The Royal Wolverhampton NHS Trust

Policy Number CP24

Bone Bank Policy

Contents **Page**

Appendices

1.0 Policy Statement

This policy details the procedures for the harvesting of femoral heads (allografts) during primary hip replacement surgery and their provision to recipient patients.

In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy (OP109) is to be considered the primary and overriding Policy.

2.0 Definitions

The Designated Individual (DI) has overall responsibility for the Bone Bank Service within the Trust. Part of the role of the DI is to ensure that the conditions of the license are complied with.

The Human Tissue Authority (HTA) is responsible for the regulation of Tissue Banks against current legislation. The HTA provides Codes of Practice which must be adhered to. The HTA also issues a License for approved activity.

3.0 Accountabilities

The License Holder is the person or establishment to whom the license is issued. The DI for the Bone Bank has overall responsibility. Delegated personnel have responsibilities particular to their involvement.

4.0 Policy Detail

The Bone Bank Manual (Attachment Q) provides the mandatory detail of all procedures that need to be followed within the Bone Bank Service. If additional assistance or information is required the DI should be contacted.

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	No
2	Does the implementation of this policy require additional revenue resources	No
3	Does the implementation of this policy require additional manpower	No
4	Does the implementation of this policy release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff.	No
	Other comments	

6.0 Equality Impact Assessment

The initial screening of this policy has not identified any adverse/negative impact and therefore a full equality assessment is not required. If this document is required in larger print please contact the DI.

7.0 Maintenance

The DI is responsible for regularly reviewing the policy to ensure it reflects up to date practice.

8.0 Communication and Training

The policy will be accessible on the Trust Intranet site and communicated through the Clinical Governance Meetings for Trauma and Orthopaedics and Critical Care.

All education and training requirements must be adhered to as per the Bone Bank Manual.

9.0 Audit Process

Criteria	Lead	Monitoring method	Frequency	Committee
Standards of best practice and appropriate use of policy	DI	Routine audit of application and use of policy, including review of actions taken by managers	Annually	HR Workforce Assurance Group QSAG

10.0 References

Human Tissue Authority General Directions 003/2010 Implementing the Guide to Quality & Safety Assurance for Human Tissues and Cells for Patient Treatment. Human Tissue Authority, 2014. Codes of Practice.
National Blood Service, Edition 203, Tissue Donor Selection Guidelines – Live Donors.
National Blood Service, 2013, Guidelines for the Blood Transfusion Services in the United Kingdom.

Part A - Document Control

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and Policy version: **CP 24 Version 9.0**	**Policy Title** **Bone Bank Policy**	**Status:** **Final**		**Author: Mr Isbister** **Chief Officer Sponsor: Chief Medical Office**
Version / Amendment History	Version	Date	Author	Reason
	1	1997	Designated Individual	Original Policy
	2	2000	Designated Individual	Policy Review
	3	2003	Designated Individual	Policy Review
	4	July 2007	Designated Individual	Policy Review
	5	June 2008	Designated Individual	Policy Amendment
	6	October 2011	Designated Individual	Policy Review
	7	November 2018	Designated Individual	Policy Review
	8	June 2019	Designated Individual	Minor amendments made to Policy
	9	January 2022	Designated Individual	Policy Review
Intended Recipients: All Staff.				
Consultation Group / Role Titles and Date: Designated Individual				
Name and date of Trust level group where reviewed	Trust Policy Group – January 2022			
Name and date of final approval committee	Trust Management Committee – January 2022			
Date of Policy issue	February 2022			
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	January 2025 (3 yearly)			
Training and Dissemination: No training needs, staff will be notified of revised policy.				

Publishing Requirements: Can this document be published on the Trust's public page: Yes	
To be read in conjunction with: 1. Consent to Treatment and Investigation Policy (CP06) 2. Hand Hygiene (IP01) 3. Infection Prevention Standard Precautions (IP12) 4. Waste Management Policy (HS10)	
Initial Equality Impact Assessment (all policies): **Completed Yes** **Full Equality Impact assessment (as required):** **Completed NA** If you require this document in an alternative format e.g., larger print please contact Policy Administrator 8904	
Monitoring arrangements and Committee	Internal Audit. Human Tissue Authority Inspection.
Document summary/key issues covered. This Policy provides the framework of required procedures for the harvesting of femoral heads (Allograft) during primary hip replacement surgery and the provision to recipient patients.	
Key words for intranet searching purposes	Bone Bank, Human Tissue
High Risk Policy?	**No**

Part B **Ratification Assurance Statement**

Name of document: Bone Bank Policy

Name of author: Mr E S Isbister

Job Title: Consultant Trauma & Orthopaedic Surgeon and Designated Individual

I, the above named author confirm that:

- The Policy presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author:

Date:

Name of Person Ratifying this document (Chief Officer or Nominee):
Job Title:
Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

Policy number and policy version: CP24 V9	Policy Title Bone Bank Policy	
Reviewing Group	Trauma & Orthopaedics Governance Meeting	Date reviewed: 22/10/2021
Implementation lead: Mr E S Isbister – Trauma & Orthopaedic Consultant Surgeon Ext 85387		

Implementation Issue to be considered (add additional issues where necessary)	Action Summary	Action lead / s (Timescale for completion)
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.		
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form		
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed		
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?		
Financial cost implementation Consider Business case development		
Other specific Policy issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation		

The Royal Wolverhampton
NHS Trust

Donating Bone

Trauma & Orthopaedics - Bone Bank

The prevention of infection is a major priority in all healthcare and everyone has a part to play.

- **Wash your hands with soap and warm water and dry thoroughly. Use hand gel, if provided, in care facilities.**
- **If you have symptoms of diarrhoea and vomiting stay at home and do not visit relatives that are vulnerable in hospital or in residential care. You will spread the illness.**
- **Keep the environment clean and safe. Let's work together to keep it that way. Prevention is better than cure.**

This leaflet is for patients considering bone donation during hip replacement surgery.

Which bone can I donate?

When you have a hip replacement bone from your old hip can be used to help another patient.

During the operation, the ball part of the hip joint [known as the head of femur] is replaced and usually discarded. Although the surface of this bone is damaged by arthritis the underlying bone is good and can be stored to use for someone else.

Can anyone donate their bone?

Most people can, there is no upper age limit. However, if you have certain health problems you will be unable to donate bone - this will be discussed with you at the time of pre-assessment.

How can donated bone be used to help others?

Sometimes hip and knee replacements can become loose and wear away the surrounding bone in which case a 're-do' [known as a revision] operation may be required. Donated bone can be very important in building up the bone that has been worn away and helping anchor the new hip replacement in place. This makes it much more likely that the revision operation will be successful and will last a long time.

Donated bone can also be used during other operations to treat bones damaged through injury or disease.

What is involved?

If you are having a hip replacement we would like you to consider donating the bone which is normally discarded. The donation of bone does not affect your operation or recovery – we simply "bank" the surplus bone.

When you visit the pre-assessment clinic a nurse will talk to you about bone donation and answer any questions you may have. You will be asked questions about your general health before signing a form to consent for bone donation. Any information that you give is kept confidential.

Some extra tests will be carried out on the blood taken at the same time as your other routine blood tests. Six months after your operation we will contact you again and arrange to take a further sample of blood. These blood tests ensure that your blood remains free of infections such as HIV / AIDS, Hepatitis B & C, Syphilis and HTLV 1. Samples are also taken of the donated bone to make sure that it is free of infection.

Will I be notified of the test results?

You will only be contacted if the blood tests are found to be positive. This is extremely unlikely to occur due to the screening process. However, if the results are positive you will be offered professional support and guidance.

If you do want to know any of the test results please contact the Bone Bank in writing at the address overleaf. Please wait until a couple of weeks after the tests were taken before you contact the Bone Bank.

How easy is it to say no?

