
- [x] Full name
- [x] Address
- [ ] NHS or CHI number
- [x] Hospital ID no.

- [ ] GP registration
- [x] Date of birth
- [x] Year of birth
- [x] Date of death
- [ ] Postcode
- [x] Other geographical identifiers

please specify

These are not stored for all collections but where a research question is linked specifically to a geographical/environmental issue (e.g. radon) broad questions about environmental exposure may be included.

Purpose for which postcode/geographical identifiers required:

- [ ] Deprivation scoring
- [ ] Lifestyle analysis
- [x] Geographical analysis

- [x] Gender
- [x] Occupation
- [x] Ethnicity
- [ ] Other identifiers

16-1. What systems will be in place to ensure the confidentiality of personal data? *What will be your policy for limiting access to identifiable data within the establishment. Say who will have access and for what purposes, what training they will have and how the confidentiality policy will be monitored and enforced.*

Staff involved in obtaining informed consent and sample collection will have access to identifiable information. The tissue bank data management team will be able to link identifiable data to anonymised data and samples, but no one else will be able to identify participants from their data or samples. Where samples are collected outside of the RD&E, the RD&E tissue bank data management team will only have access to the year of birth, initials and hospital number of donors so that they need to go via the recruiting hospital in order to re-link samples and data to a donor's medical record.

17. What security and audit measures will be in place to secure access to identifiable data held by the bank?

The data will be held in a password protected database on the N3 environment.

Use of samples or data in future research

Questions 18 - 27 apply where the bank/establishment will be conducting its own research using the samples or data. Answer in relation to this research programme.

Questions 28 - 39 apply where the bank will be releasing its own samples and data to other researchers.)

18. Do you wish to seek generic ethical approval for research projects conducted by the bank/establishment using the stored samples/data, under conditions agreed with the REC, without requirement for the researchers to apply individually to the REC for approval?

- (●) Yes
- ( ) No

If Yes, questions 19 - 27 will be enabled.
If No, questions 19 - 27 will be disabled. Researchers will be required to apply individually to obtain ethical approval using the project-based application form.

19. What types of research will be undertaken and in what field(s) of biomedicine?

The tissue bank will be managed by the NIHR Exeter Clinical Research Facility and will provide samples for other studies within the facility and external applications. All applications will go via a steering committee. Research at NIHR Exeter Clinical Research Facility focuses on understanding the mechanisms of common diseases such as diabetes, heart disease, cancer and autoimmune conditions.

20. What types of test or analysis will be carried out on the samples or data?

Chemical, Molecular and Genetic Analysis. The tissue bank aims to be able to facilitate research for decades to come and cannot predict the types of analysis that might be developed in the future. Current tests would include histopathological analysis, RNA and DNA extraction and the examination of other biomarkers.

21. Will the research involve the analysis of human DNA in the samples?

◉ Yes ○ No

22. Is it possible that the research could produce findings of direct clinical significance for individuals? *(This may include relatives as well as donors.)*

◉ Yes ○ No

23. Where research findings are clinically significant for individuals, will arrangements be made to notify the individuals concerned?

◉ Yes ○ No

If No, please justify. If Yes, say what arrangements will be made and give details of the support or counselling service.
Participants will be given the opportunity to opt in or out of being informed of incidental findings. There will be no active pursuit of incidental findings and it is unlikely that research teams will find information of direct clinical relevance. However is the case that a finding is made and the donor has consented to be told about it the steering committee will discuss the finding with the donor's clinician and they will take responsibility for liaising with the patient where feasible (i.e. still registered with the hospital).

24. Will the samples be used in animal research?

○ Yes ◉ No

25. Will the samples be used in research into termination of pregnancy or reproductive cloning?

○ Yes ◉ No

26. What arrangements will be made to consider applications from researchers for use of the samples or data? How will decisions on access be made and who will be involved?

A steering committee that includes a lay member, clincian, scientist and statistiican will review all applications for use of tissue bank tissue and data. Applicants will need to demonstrate a good track record of related work and must provide a details of the planned analysis. Recipients of tissue/samples must agree to providing results back to the tissue bank manager and inform the tissue bank manager if data arising has any effect on the volunteer's clinical care. See a copy of suggested application form in supporting documents.

