Researchers wishing to use tissue samples either retrospectively or prospectively should follow the guidance detailed in this document. It is also intended to explain how the standard staged consent template should be completed. Useful additional information is contained in the recent MRC Guidelines which can downloaded at www.mrc.ac.uk

Completion of the staged consent form:

- You will see that the Consent Form is now in three parts:
  - PART: A is to be completed in ALL cases. This section may be modified to provide additional consent for specific tests, tape-recording of interviews etc.
  - PARTS: B & C relate to situations where researchers wish to STORE samples. Copies of the master template should be submitted with the ethics application. An indication of which points do not apply should be made by placing N/A in the box(es). Careful consider should be given as to whether the study is linked anonymised1 or unlinked anonymised2 in nature.
  - The method of consent to be used should be fully explained in the patient information sheet

Retrospectively stored tissue samples:

It is acknowledged that large, potentially useful collections (libraries) of human tissue samples exist for which specific consent for storage and research investigation was not obtained at the time of removal of the tissue. Until formal guidance is issued by the DoH or Chief Medical Officer, any research using such stored tissue (eg: paraffin blocks) should be carried out anonymously. This would be classed as unlinked anonymised as there would be no means of tracing back to the original donor.

Until further guidance is received all linked anonymised studies would require consent of the donor.

For Southampton University/University Hospitals Trust: The peer review procedure implemented by the Research & Development Department for such research studies must be followed in all cases.

Prospectively stored tissue samples:

Tissue samples collected for research purposes might be stored for many years and the exact nature of the research to be carried out on the sample might not be clear at the time of collection. Staged Consent should therefore be obtained. PART A of the initial consent form should outline, in general terms, the nature of the research to be carried out on the sample (eg: new ways into treating breast cancer). An application to use the samples in future studies will need to be reviewed and approved by the Local Research Ethics Committee for each study.

If the researcher wishes to use the tissue:
- for which specific consent was not been obtained under the original protocol,
- and/or which involves the study of a subjects germ-line DNA (affecting future generations),
- and/or for which, there is potential commercial use

the subject should be contacted for re-consent and an application submitted to the ethics committee. In some circumstances it may be possible to obtain consent from the subject to permit use of the sample without going back to them for re-consent providing the standard staged consent template* (as attached) has been used.

- Details of Part B of the consent form needs to be included in the patient information sheet.
The Clinical Management Group for Southampton University Hospitals Trust is considering amendment to their surgical consent form so that the patient may give consent for tissue removed (and usually classified as ‘waste’) to be used for research. If this were to be adopted across the region, pathology specimens referred to Southampton General Hospital for diagnoses could be included in research studies. For collaborative studies where such samples are to be used, researchers should satisfy themselves that the appropriate consent (and ethics approval) has been obtained.

**Post-mortem tissue (retrospective & prospective)**

Where consent to store tissue has been obtained, the nature of the research which can be carried out on the tissue is restricted to that for which consent was obtained. The revised post-mortem consent form now assures families that research will not take place without their knowledge on organs or tissues removed at autopsy. This relates to hospital and coroner’s autopsy.

A report from the Chief Medical Officer is awaited on the use of stored tissue obtained without consent.

**Glossary of Terms:**

**Human Tissue/material**
All biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails, and substances extracted from such material such as DNA or RNA.

**Anonymised samples:**
Anonymised samples or data which have had any identifying information removed, such that it is not possible for the researcher using them to identify the individual to who they relate. The term is used in these guidelines to refer to both linked and unlinked anonymised data and samples.

- **Linked anonymised** samples or data are fully anonymous to the people who receive or use them (eg: the Research team) but contain information or codes that would allow others (eg: the clinical team who collected them or an independent body entrusted with safe keeping of the code) to link them back to identifiable individuals.

- **Unlinked anonymised** samples or data contain no information that could reasonably be used by anyone to identify the individuals who donated them or to whom they relate.