There is no obligation or pressure put on you to donate bone.

When you visit the pre-assessment clinic and donation is discussed you are free to say no for whatever reason. You can contact the Bone Bank at any point if you have any questions or uncertainties.

Where can I find further information?

Please contact the Bone Bank at the address below.

Bone Bank
Pre-operative Assessment Clinic
Hollybank Day Case Unit
Level 3
Cannock Chase Hospital
Brunswick Road
Cannock
WS11 5XY
Telephone: 01543 576589

Further information about tissue donation can be obtained from:

The National Blood Service:
www.blood.co.uk/

The Human Tissue Authority:
www.hta.gov.uk/

The British Association of Tissue Banking:
www.batb.org.uk/

Glossary of Terms:

TB:	Tuberculosis
HIV:	Human Immuno-deficiency virus
AIDS	Acquired Immune Deficiency Syndrome
HTLV 1:	Human T-Lymphotropic Virus type 1

English

If you need information in another way like easy read or a different language please let us know.

If you need an interpreter or assistance please let us know.

Lithuanian

Jeigu norėtumėte, kad informacija jums būtų pateikta kitu būdu, pavyzdžiui, supaprastinta forma ar kita kalba, prašome mums apie tai pranešti.

Jeigu jums reikia vertėjo ar kitos pagalbos, prašome mums apie tai pranešti.

Polish

Jeżeli chcieliby Państwo otrzymać te informacje w innej postaci, na przykład w wersji łatwej do czytania lub w innym języku, prosimy powiedzieć nam o tym.

Prosimy poinformować nas również, jeżeli potrzebowaliby Państwo usługi tłumaczenia ustnego lub innej pomocy.

Punjabi

ਜੇ ਤੁਹਾਨੂੰ ਇਹ ਜਾਣਕਾਰੀ ਕਿਸੇ ਹੋਰ ਰੂਪ ਵਿਚ, ਜਿਵੇਂ ਪੜ੍ਹਨ ਵਿਚ ਆਸਾਨ ਰੂਪ ਜਾਂ ਕਿਸੇ ਦੂਜੀ ਭਾਸ਼ਾ ਵਿਚ, ਚਾਹੀਦੀ ਹੈ ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਸਾਨੂੰ ਦੱਸੋ।

ਜੇ ਤੁਹਾਨੂੰ ਦੁਭਾਸ਼ੀਏ ਦੀ ਜਾਂ ਸਹਾਇਤਾ ਦੀ ਲੋੜ ਹੈ ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਸਾਨੂੰ ਦੱਸੋ।

Romanian

Dacă aveți nevoie de informații în alt format, ca de exemplu caractere ușor de citit sau altă limbă, vă rugăm să ne informați.

Dacă aveți nevoie de un interpret sau de asistență, vă rugăm să ne informați.

Traditional Chinese

如果您需要以其他方式了解信息，如易读或其他语种，请告诉我们。

如果您需要口译人员或帮助，请告诉我们。

Designed & Produced by the Department of Clinical Illustration,
New Cross Hospital, Wolverhampton, WV10 0QP Tel: 01902 695377.

Review Date 03/22 Date Produced 2011 WCA_1552_24.06.19_V_4

CP 24 Appendix B

The Royal Wolverhampton NHS Trust Bone Bank - Consent Form

Bone Bank Reference Number

Name Address

DOB

Unit No

Affix Patient Label Here

I confirm that:

- I give consent for the surplus bone, removed during my operation, to be stored in The Royal Wolverhampton NHS Trust Bone Bank. It may then be used for donation to another patient.
- The leaflet 'Donating Bone' (WCA 1552) has been provided
- I have had the opportunity to ask questions and have been provided with satisfactory answers
- Any information that I have given is true and to the best of my knowledge
- I agree to the extra blood tests, which includes checking for the HIV 1 and 2 virus, Syphilis, Hepatitis B and C and the HTLV-1virus. I also agree for the blood tests for HIV 1 and 2, HTLV 1 and Hepatitis B and C to be repeated at least 6 months later
- If the bone appears unsuitable to be used for another patient it may be used for teaching, education, quality assurance, audit, research or diagnostic purposes.
- YES / NO (please circle)
- I am aware that if the bone is not used for any of the above purposes it will be disposed in a lawful and respectful manner.
- If necessary, further clinical details may be obtained from or passed on to other Health Care Professionals.
- I am aware that I can withdraw my consent to donation

Signed…….....

PRINT NAME…… Date……

Interviewed by (sign)…….…… Designation……

PRINT NAME……..… Date……

Copy accepted by patient: Yes / No (please circle)

NHS
The Royal Wolverhampton
NHS Trust

The Royal Wolverhampton NHS Trust Bone Bank

Bone Donor Consent Form Checklist

Bone Bank Reference Number: ……..

Before accepting your bone into our Bone Bank we need to check that your bone is suitable. Please circle Yes or No to the following questions. Have you ever had:

				Details
1	Tuberculosis (TB) ?	Yes	No	
2	Sarcoidosis?	Yes	No	
3	Any recent immunisations?	Yes	No	
4	Any recent infections?	Yes	No	
5	Hepatitis or Jaundice?	Yes	No	
6	Typhoid?	Yes	No	
7	Malaria within the last 3 years or recent contact with any infectious diseases?	Yes	No	
8	Have you travelled abroad within the last 6 months, particularly to any tropical countries? If yes, have you remained well?	Yes Yes	No No	
9	Acupuncture, tattooing or body piercing?	Yes	No	
10	HIV, HTLV1 or Syphilis?	Yes	No	
11	A blood transfusion or any other blood products since 1st Jan 1980?	Yes	No	
12	Cancer?	Yes	No	
13	Leukaemia, Sickle Cell Disease or Thalassaemia?	Yes	No	
14	Rheumatoid Arthritis?	Yes	No	
15	Ulcerative Coilitis or Crohns Disease?	Yes	No	
16	Any central nervous or prion associated disease (or if you have been told you are at risk of developing these conditions) including rapid progressive Dementia, Parkinson's Disease, Multiple Sclerosis, Creutzeldt Jakob Disease [CJD] or Myaesthenia Gravis?	Yes	No	
17	Any tissue or organ transplant?	Yes	No	
18	Brain surgery?	Yes	No	
19	Treatment with human growth hormone or Human Pituitary Extract?	Yes	No	
20	Recent ingestion or exposure to cyanide, lead, mercury or gold?	Yes	No	
21	Any other treatment tests or operations that you think may be significant. For example if you have had any recent surgery or procedures such as an examination with a flexible endoscope or if you are involved in a clinical trial.	Yes	No	

Furthermore, we would not be able to accept your bone if;

- You have ever worked as a prostitute
- Within the last year you have completed treatment for a sexually transmitted disease
- You have ever injected yourself or been injected with drugs other than drugs that have been prescribed / supplied to you by a health care professional.
- You are a man who has ever had sex with another man even safe sex using a condom

Also, you must not donate your bone if you have had sex (even safe sex using a condom) in the last 12 months with;

- Someone you think may be infected with the HIV 1&2 or HTLV1 virus or is known to have Hepatitis or be a carrier
- (If you are a woman) a man who has ever had sex with another man.
- Someone who has ever worked as a prostitute.
- Someone who has completed treatment for a sexually transmitted disease within the last year
- Anyone who has injected themselves or been injected with drugs other than drugs that have been prescribed / supplied to you by a health care professional.
- Anyone who has or you think may have been sexually active in parts of the world where HIV/AIDS is very common. This includes most countries in Africa

Do any of the above apply to you? Yes / No

Signature: .....

PRINT NAME: .....

Date:.....

Staff use: I have reviewed the above checklist and the **patient is / is not** (delete as appropriate) suitable to proceed with bone donation.

Signature: ..... Designation: .....

PRINT NAME: ..... Date: .....