27. What conditions will apply to the sharing of data with researchers? *Please say how this will be monitored and enforced.*

The most usual scenario would be that all data is collected and input into the tissue bank database and samples released in a blinded anonymised fashion to researchers. Once the samples have been analysed the researcher would request linked (but non-identifiable) data. No identifiable data will be released to researchers. In some cases

however the researcher may be a clinician within the RD&E with access to data for clinical care purposes. In this case the tissue bank data management team will try to process and blind/un-blind data for scientific robustness.

Questions 28 - 39 apply where the bank will be releasing samples and data to other researchers.

28. Do you wish to seek generic ethical approval on behalf of external researchers who will be using samples or data supplied by the bank, under conditions agreed with the REC, without requirement for researchers to apply individually to the REC for approval?

(●) Yes ( ) No

If Yes, questions 29 - 39 will be enabled
If No, questions 29 - 39 will be disabled. Researchers receiving tissue or data will be required to apply individually to the REC to obtain ethical approval using the REC project-based application form.

29. What types of research will be undertaken by other individuals/organisations using the samples or data and in what field(s) of biomedicine? *Name any research organisations or units you plan to collaborate with at this stage.*

The bank will be predominantly a resource to be used by staff within the NIHR Exeter Clinical Research Facility for experimental medicine research into the mechanisms of common disease and healthy ageing. All research should be carried out in collaboration with CRF staff/members of the University of Exeter or RD&E.

30. Will any types of research or research organisation be excluded from receiving samples or data?

(●) Yes ( ) No

If Yes, please give details:
This research bank is for predominantly for use in experimental medicine but all applications from internal and external groups will be judged on their scientific merit. No organisation may recieve samples if they plan to use the samples for direct profit (although indirect profit, e.g. commercially developing a new drug based on research using the samples is acceptable).

31. Will samples be released for use in animal research?

( ) Yes (●) No

32. Will the samples be used in research into termination of pregnancy or reproductive cloning?

( ) Yes (●) No

33. What arrangements will be made to consider applications from researchers for use of the samples or data? How will decisions on access be made and who will be involved?

A steering committee that includes a lay member, clincian, scientist and statistiican will review all applications for use of tissue bank tissue and data. Applicants will need to demonstrate a good track record of related work and must provide details of their planned analysis. Recipients of tissue/samples must agree to providing results back to the tissue bank manager and inform the tissue bank manager if data arising has any effect on the volunteer's clinical care. See a copy of suggested application form in supporting documents.

34. What conditions will apply to the sharing of data with researchers? *Please say how this will be monitored and enforced.*

The most usual scenario would be that all data is collected and input into the tissue bank database and samples released in a blinded anonymised fashion to researchers. Once the samples have been analysed the researcher would request linked (but non-identifiable) data. No identifiable data will be released to researchers.

35. Please give details of how data will be effectively anonymised or pseudonymised to protect the confidentiality of subjects. What measures will you take to prevent possible re-identification by linking to other databases?

Samples will all be labelled with barcoded labels without personal identifiers. Data forms will also be coded without identifiers and all identifiable information will be kept by the tissue bank data management staff in locked cabinets and in separate tables of password protected databases.

Projects receiving identifiable samples or data should apply separately for ethical review using the project-based application form and give details of the consent arrangements.

36. Will samples or data be released to individuals/organisations conducting research outside the UK?

◉ Yes ○ No

If Yes, please give details and describe any additional safeguards you will put in place:
We do not want to state categorically that this would not be the case in the future, but have no immediate plans to transfer tissue overseas. Any transfer of tissue overseas will be in line with EUTCD guidelines.

37. What will your policy be for requiring feedback of research findings specific to the donor to be linked with the stored samples/data?

From April 2016 we will ask all donors whether they consent for research findings to be linked back to their identifiable data and will have a choice what kind of findings are linked back and shared with their clinician. As the tissue bank is not actively keeping up-to-date contact information of donors the tissue bank will not take responsibility for feeding back any information but will share this information with the donor's referring clinical team if the donor consents for this to happen.