**Coded Samples:**
Coded samples or data have a coded identification to protect the confidentiality of the individual during routine use, but it is possible for the user to break the code and thus identify the individual from whom they were obtained.

**Genetic Research:**
Investigation of variation in the nuclear or mitochondrial DNA that forms the genome of an individual and may be inherited from patient to child. This may involve direct analysis of DNA or analysis of gene products.

**Genetic Testing:**
Tests to detect the presence of absence of, or alteration in, a particular gene, chromosome or gene product, in order to provide diagnostic or predictive information in relation to a genetic disorder. (such testing does not necessarily require the use of genetic technology).

STANDARDISED CONSENT TEMPLATE FOR STUDIES USING HUMAN TISSUE

(Form to be on headed paper)

Centre Number:
Study Number:
Subject Identification Number for this trial:

CONSENT FORM (Staged)

PART A  Consent for the main study

Title of Project:
Name of Researcher:

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1. I confirm that I have read the information sheet dated ........................................, (version .......) for the above study, have had the opportunity to ask questions, understand why the research is being done and any possible risks which have been explained to me.

2. I understand that my participation is voluntary and that I am free to withdraw at any time by contacting (lead researcher...) without giving any reason and without my medical care or legal rights being affected. If I withdraw I understand that any unused donated tissue will be disposed of, in the case of linked anonymised samples.

3. I understand that sections of any of medical notes may be looked at by responsible individuals from (company name) or from regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to my records.

4. I understand that (my Doctor and/or I, as appropriate) will be informed if any of the results of the medical tests done as part of the research are important for my health.

5. I agree to take part in the above study to collect a sample of (specify.........................) to (purpose of the study ...........................)

Samples gifted for storage and use in future studies

(The researcher should place N/A in the boxes which are not relevant)

PART B  Linked Anonymised Samples:

6. Provided that specific study protocols have been reviewed and approved by the Local Research Ethics Committee,, I indicate my consent for the sample and its derived cells to be stored (potentially for many years) for the following types of studies. I understand that these studies are not for the purpose of directly benefitting my health:

a) I give permission for the sample to be used for Treatments/investigations of medical conditions relating to (disease specific............)
b) I give permission for the sample to be stored for use in other unrelated research studies the precise nature of which will depend upon future scientific advances, but excluding genetic studies and germ-line research.

c) I give permission for *(name of genetic test)* to be carried out on the sample I give, as part of this project. I have received written information about this test and I understand what the result could mean to me and/or members of my family.

d) I want / do not want *(delete as applicable)* to be told the results of this test. I understand I can change my mind about this later.

e) I understand that *(the project/future research, as appropriate)* using the sample I give may include genetic research aimed at understanding the genetic influences on *(complete as appropriate)* but that the results of these investigations are unlikely to have any implications for me personally.

f) In the case of linked anonymised samples, I give permission for a member of the research team to look at my medical records, to obtain information on ............ I understand that the information will be kept confidential.

__________________________________________________

**PART C: Unlinked Anonymised Samples:**

7. 
   a) I give permission for the sample to be used for Treatments/investigations of medical conditions relating to *(disease specific.............)*

b) I give permission for the sample to be stored for use in other unrelated research studies the precise nature of which will depend upon future scientific advances, but excluding genetic studies and germ-line research.

c) I understand that *(the project/future research, as appropriate)* using the sample I give may include genetic research aimed at understanding the genetic influences on *(complete as appropriate)*.

8. I understand that the sample may be used for Commercial development, without financial or other benefit to myself, for the investigation and treatment of medical conditions, potentially leading to new preventative measures against such conditions in keeping with the gift nature of my sample.

Name of Patient ________________________ Date __________ Signature ________________

Name of Person taking consent ________________________ Date __________ Signature ________________ (if different from researcher)

Researcher ________________________ Date __________ Signature ________________

1 for patient, 1 for researcher, 1 to be kept with hospital notes.