NHS
The Royal Wolverhampton
NHS Trust

Donor Sheet

Bone Donor Reference Number: .....

Surname	Unit No
Forename	NHS No
Address	DOB
Postcode	(or affix patient label)

Section A Donor Details

Blood group: .....

Section B – be completed by Bone Bank Theatre Personnel

Surgeons name: .....

Bone harvested at: Date: ..... Time: .....

Expiry date: ..... [Five years from harvesting]

Femoral head weight: ..... g

Bone Container Lot number: .....

Bone swab taken ☐

Bone sample taken ☐

Container labelled ☐

Labelled with red sticker i.e. NOT FOR IMPLANTATION ☐

Bone placed into freezer on Date: ..... at time: .....

Bone not taken – Reason: .....

Signature: ..... Designation: .....

Print Name: .....

Please return this form to the patient's casenotes

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Section C – to be completed by the Bone Bank Co-ordinator:

Surname	Unit No
Forename	NHS No
Address	DOB
Postcode	(or affix patient label)

Test	Result	Date taken	Lab ref no
Syphilis	+ve / -ve		
Hepatitis B	+ve / -ve		
Hepatitis C	+ve / -ve		
HIV 1 and 2	+ve / -ve		
HTLV-1	+ve / -ve		
Micro swab	+ve / -ve		
Micro bone	+ve / -ve		
6 month HIV 1 and 2	+ve / -ve		
6 month Hepatitis B	+ve / -ve		
6 month Hepatitis C	+ve / -ve		
HTLV-1	+ve / -ve		

Second bloods taken; Fracture Clinic / patients home / other .....

Section D–to be completed at the bone freezer authorised for transplant by:

Signature: ..... Designation: .....

Print Name: ..... Date: .....

Signature: ..... Designation: .....

Print Name: ..... Date: .....

Bone Discarded: Yes / No [if Yes, detail as follows]

Signature: ..... Designation: .....

Print Name: ..... Date: .....

Signature: ..... Designation: .....

Print Name: ..... Date: .....

Reason: .....

Recipient Details:

Recipient Name: ..... Date of birth: .....

Hospital No: ..... Date of sample: .....

Recipient swab result +ve / -ve Lab reference No: .....

	Result	Date taken	Lab ref no
Syphilis Test	Pos/Neg		
Hepatitis B	Pos/Neg		
Hepatitis C	Pos/Neg		
HIV 1and2	Pos/Neg		
HTLV-1	Pos/Neg		
Micro swab	Pos/Neg		
Micro bone	Pos/Neg		
6 month HIV 1and2	Pos/Neg		
6 month Hepatitis B	Pos/Neg		
6 month Hepatitis C	Pos/Neg		
6 month HTLV-1	Pos/Neg		

Second bloods taken; Fracture Clinic / patients home / other……

SECTION D–to be completed at the bone freezer authorised for transplant by -

Signed ……..... Date…….....
PRINT NAME…..... Designation…….....

Signed ……..... Date…….....
PRINT NAME…..... Designation…….....

BONE DISCARDED - Yes / No

If Yes, detail as follows -

Signed ……..... Date…….....
PRINT NAME…..... Designation…….....

Signed ……..... Date…….....
PRINT NAME…..... Designation…….....
Reason…….....

RECIPIENT DETAILS

Recipient name…..... Date of birth…….....
Hospital number…..... Date of sample…….....
Recipient swab result Pos/Neg Lab reference no ……..

Second bloods letter

Direct telephone number: Pre op assessment clinic
Cannock Chase Hospital
01543 576589

Monday-Friday 8.00am to 4.00pm

Date.....

Dear.....

Prior to your recent hip replacement, you kindly agreed to donate the bone from your head of femur. However, before this bone can be donated to another patient a further sample of blood needs to be taken.

In order for this blood to be taken, would you please attend the outpatients 1 department New Cross Hospital or Cannock Chase Hospital phlebotomy department at your earliest convenience.

The outpatients 1 at New Cross Hospital blood test department is open Monday-Friday 09.00am to 5.00pm.

Phlebotomy department at Cannock Chase Hospital is open Monday-Friday 09.00am-5.00pm.

Please do not hesitate to contact us on the above number if there are any problems.

Yours sincerely

Sister Sara Finazzi

Unable to Contact Patient

Direct telephone number: 01543 576589

Monday-Friday 8.00am to 4.00pm

Date.....

Dear.....

Prior to your recent hip replacement, you kindly agreed to donate the bone from your head of femur. However, before this bone can be donated to another patient a further sample of blood needs to be taken.

We would now like to arrange with you a convenient time to take this blood, but unfortunately we have been unable to contact you. Therefore, could you please contact the Bone Bank on the above number to arrange an appointment.

Yours sincerely

Sister Sara Finazzi

The Royal Wolverhampton
NHS Trust

Receiving Donated Bone

Trauma & Orthopaedics - Bone Bank

The prevention of infection is a major priority in all healthcare and everyone has a part to play.

- **Wash your hands with soap and warm water and dry thoroughly. Use hand gel, if provided, in care facilities.**
- **If you have symptoms of diarrhoea and vomiting stay at home and do not visit relatives that are vulnerable in hospital or in residential care. You will spread the illness.**
- **Keep the environment clean and safe. Let's work together to keep it that way. Prevention is better than cure.**

In preparation for surgery your Consultant will have discussed the possibility of receiving donated bone from another patient. This leaflet helps to explain what is involved.

How is bone donated?

Bone is donated by another patient during hip replacement surgery when the ball part of the hip joint [known as the head of femur] is removed and replaced. Instead of discarding this bone it is donated and stored.

How can donated bone be used to help me?

Donated bone (known as allograft) is "ground-down" at the time of your operation and then used to build-up the bone that has become worn or damaged. Allograft can take many months to incorporate so if your surgery has been to your hips or lower limbs you may need to use crutches while the bone heals. Your Consultant will give you advice about any precautions that you will need to take.

How are donors checked?

All potential donors are carefully assessed and questioned about their suitability by an experienced Nurse.

Blood samples are taken to ensure that the donor is free of infections such as HIV/AIDS, Hepatitis B&C, Syphilis and HTLV-1. Samples of the donated bone are also tested for signs of infection.

How safe is donated bone?

By carrying out the above tests all reasonable precautions will have been taken to minimise any risks to you. Furthermore, donated bone will not be available to any patient until all the above tests and checks have been completed.

Where can I find further information?

If you have any questions or concerns please contact your Consultant or the Bone Bank at the address below.

Bone Bank
Pre-operative Assessment Clinic
Hollybank Day Case Unit
Level 3
Cannock Chase Hospital
Brunswick Road
Cannock
WS11 5XY
Telephone: 01543 576589

Further information about tissue donation can be obtained from:

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www.blood.co.uk/

The Human Tissue Authority:
www.hta.gov.uk/

The British Association of Tissue Banking:
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Glossary of Terms:

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HIV: Human Immuno-deficiency virus
AIDS: Acquired Immune Deficiency Syndrome
HTLV 1: Human T-Lymphotropic Virus type 1

English

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Punjabi

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ਜੇ ਤੁਹਾਨੂੰ ਦੁਭਾਸ਼ੀਏ ਦੀ ਜਾਂ ਸਹਾਇਤਾ ਦੀ ਲੋੜ ਹੈ ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਸਾਨੂੰ ਦੱਸੋ।

Romanian

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Traditional Chinese

如果您需要以其他方式了解信息，如易读或其他语种，请告诉我们。

如果您需要口译人员或帮助，请告诉我们。

Designed & Produced by the Department of Clinical Illustration,
New Cross Hospital, Wolverhampton, WV10 0QP Tel: 01902 695377.

Review Date 03/22 Date Produced 2011 WCA_1553_28.03.19_V_3

Change of Procedure or Documentation Form

To the Designated Individual of the Bone Bank

Date.....