38. Where research findings are clinically significant for individuals, will arrangements be made to notify the individuals concerned?*If Yes, please say what arrangements will be made and give details of the support or counselling service. If No, please explain the reasons why the findings will not be notified to subjects or other healthcare professionals.*

◉ Yes ○ No

It is unlikely that findings will have direct clinical relevance. From April 2016 we will ask all donors whether they consent for research findings to be linked back to their identifiable data and will have a choice what kind of findings are linked back and shared with their clinician. As the tissue bank is not actively keeping up-to-date contact information of donors the tissue bank will not take responsibility for feeding back any information but will share this information with the donor's referring clinical team if the donor consents for this to happen.

39. What arrangements will be made with researchers for return, disposal or further storage of samples and data when studies are completed? What mechanisms will be in place for approving further studies?

Researchers will be expected to return unused samples to the tissue bank after their studies have been completed or to provide aliquots of extracted macro-molecules (e.g) DNA to other researchers approved by the Tissue Bank.

Sample collection and informed consent arrangements

Questions 40 - 41 apply only to the bank's existing collections of stored samples/data:

40. Has informed consent already been given for use of samples/data in research?

◉ Yes ○ No ○ Not applicable

If Yes, for what purposes has consent been given?

The bank will provide governance for use of samples where broad consent was given for future research. If the consent was specific, e.g. "for diabetes research" the steering committee will ensure that samples are only released for studies in this area.

Please enclose a copy of the information sheet and consent form used (if available).

41. If informed consent has not been given, is it proposed to seek consent for future use of samples/data in research?

○ Yes ○ No ◉ Not applicable

Application should be made to the Confidentiality Advisory Group' (CAG) to process the identifiable data of living donors without consent in England and Wales – see guidance notes.

Question 42 applies to collections from the deceased only:

42. What arrangements will be made to seek appropriate consent (or authorisation in Scotland)? *Please describe the involvement of collaborators.*

n/a

Please enclose copy of information sheet(s) and consent form(s).

Questions 43 - 46 apply to prospective collection of samples or data from the living:

43-1. How and by whom will donors be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

For each tissue collected there will be a named Clinician (e.g Urology surgeon for prostate tissues.) They, or their delegate will identify patients suitable to be donors and will arrange for a research practitioner or themselves to obtain informed consent. Once consent has been given the sample will be collected from the clinical setting and moved into the research bank where it will be logged against a anonymous code.

43-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

44. How and by whom will donors first be approached? *Indicate whether this will be in the course of healthcare provision or whether additional procedures will be involved?*
In the case of additional procedures, what burdens could arise for participants?

Donors will be approached in the course of their healthcare provision.
Donors will be approached by their clinician or referred by their clinician to a research practitioner who will provide a Patient Information Sheet ask them to consider consenting to tissue donation. This will be undertaken at a time considered by the clinician to be appropriate, such as at a pre-op clinic and timing will depend on the nature and sensitivity of the donation.

Please enclose a copy of any questionnaire to collect data from donors which is additional to data collected in the course of normal healthcare provision.

45. Will there be any further contact with donors to collect additional samples or data following the initial donation?

◉ Yes ○ No

If Yes, please give details:
Usually samples will be provided as a one-off donation, but in some procedures collection may take place at different time points e.g peripheral blood at the time of routine venepuncture and then collection of tumour materials at surgery. The donors will not be contacted, except at their routine clinic appointments.

46. Will you obtain informed consent to use samples and data in research?

◉ Yes ○ No

If you will be obtaining consent from adult donors, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 1, and for children in Part B Section 2. If you plan to seek informed consent from other vulnerable groups, say how you will ensure that consent is voluntary and fully informed.
*If you will not be obtaining informed consent, please complete question 47.*Informed Consent will be obtained by clinician or research staff with adequate training and experience in this procedure. Clear statements in the volunteer information sheet and consent form about the storage of tissue and data in the tissue bank will be given.

Please enclose a copy of the information sheet(s) and consent form(s).

Questions 48-49 apply in all cases where consent to research is to be sought:

48. Will you record informed consent in writing?

◉ Yes ○ No ○ N/A

49-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information in English, or who have special communication needs? *(e.g. translations, use of interpreters)*

Due to the local demographic the majority of people approached will be sufficeintly fluent in English to understand the information provided. Volunteer information about the tissue bank will be included in the PIS for each study. This may be provided in large print for those with impaired vision. For those volunteers who are unable to read may be given the volunteer information aurally. If necessary we will utilise the NHS language line services to assist in translation.