1. Change requested by (PRINT).....

   Designation.....

   Signature.....

2. Type of change or amendment(s) proposed.....

   .....

   .....

   .....

   .....

   .....

   .....

3. Reason for change.....

   .....

   .....

   .....

   .....

   .....

   .....

4. Has a new procedure been written? YES / NO

5. Has a new master copy been added to the procedure manual? YES / NO

6. Have relevant staff been informed? YES / NO

7. Has a copy of the original been kept as an archive? YES / NO

8. Date to be implemented.....

Designated Individual Signature.....

Revision number.....

Amendments Record

Manual; Issue Number	Procedure	Change	Date	Approval by Designated Individual

Help us to keep bone transplants safe.
Please notify us if, prior to your operation you;

1. Undergo acupuncture, tattooing or body piercing.
2. Receive a blood transfusion.
3. Travel outside Europe or North America.
4. Are exposed to the risk of hepatitis or HIV infection.
5. Are diagnosed with a serious disease or infection.
6. Have any queries about bone donation.

Furthermore, if you want to know the results of any of your tests please contact the Bone Bank in writing.

The Royal Wolverhampton
NHS Trust

Bone Bank

New Cross Hospital
Wolverhampton, WV10 0QP
Tel: 01543 576589

Thank you for offering to donate your bone,

Between now and your operation the medical information you have given may change.

Please read the reverse of this card carefully.

MI_442408_16.11.18_V2

End User Form

Section A: To be completed by Staff at the Bone Bank New Cross Hospital when allograft is removed from the Green Freezer.

Allograft reference number ……

Date of removal from the freezer……..……at …….. (time)

Recorded in the Theatre Bone Bank Ledger ( )

Expiry Date…….. Blood Group……..

Signature……..PRINT NAME……

Designation……...

Section B: To be completed by Staff receiving and preparing allograft

Hospital receiving allograft……

Date received……at…….. (time)

Signature……..PRINT NAME……

Designation……...

Packaging of allograft intact yes ( ) no ( ) Comments……

Recipient details:

Name Address DOB Unit No Male / Female Affix Patient Label Here

Name of surgeon……

Name of scrub practitioner……...

Pre-implantation swab taken ( )

Bone implanted; ( )

Time implanted……..

If not implanted please state reason ……

Allograft bone processed by Wolverhampton Bone Bank has undergone all of the required biological determinations and is fully compliant with the Codes of Practice as laid down by the Human Tissue Authority and National Blood Service. If allograft bone is not used this must be recorded above and disposed of as per the local Infection Prevention Policy.

Please return this form to the Bone Bank, New Cross Hospital.

If bone is used at the Nuffield Health Hospital Wolverhampton please turn over.

Responsibilities of the Nuffield Health Hospital Wolverhampton:

- To complete section B of the End User Form (overleaf)
- To take a pre-implantation swab from the surface of the allograft bone and send it to the Nuffield Laboratory for culture and sensitivity testing. The result must then be sent to:

  The Bone Bank
  The Royal Wolverhampton NHS Trust
  New Cross Hospital
  Wolverhampton WV10
  OQP

- To return the End User Form and the transport bag to the address above.
- If a serious incident occurs e.g. a serious related illness of the recipient following implantation, this must be reported within 24 hours to the Bone Bank at New Cross Hospital. Please contact either:

  Mr. E S Isbister (Designated Individual) extension 5387

  Sister Jayne Cooper (Theatre coordinator) extension 6287 or mobile phone via Switchboard

  In exceptional circumstances if no personnel at the Bone Bank can be contacted the incident should be reported to the Human Tissue Authority at:

  151 Buckingham Palace Road
  Victoria
  London
  SW1 9SZ
  Tel: 020 7269 19

Label to be used when sending bone from New Cross Hospital to the Nuffield Hospital

FROM NEW CROSS HOSPITAL TO THE NUFFIELD

From: The Bone Bank
The Royal Wolverhampton NHS Trust New
Cross Hospital
Wolverhampton WV10 OQP

Contact person: Nurse in Charge of Orthopaedics or General Theatres
Telephone 01902 307999 extension 86280

Date / time of transportation

Date…… Time……

……..

To: Name of person to accept delivery……

Nuffield Health Wolverhampton Hospital
Wood Road
Tettenhall
Wolverhampton
WV6 8LE

Telephone 01902 754177

Checklist for the release of bone from quarantine Bone Donor reference number……..

Requirement	Yes	No
Donor reference number matches all documentation and ledgers		
Blood group recorded on Donor Sheet and theatre ledger		
Expiry date recorded		
Second blood tests taken over 180 days after harvesting of bone		
Blood and bone swab / sample tests confirmed as negative		
Packaging and labels intact to bone		
Comments		

Signature……	Signature……..
PRINT NAME……	PRINT NAME……
Designation…….	Designation……..
Date……..	Date……..

NHS
The Royal Wolverhampton
NHS Trust

Bone Bank
Autograft Consent Form

Bone Bank Reference Number……..

Surname	NHS No
Forename	
Address	DOB
Postcode	(or affix patient label)

I confirm that:

- I give consent for the surplus bone, removed during my operation, to be stored in the Royal Wolverhampton NHS Trust Bone Bank. It may then be used for any appropriate surgery that I may require within the next five years.
- I have had the opportunity to ask questions and have been provided with satisfactory answers
- I agree to the extra blood tests, which includes checking for the HIV 1&2 virus, Syphilis, Hepatitis B&C and the HTLV-1virus. I also agree for the blood tests for HIV 1&2, HTLV-1 virus and Hepatitis B&C to be repeated 6 months later if the bone has not been used
- If the bone appears unsuitable to be used for myself it may be then be used for teaching, education, quality assurance, audit, research or diagnostic purposes.
- YES / NO (please circle)
- I am aware that if the bone is not used for any of the above purposes it will be disposed in a lawful and respectful manner.
- If necessary, further clinical details may be obtained from or passed on to other Health Care Professionals.
- I am aware that I can withdraw my consent

Signed .....

PRINT NAME ..... Date .....

Interviewed by [sign] ..... Designation .....

PRINT NAME ..... Date .....

Copy accepted by patient: Yes / No [please circle]

Top copy to be retained in patients notes
Second copy to be given to patient
Third copy to be retained in Bone Bank records

The Royal Wolverhampton NHS Trust

HARVESTED DONOR BONE TRANSFER SHEET

Use for all bone transferred from CCH to New Cross Bone Bank.

Please complete and send with donated femoral head in green transfer bag.

N.B. Outer white pot should be labelled with RED 'Not for Implantation' sticker on the top of lid, one 'Instructions for use' white sticker, and one white Information Sticker. It should then be put into a clear swab bag and tied at the top.

Please ring ahead to New Cross Theatres (Ext. 85693) to let them know Bone will be arriving.

PLEASE ATTACH PATIENT ID LABEL HERE…….

SURGEONS' NAME: ……..

DATE & TIME BONE HARVESTED: …….

BONE REFERENCE NUMBER: ……WEIGHT……

DONOR BLOOD GROUP: ……..

SCRUB PRACTITIONERS NAME: ……..

APPROXIMATE TIME OF HOSPITAL TRANSPORT TO NEW CROSS: ……

HAS NEW CROSS BEEN CONTACTED? CONTACT NAME AT NEW CROSS: ……

- *Please also include a loose Patient ID sticker to go into Bone Bank Register at New cross Bone Bank.*

TO BE COMPLETED AT NEW CROSS BONE BANK

TIME BONE PLACED INTO RED FREEZER AT NEW CROSS BONE BANK: ……

PLACED INTO FREEZER BY (PRINT NAME)……SIG/STAMP……..

Bone Bank Manual

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Appendix O – Autograft Consent Form

Appendix P- Donor bone transfer sheet

Introduction

The Royal Wolverhampton NHS Trust Bone Bank (established in 1997) is based at New Cross Hospital. The Trust now has two sites for elective orthopaedic surgery: New Cross Hospital and Cannock Chase Hospital. At both sites femoral heads are donated from suitably screened living donors who have given fully informed consent, as per Trust Consent Policy CP06. Facilities for freezing and storage of bone are based at New Cross Hospital. Bone is transferred between the two sites after donation or for use at Cannock Chase Hospital.

Currently, patients undergoing primary total hip replacement surgery at both sites are considered for donation.

The Bank is facilitated by staff in the Directorates of Trauma and Orthopaedics and Critical Care Services. Other departments in the Trust e.g. Microbiology also provide essential services in the processing of the allograft.

Aims and Objectives

The principle aim of the Bank is to procure and store allograft bone for use in reconstructive surgical procedures at both hospital sites.

Statement for Quality Assurance

In order to provide safe tissue of reliable quality, current good practice standards must be observed in the selection of donors and retrieval of tissues, and in the testing, processing, storage and delivery of finished tissues. This Manual, based on professional guidelines, aims to address these issues by specifying the activities within this particular Bone Bank. The quality system approach utilised will also demonstrate the framework of good manufacturing practice by defining and documenting each systematic process to ensure the safety and quality of the tissue and services provided.

Quality Systems

The quality systems described in this manual cover the following;

- Tissue bank buildings and premises;
- Environmental controls;
- Managerial responsibilities;
- Donor selection and testing;
- Testing of tissues to specifications;
- Standards for the processing and storage of tissue;
- Documentation and record keeping;
- Transportation.

This quality system depends on effective and adequate documentation for all aspects and stages of the Bank's work. Reference can be made to standard operating procedures (SOP's) and associated documents for all activities affecting the safety and quality of tissues. The responsibilities and reporting relationships of all key personnel are defined.

The resources required for training, performance, verification activities and internal audit are also described in this manual.

Tissue Bank Facilities

Bone is procured at New Cross and Cannock Chase Hospitals and stored in a designated room situated in Nucleus Theatres at New Cross Hospital in order to avoid contamination of bone tissue.

The walls are painted plaster and the flooring sheet vinyl with welded joints. Both the walls and floors are washable and are cleaned as per the Trust's Infection Prevention Policy.

All personnel entering the theatre or bone bank areas must change into designated theatre clothing. Staff directly involved in surgical procedures, are required to wear protective clothing and to decontaminate their hands as per the Infection Prevention Policy IP01. Infection Prevention Policy instructs on the use of gloves, hand-washing, disposal of waste etc.

Ancillary materials used in the procurement process, e.g. storage jars are sterile. Other single use, sterile products such as saline and swabs are used as required.

Cross-contamination of bone tissue is prevented by the segregation of bone into different freezers. Bone in quarantine (i.e. awaiting results of second blood tests) is stored in a separate freezer to bone available for transplantation. Bone stored for research purposes is stored in another, separate freezer. Each freezer is clearly identifiable and the contents of each freezer are logged on a data sheet. Each individual bone sample is stored in a sterile container, which is appropriately labelled with the donors details.

All equipment used in the procurement of bone tissue is identified and listed in the Bone Bank. Details of the equipment including the frequency and method of checking and calibration are logged. Identified Bone Bank personnel hold responsibility for the maintenance, handling and storage of specific equipment.

Organisation of Personnel

License Holder (LH)

Designated Individual (DI)
Accountable to the LH

Bone Bank coordinator
Accountable to the DI

Theatre coordinator
Accountable to the DI

Pre-op assessment Nurses
Accountable to the DI

Medical Microbiologist

Genito-Urinary Specialist

Responsibilities of Personnel

Designated Individual (DI)

- The DI has a statutory duty to ensure that:
    a. the other persons to whom the license applies are suitable persons to participate in carrying out licensed activities.
    b. suitable practices are used in the course of carrying out the licensed activities.
    c. the conditions of the license are complied with.
    d. licensable activities carried out by third parties are subject to suitable practices and are carried out by suitable persons; and
    e. the requirements of Regulation 13(1) relating to information and confidentiality are complied with.
- In addition, the DI has the following responsibilities:
    a. Ensuring that tissues and cells for human application in the establishment are procured, tested, processed, stored, distributed and imported and exported in accordance with these requirements set out here.
    b. Ensuring that the establishment carries out all appropriate control measures as required by the HTA to ensure adherence to the Regulations.
    c. Keeping a record of the establishment's activities (as outlined in the register and reporting obligations section) and submitting to the HTA an annual report on these activities.
    d. Notifying the HTA of any serious adverse event or serious adverse reaction within 24 hours of discovery (see section on serious adverse events and reactions).
    e. Ensuring that the establishment puts in place and updates a quality management system as outlined in the quality management section.
    f. Ensuring that the donor selection and evaluation is carried out in accordance with the Regulations.
    g. Ensuring that acceptance or rejection of tissues and cells for human application is carried out in accordance with the Regulations.
    h. Ensuring (in conjunction with the LH) that third party agreements are in place and maintained whenever a third party undertakes one of the licensable activities on behalf of the licensed establishment, or supplies any goods or services which affect the quality or safety of tissues and cells (see section on third party agreements).
    i. Ensuring that any third party with whom there is a third party agreement is made aware of, and provided with, copies of all relevant HTA Directions, regulatory alerts or other communications from the HTA without delay;
    j. Supervising the establishment's system for verification that tissues and cells meet all appropriate specifications prior to release (see storage and release of products section).

k. Approving the documented risk assessment undertaken to determine the fate of all stored tissues and cells following the introduction of any new donor selection or testing criterion or any significantly modified processing step (see storage and release of products section).

l. Ensuring, in conjunction with the LH, that all imports of human tissues and cells from non-EEA states meet standards of quality and safety equivalent to those set down in the Regulations.

- Where the DI is unable to carry out their duties, whether permanently or temporarily, (e.g. where the DI is suspended pending investigation or is on extended sick leave) the LH must immediately apply to the HTA for a license variation to nominate a substitute DI. This nominated substitute DI must not commence their post unless and until the HTA decides that they are suitable.
- The DI must attend regular meetings of Bone Bank Personnel

<u>License Holder</u>

- The LH has responsibility for the following:

a. Entering into and maintaining third party agreements on behalf of the establishment in line with the requirements set out in the section on third party agreements. This responsibility can be delegated to the DI, but the LH will nonetheless retain responsibility for ensuring that third party agreements comply with requirements ensuring that any information from which a donor or recipient may be identified is kept confidential and not disclosed other than in circumstances permitted by law (see section on data protection and confidentiality).

b. Making any necessary application to the HTA for approval for direct distribution and, or import or export from where procurement takes place to an organisation responsible for human application (see section on distribution and recall).

c. Ensuring that the establishment complies with the requirements relating to serious adverse events and reactions (see section on serious adverse events and reactions).

d. Ensuring that procurement organisations and end users have the necessary procedures to retain records of tissues and cells and to comply with the notification requirements for serious adverse events and reactions.

e. Ensuring, in conjunction with the DI, that all imports of human tissue and cells from non-EEA states meet the standards of quality and safety equivalent to those required for tissues and cells procured, tested, processed, stored and distributed within the EEA.

- Further, it is the responsibility of the LH to support the DI, to ensure that human tissues and cells, intended for human application, are procured, tested, processed, stored, distributed and imported and exported in accordance with the Regulations. If the license holder is a corporate body, the HTA requires that a person is nominated to act as a point of contact for the corporate license. The HTA terms this person the corporate license holder contact and they should be in a position to act as a representative of the corporate body.

- To attend regular meetings of Bone Bank Personnel

Medical Microbiologist

- To ensure that the requested serological testing of donors is carried out based on professional guidelines.
- To provide advice in the event of a positive pre-implantation swab.
- To advise on all relevant microbiological aspects of femoral head procurement and storage.