Questions 50 - 51 apply to all applications

50. Will any financial or other incentives be offered to donors?

○ Yes ◉ No

51. What steps will be taken where donors or relatives subsequently withdraw consent to the use of samples/data for research? What information will participants be given about this?

Donors may withdraw at any point and their data will be removed from the database and their samples destroyed if they wish to withdraw. Volunteers need give no reason for withdrawal. The donor's copy of the consent form will have clear information on how to withdraw consent statements. Participants will be able to change their mind about whether their samples and data are stored and what information is fed back to their clinician.

Sample collection and informed consent arrangements

Summary of the application

56. Please provide a brief summary of the application in a form suitable for publication, using language easily understood by patients and public. *The summary will be published on the website of the National Research Ethics Service following the ethical review. You may cut and paste from answers to other questions.*

Title of the bank: Royal Devon & Exeter Tissue Bank (Five Year Extension)
Human Tissue Authority storage licence no:
12276

Establishment responsible for management of the bank:

Organisation	NIHR Exeter Clinical Research Facility
Address	RILD Building
	Barrack Road
	Exeter
PostCode	EX2 5DW
Telephone	01392408187
Fax	01392406767

Please give details of the locations at which tissue will be stored:

Samples/data to be stored and collection/consent arrangements (maximum 200 words):
The bank will provide centralised governance and management of any samples available during routine clinical care at the RD&E Hospital or collaborating NHS organisation. Samples will only be collected when there is a proposed research question and samples can be obtained without incurring any extra risk to patients or interfering with their diagnosis. Samples collected could include anything from a urine sample to an amputated limb. The data collected with samples will include any information available from medical notes or the donor themselves that would be necessary in answering scientific questions about the samples. Identifiable information (name, hospital number and date of birth) will be collected but will held securely by the tissue bank data management team and not shared with researchers or external organisations.
Research programme/community supported by the bank (maximum 200 words):
The samples and data may be used by any scientific / medical / clinical researcher to understand the causes of disease with an view to improving understanding, diagnosis and treatment of disease. Al requests to use samples will be referred to a steering committee which is comprised of scientists, clinicians and lay people. All donors may feed into the steering committee by providing online feedback on requests for use of samples if they wish.

B. All research other than CTIMPs

In this sub-section, an adult means a person aged 16 or over.

B1. What impairing condition(s) will the participants have?

The study must be connected to this condition or its treatment.

The steering committee will be consulted on a case-by-case basis whether to include participants who lack capacity. Authorisation to obtain consultee consent will only be allowed when the samples are being collected for a study that aims to improve understanding or improve treatment of a condition that is prevalent in people lacking capacity (either because the condition causes lack of capacity, e.g. C. difficile infection-induced delirium or dementia or because the condition is associated with developmental delay, e.g. some genetic forms of diabetes.

B2. Justify the inclusion of adults unable to consent for themselves. It should be clear why the research could not be carried out as effectively if confined to adults capable of giving consent.

In order to understand conditions such as dementia samples are required from patients suffering from such conditions. Where possible consent will be obtained from people with capacity but where lack of capacity is co-morbidity associated with the condition of interest it is important to be able collect samples from these patients. A specific consultee consent form is available as well as a process for withdrawal/ reconsent if a person regains capacity.

B3. Who in the research team will decide whether or not the participants have the capacity to give consent? What training/experience will they have to enable them to reach this decision?

Clinicians trained specifically in assessing capacity will complete the standard NHS capacity assessment. If they have capacity they will be given a donor consent form to sign themselves. If they lack capacity a representative will be sought to sign a consent form on their behalf. The patient will be given a donor information letter, consent form and letter to allow them to consent or withdraw if they regain capacity following their infection.

B4. Does the research have the potential to benefit participants who are unable to consent for themselves?

◉ Yes ○ No

If Yes, please indicate the nature of this benefit. You may refer back to your answer to Question A24.

It would depend on the length of their condition, as the results of the research may not be disseminated in time to help individual patients, but the research is likely to help other patients suffering from the same condition as the donor.

B5. Will the research contribute to knowledge of the causes or the treatment or care of persons with the same impairing condition (or a similar condition)?