Genito-urinary Specialist

- To appropriately counsel and manage patients who have positive tests for transmittable genito- urinary diseases.
- To advise on all relevant Genito-urinary aspects of the Bone Bank Service.

Bone Bank coordinator

- To ensure that the guidelines used are the latest version;
- To collate the microbiological and serological screening tests on donors and on femoral heads and to organise the re-testing of donors;
- To release femoral heads for use after quarantine with the Pre-op Assessment Coordinator;
- To maintain and validate records, ensuring the traceability of donated femoral heads;
- To assist with ensuring that the Policy and Manual are kept up to date;
- To organise and attend regular meetings of Bone Bank Personnel.

Pre-operative Assessment Nurses

- To identify potential donors at the time of pre-assessment based on the relevant Standard Operating Procedure.
- To counsel and obtain informed consent from potential donors based on the relevant Standard Operating Procedure.
- To arrange for serological testing of potential donors based on the relevant Standard Operating Procedure.
- To ensure that the appropriate clerical staff are aware of potential donors based on the relevant Standard Operating Procedure;

- To ensure that the appropriate documentation is completed and forwarded or returned from theatre as per the relevant Standard Operating Procedure;

- To attend regular meetings of Bone Bank Personnel.

Theatre Co-ordinator

- To oversee the processing of bone in theatre based on the relevant Standard Operating Procedures.

- To maintain adequate levels of storage pots and labels and bags.

- To maintain a record of the processing of femoral heads.

- To oversee the maintenance and function of the freezers.

- To organise the training and education of theatre staff involved in the Bone Bank process and maintaining the appropriate records.

- To attend regular meetings of Bone Bank Personnel.

Staff Training and Education

Staff training and education will be appropriate to the individual's area of Bone Bank processing and will be the overall responsibility of the DI. The DI has a responsibility to participate in regular and continuing education and professional development in particular when procedures change or scientific knowledge develops.

The core members of the Bone Bank Team are:

- The License Holder;
- The Designated Individual;
- The Bone Bank Coordinator;
- The Theatre Coordinator;
- The Pre-Assessment Coordinator;
- Pre-Assessment Nurses.

Each member of the Core Team should attend the regular Bone Bank meetings which provide the opportunity to share information and ensure that each individual is aware of current developments. The meetings are held at least annually. Minutes and records of attendance are logged for each meeting. The Medical Microbiologist and Genito-urinary Specialists will be invited to meetings on an ad-hoc basis.

The Pre-assessment staff, who are specifically involved in taking consent, must have evidence of assessment. These records are kept in the Bone Bank Office.

The Theatre coordinator is responsible for the training of staff and for providing regular updates for staff involved in Bone-Banking in the theatre department. All training and updates are logged and records kept in this Department.

Donor Selection

All donors are selected by reference to documented policies and procedures which are based upon current professional guidelines and exclusion criteria. This includes

consideration of medical and behavioural history, microbiological testing, consent and blood sample testing. Information about the medical and behavioural history of the patient is obtained by a specifically trained registered nurse who interviews the patient with the relevant hospital health records for further reference. All stages of the donor selection are carried out as per a specific Standard Operating Procedure.

Medical and Behavioural History

A system exists to assess the patient to minimise the transmission of disease based on exclusion criteria. Reference is made to the relevant Standard Operating Procedures. For guidance on conditions that may affect donor eligibility, information is obtained as required from professional guidelines and other medical professionals e.g. the DI, Medical Microbiologist etc.

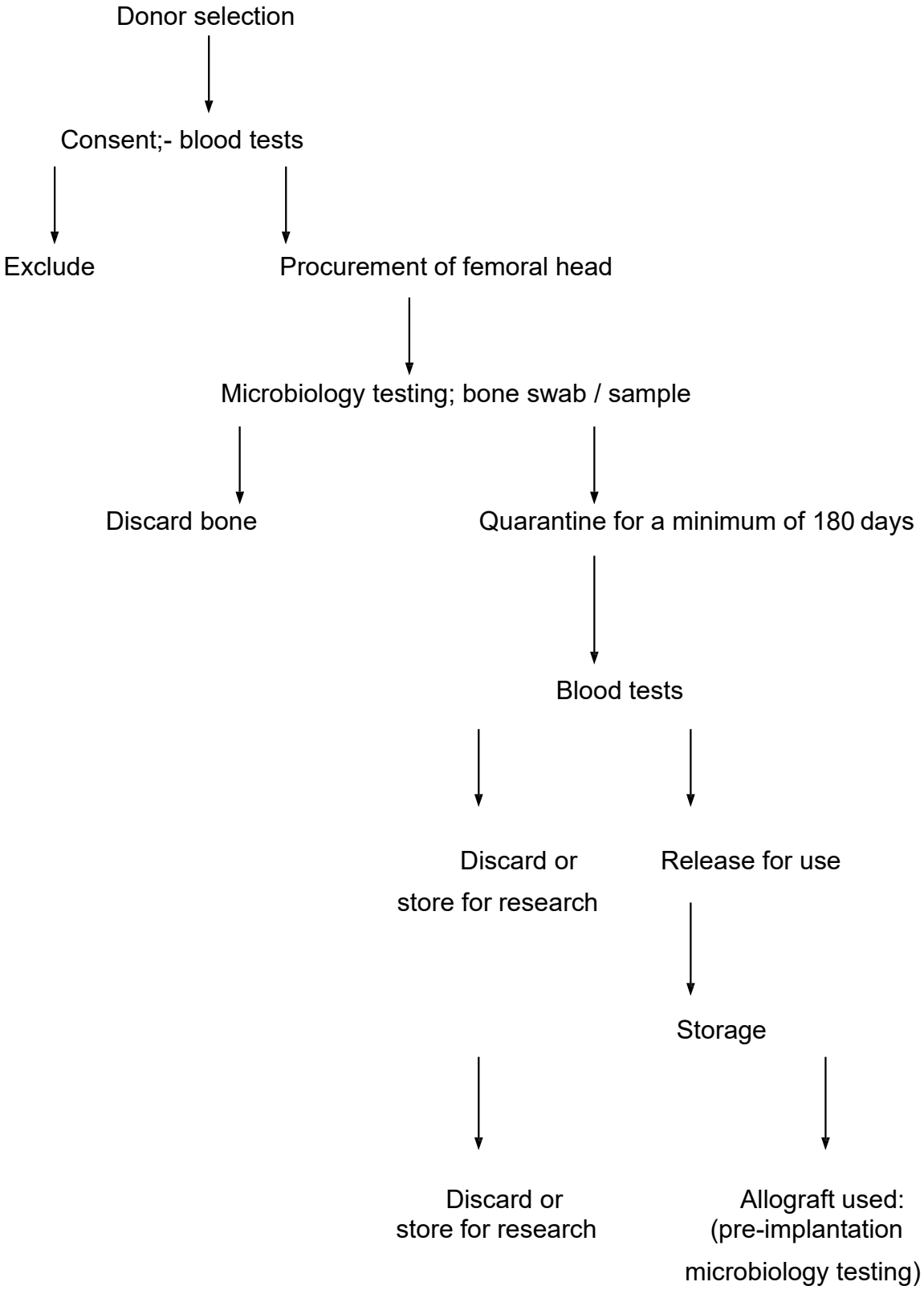
Microbiological Screening

All microbiological testing, including the timing of sampling, is instigated by the relevant Standard Operating Procedure.

The Microbiology Laboratory used by the Bone Bank is based within the New Cross Hospital site and has current Clinical Pathology Accreditation.

Standard Operating Procedures provide guidelines for the action to be taken in the event of positive testing in relation to the counselling of donors and acceptance or rejection of donors.

Process of Allograft Bone Donation



Control of Non-conforming Products

Bone may be found to be unacceptable for further processing or issue at any stage in the production process from collection to release. The Royal Wolverhampton NHS Trust Bone Bank has systems in place at every stage to record, identify and segregate the non-conforming products. Records of these products are reviewed so that trends may be observed and appropriate corrective action may be taken.

Disposal of non-conforming products are documented so that there is a positive record of disposal which completes the audit trail for that product. Disposal complies with the local Infection Prevention Policy.

The purpose of this process is to control the identification of products and services which do not conform to specified requirements and to define the procedure through which non-conforming products are reviewed and disposed of.

The DI is responsible for ensuring that the procedures are implemented. However, any member of staff receiving a complaint is responsible for ensuring that appropriate action is taken.

Procedure for the Handling of Non-conformance

Any complaint or comment which is made about the standard of service offered by the Bone Bank is a potential failure of the Quality System and should be treated as such.

A complaint or incident that occurs in any part of the production system should be dealt with as per the relevant Standard Operating Procedure and discussed as soon as practicably possible with the Designated Individual to determine the reason for the non-conformity e.g.

- near miss, unavoidable accident etc.
- actual failure of the Quality System.

Incident Reporting

Reporting of incidents is documented using the appropriate incident reporting system as part of the risk management procedures within the framework of Clinical Governance. The Trust also has a Policy which details the handling of complaints. However, all incidents and complaints are initially referred to the Designated Individual and a copy held on file.

Tissue Recall

Tissue recall, if necessary, is the responsibility of the DI but may be initiated by the Bone Bank Co-ordinator. Any action to be taken is decided on an individual risk assessment after consultation with the DI. All action is fully documented.

Discarded Tissue

Tissue may have to be discarded for a variety of reasons. However, this may not always be as a result of product failure or non-conformance (e.g. wastage because bone has been thawed and is not required for implantation). In this situation, an SOP outlines the procedures to be taken to discard bone and the relevant documentation to be completed

which complies with the local policy for Infection Prevention.

Documentation

The Royal Wolverhampton NHS Trust Bone Bank establishes and maintains documented procedures to control all documents and data handled.

This section of the manual covers all documentation which may affect the quality of the product. For example;-

- Standard Operating Procedures;
- Reference / specification documents;
- Donor records.

A system exists to review and approve documents before issue and to ensure that current documents are available.

The DI is responsible for the implementation and co-ordination of the control and changes to all documents and data.

Approval and Issue

The Bone Bank Manual and all related documents will be approved by the DI prior to their formal issue.

Formal notification of changes to documents is communicated to holders of the manual.

Document and Data Changes

Only authorised, up-to-date documents are used and any changes are reviewed and approved. Final authorisation will be made by the DI.

Document Changes and Modifications

Any changes to Standard Operating Procedures or documentation will be recorded and controlled. A full description and reason for change will be submitted by the proposer to the DI.

On receipt of the Procedure / Change Form the DI will liaise with the appropriate experts to evaluate the proposed change if necessary. Change will be implemented by the DI on receipt of the appropriate authorisations. All relevant superseded documentation will be removed from the relevant departments and destroyed.

Distribution

The Policy and Manual are available on the Trust Intranet Site.

Control of Quality Documents

The Royal Wolverhampton NHS Trust Bone Bank has procedures to maintain a product record in the form of a donor file. This file includes the following information;-

- The unique donation number allocated to each donation of bone;
- The processing record relating to the date performed, the designated person or when appropriate the names of team members performing each procedure;
- A record of the donor data for each sample of bone;

- A record of the recipient details;
- The records for each product to ensure traceability to the original donor.

The purpose of this process is to demonstrate that necessary and sufficient records have been maintained as part of the Quality System.

The procedure relates to the records used to process procedures and the retention of those records for a defined period of time after delivery of the service.

The DI is responsible for ensuring that records are collected, analysed and audited regularly.

Documentation is to be filed either by date or numerical sequence and stored in the Bone Bank offices.

All records are retained for 30 years after the expiry date of the tissue. Following this, any destruction of records will be carried out as per Trust Policy. Destruction of other records e.g. SOP's following amendment, will be by shredding.

Storage of Documents

All documents will be stored as follows:

- Bone Bank Policy and Manual

  Available via The Royal Wolverhampton NHS Trust Intranet
- Bone Bank meetings – agendas / minutes; Bone Bank Office

  Stored in date order
- Audit records; Bone Bank Office

  Stored in date order
- Donor records;

  Pre assessment clinic
  Bone Bank Office
- Theatre Ledger stored in designated area in theatre
- Training records

  Individual profile – Bone Bank Office for pre-assessment staff
  Training records for theatre staff stored in theatre
- Master copies / obsolete records

  Stored in Bone Bank Offices in date order or centrally within the Trust

Packaging and labelling

The packaging of bone tissue ensures that the quality of the product is maintained and that contamination is prevented.

Bone will be stored in specific, single-use containers which have been supplied by companies with approved Quality Standards.

Following procurement, each container is labelled (SOP BB6). The member of staff responsible for labelling the container is identifiable from the patient Donor Sheet.

The procedure for the transfer of allograft bone from the Bone Bank freezer to the operating theatre is documented. Thawed or frozen unused bone is not returned to the freezer but discarded as per the relevant Standard Operating Procedure.

Internal Audit

The purpose of audit is to verify that the Quality System is operating effectively, that the products and services meet the specified quality standards and that all procedures comply with planned requirements.

The DI is responsible for ensuring that the quality system is operating effectively by a documented annual audit programme. This will examine the documentation / procedures involved and the effectiveness of the current system. The DI is also responsible for ensuring that the audit procedures are planned and implemented.

Choice of audit personnel

Audits will be undertaken by staff who;-

- are knowledgeable of the procedures being examined;
- have been trained in the techniques required to carry out an audit;
- are independent of the task being performed.

Planning

The DI will be involved in preparing the processes to be reviewed. The audit

schedule may be changed in response to;-

- customer feedback;
- organisational or functional changes;
- management review.

Audit Methodology

- Introduction

  The auditor will make contact with the Department / Managers to explain and agree the approach to be adopted and arrange access to the evidence required.

- Investigation

  The audit investigation is based on objective criteria e.g. standards, procedures etc. which shall be systematically reviewed.

- Review of findings

On completion of the investigation the auditors will prepare a report of the findings which will include any corrective action. This will then be discussed with the DI to ensure mutual understanding and agreement. The DI is responsible for ensuring the corrective action required within an acceptable timescale and for the dissemination of information to the relevant Managers or Departments.

Corrective action will be monitored by the auditor and reviewed by those involved in Bone Bank management as part of the review of quality performance. The documentation relating to the audit process will be stored in the Bone Bank Office.

SOP: BB 1 Identification of Bone Donor

Detail

1. Surgeons will identify in advance patients who are unsuitable to donate bone. Examples are as follows:-
   i. Small or absent femoral head;
   ii. Femoral head required for autograft.
2. This will be recorded in the patient's health records.
3. All patients due to have a primary total hip replacement, who are sent a letter inviting them to attend the Orthopaedic Pre-Assessment Clinic, will also be sent an information leaflet (Appendix A). This will be instigated by clerical staff.
4. All patients attending the one stop clinic for primary total hip replacements will be given the information leaflet. This will be initiated by the pre-operative assessment nurses.
5. Suitable donors will be identified during Pre-Assessment using the exclusion criteria stated on the consent form checklist (Appendix C).

SOP: BB 2 Obtaining Consent for Bone Donation

Detail

1.0 Bone donors will be identified as per SOP BB 1 at the time of attending the orthopaedic pre-assessment clinic prior to surgery. A designated area is provided for this assessment to ensure patient confidentiality.

2.0 Following a nursing assessment, and with reference to the health records, donors will be identified using the exclusion criteria outlined in the consent form checklist (Appendix C) by the pre-assessment nurse.