◉ Yes ○ No

If Yes, please explain how the research will achieve this:

Samples from people lacking capacity will only be taken for studies aiming to improving understanding and treatment of the condition with which they are suffering.

B6. Will the research involve any foreseeable risk or burden for these participants, or interfere in any way with their freedom of action or privacy?

○ Yes ◉ No

B9. What arrangements will be made to continue to consult such persons during the course of the research where necessary?

N/A. This is a one-off donation.

B10. What steps will you take, if appropriate, to provide participants who are unable to consent for themselves with information about the research, and to consider their wishes and feelings?

It is envisaged that verbal consent will be taken where possible, but it is considered that asking an acutely ill person to take on board all the information on an information sheet and then to sign a lengthy consent form would be too much of a burden, so in these cases we will ask a representive to provide the written informed consent and get verbal assent from the patient.

B11. Is it possible that the capacity of participants could fluctuate during the research? How would this be handled?

Participation usually involves one-off donation of samples and so this is not considered applicable. However there are processes to be able to withdraw consultee consent or re-consent for one's self.

B12. What will be the criteria for withdrawal of participants?

Participants may ask for their samples to be withdrawn from the bank at any time.

B13. Describe what steps will be taken to ensure that nothing is done to which participants appear to object (unless it is to protect them from harm or minimise pain or discomfort).

No procedures over and above clinical care will be undertaken.

B14. Describe what steps will be taken to ensure that nothing is done which is contrary to any advance decision or statement by the participant?

This representative will be asked to consider such things before providing consent.

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

There are specific collections of tissue that are predominantly available in a younger population. For example there is a proposed collection of sputum/cough swabs from children with cystic fibrosis. We therefore like to obtain ethical approval for information sheets specifically for use in obtaining samples during routine clinical care from those under 16. The tissue bank's steering committee will only allow collection of tissue from children where the condition being studied predominantly effects children.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

Only children under-going clinical care at the collection centre are eligible to participate.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

We have produced information sheets and assent/consent forms for both parents and children.

4. 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.

We have an information and assent form for children over the age of 8 as well as parental information and assent. We have kept this very simple as this is asking consent for spare samples and we need to ensure that the consent process is not more burdensome to the patient and their family than the donation itself.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

Part C: Tissue Collection Centres

Please enter details of the organisations (NHS or other) in the UK that will act as tissue collection centres for this research tissue bank.

Tissue collection centre	Local collaborator
Plymouth Hospital Trust	Christopher Rollinson
Royal Cornwall Hospital Trust	Clark Crawford
Yeovil Hospital	
Torbay Hospital	
North Devon Hospital	
Musgrove Park Hospital	

Part D: Declarations

D1. Declaration by the applicant:

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. If the application is approved I undertake to adhere to the terms of the application of which the REC has given a favourable opinion and any conditions set out by the REC in giving its opinion.
3. I undertake to seek an ethical opinion before implementing substantial amendments to the terms of the application of which the REC has given a favourable opinion.
4. I undertake to submit annual progress reports to the REC.
5. I understand that the information contained in this application, any supporting documentation and all correspondence with NHS Research Ethics Committees or their operational managers relating to the application:
    - Will be held by the main REC indefinitely (or until 3 years after the closure of the tissue bank).
    - May be disclosed to the operational managers or the appointing body for the REC in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed by the National Research Ethics Service to undertake accreditation of the REC.
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
6. I understand that a summary of this application will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication

NRES would like to include a contact point with the published summary of the application for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- ○ Applicant named at A3
- ◉ Designated Individual
- ○ Other – please give details
- ○ None

Access to application for training purposes

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to the establishment and other research units and collaborators would be removed.

This section was signed electronically by mr malcolm crundwell on 11/02/2016 12:32.

Job Title/Post:	Consultant Urologist
Organisation:	Royal Devon and Exeter Hospital
Email:	malcolm.crundwell@nhs.net

D2. Declaration by the Designated Individual

I confirm that the information in this form is true and accurate to the best of my knowledge and I support the application.

This section was signed electronically by Dr Gillian Baker on 10/02/2016 17:02.

Job Title/Post:	Designated Individual
Organisation:	RD&E
Email:	G.C.Baker@exeter.ac.uk