3.0 The patient's capacity to consent will be established as per professional and Trust guidelines and policies.

4.0 A full explanation of the patient's involvement will then be discussed. This will include the consent, blood tests and follow-up appointments as described below.

5.0 Patients will be asked if they have received and read the information leaflet (Appendix A). If this has not occurred the patient will be offered the opportunity to read this information.

6.0 The nurse will then offer a further verbal explanation of the process of bone donation. This will include how bone is taken, stored and used (as per Appendix A).

7.0 The nurse will then outline the bone donors involvement in this process. This will include signing a consent and checklist form and undergoing extra blood tests (as per SOP BB 3 and 8).

8.0 The nurse will then ask the patient if they are willing to donate their bone. Patients are however notified that they are under no obligation to be a donor.

9.0 Patients will be notified that requests for test results must be put in writing to the Bone Bank.

10.0 Patients unwilling to donate their bone will not be questioned further.

11.0 If the patient expresses verbal agreement to become a donor, they will be asked to complete the Donor Checklist (Appendix C). If the patients refuse to disclose the required information or has experienced any of the conditions or illnesses, they may be excluded from bone donation. The nurse must also countersign the Donor Checklist to state whether the donor is safe to proceed to the next stage.

12.0 Once the Donor Checklist has been completed the patient will be asked to sign and date the consent form (Appendix B) following the addition of patient identity labels. The interviewing nurse obtaining the consent will countersign this. The patient will be offered a copy of the consent form. One copy will be filed in the patient's health records and another copy retained in the Bone Bank records.

13.0 Consent for bone donation will also be documented in the patient's health records by the pre-assessment nurse.

14.0 The pre-assessment nurse will then assign the patient with the next numerical reference number from the Bone Bank Ledger. This number will be added to the Bone Bank consent form (Appendix B) and Donor Checklist (Appendix C) and the Donor Sheet (Appendix D).

15.0 The documents will be stored in a locked filing cabinet in the pre-assessment clinic (as per SOP BB 14).

16.0 The patient will be given a Bone Bank card (Appendix K), which gives details of who to contact if their medical condition changes or if they decide not to donate their bone.

SOP: BB 3 Preparation of the Donor Blood Samples

Detail

1.0 Once written consent has been obtained blood will be taken as per the current Clinical Practice, by pre assessment staff or a phlebotomist for;-

1.1 HIV 1 and 2 Antibodies;

1.2 Hepatitis B Surface Antigen and Core Antibody;

1.3 Hepatitis C Antibody;

1.4 Syphilis;

1.5 HTLV 1.

2.0 The blood samples will be taken up to 30 days prior to donation. If surgery is delayed by over 30 days repeat blood tests are required.

3.0 Two individual samples of clotted blood will be taken. One sample will test for syphilis and HTLV1 and the second sample will screen for all the other tests listed above. Each sample will require a separate accompanying microbiology form.

4.0 The request forms relating to these samples must be completed stating Bone Bank as the address and authorised by the pre-assessment nurse.

5.0 The blood samples will then be forwarded to the microbiology laboratory at New Cross Hospital via the transport system.

SOP: BB 4 Preparation of the Donor / Documents

Detail

1.0 The pre-assessment nurse will enter the following details relating to the patient into the Bone Bank Ledger documented in sections 2 to 4.

2.0 Bone Bank reference number.

3.0 Identification label, name, address, hospital unit number, date of birth, NHS number and telephone number.

4.0 Date of admission to hospital and operation date.

5.0 The Bone Bank Ledger will be stored as per SOP BB14.

6.0 The consent, checklist and donor forms will then be stored in a locked filing cabinet in the pre-assessment clinic by the pre-assessment nurse. The pre-assessment nurse will also complete two microbiology forms, which will be stored with these documents. These forms will state Bone Bank as the address and request microscopy, culture and sensitivity on the theatre specimens for bone sample / swab.

7.0 After consent has been taken, the pre-assessment nurse will add the Bone Donor reference number to the Bone Bank Donor Sheet (Appendix D) and to the checklist.

8.0 Fill in Section A of the Donor Sheet and apply a patient identification label.

9.0 The admissions clerical staff will be notified by the pre-assessment nurse that the patient has agreed to donate bone. The patient's consent to donate bone will therefore be added to the appropriate theatre list.

10.0 Prior to admission, the pre-assessment nurse will ensure the donor and microbiology forms are stapled, in a plastic wallet, to the front of the patient's notes. These documents will accompany the patient to theatre. The pre-assessment nurse will record the patient's name and that bone bank documents have been removed from pre- assessment clinic to ensure these records are returned to the Bone Bank.

SOP: BB 5 Procedure for the return of blood sample results

Detail

1.0 All blood sample results will be returned to the Bone Bank via the ICE electronic blood requesting and report system.

2.0 The Bone Bank Co-ordinator will check all blood sample results, both paper format and electronically.

3.0 The receipt and result of the tests will then be logged in the Bone Bank Ledger and on the patient's Donor Sheet (Appendix D).

4.0 In the unlikely event of tests proving positive, the patient's Consultant and the Bone Bank's Designated Individual will be informed by the Bone Bank Co-ordinator. Patients will be notified of the results and referred for specialist medical opinion as required.

5.0 All results will be stored as per SOP BB 14.

SOP: BB 6 Procedure for the Donation of Bone during Surgery

Detail

1.0 Theatre staff will identify patients who have given consent for bone donation from the operating list and the presence of the consent and donor forms which will have been attached to the health records. It is the responsibility of the receiving trained theatre practitioner to check the Bone Donor Consent Form.

2.0 After removal of the donated bone, the allograft will be handed to the scrub practitioner by the surgeon. Two specimens will be taken by the scrub practitioner for culture and sensitivity: a surface swab and a small sample of the donated bone.

3.0 The surface bone swab will be taken using a sterile swab. The swab will be taken using the manufacturer's guidelines as indicated on the packaging by the scrub practitioner.

4.0 The bone sample will be taken by the scrub practitioner and placed in a sterile dry pot.

5.0 The bone swab and sample will be handed to the circulating theatre staff and sent to the microbiology laboratory at New Cross Hospital via the transport system using the accompanying microbiology request forms.

6.0 A trained, designated member of the theatre staff will place the donated bone in the container. The container will be labelled with the following information:

Label One

- The full name of the tissue bank;
- A description of the contents i.e. one allograft femoral head;
- The weight of the allograft;
- Patient Bone Bank reference number;
- Date of harvesting;
- Expiry date i.e. to be calculated 5 years following date of harvesting;
- Blood group / RhD type.

Label Two

- Open and handle aseptically;
- For single patient use;
- Store at -80°C;
- Human graft with the potential to transmit diseases;
- Package integrity must be checked prior to use.

A red label indicating 'NOT FOR IMPLANTATION' and the reference number are secured on the outer bone container.

The lot number for the container must be recorded on the Donor Form.

7.0 The container will then be transported and placed in the Red Bone freezer designated as 'BONE NOT FOR IMPLANTATION' within 4 hours of harvesting. The Bone is stored at -80º C for a maximum of 5 years.

7.1 Bone harvested at Cannock is sent on hospital transport to New Cross theatres bone bank. A member of theatre staff at Cannock Chase Hospital will contact a

member of staff at New Cross theatres to inform them that bone is on transport. The bone transfer form must be completed (Appendix P) to accompany the bone.

7.2 The member of staff delivering the harvested bone to New Cross theatres must hand the transport bag directly to a member of theatre staff to ensure that it is entered into the freezer in a timely manner that complies with the four-hour window from harvest to freezing.

7.3 A bone donor transfer sheet is completed with the time of harvest, and time of entry into the freezer is recorded by the theatre staff at New Cross (Appendix P). This will then be collected by the bone bank coordinator and will be repatriated with the other donor documents.

8.0 The stock sheet on the red freezer door must then be updated.

9.0 The member of the theatre personnel will then complete section B of the Donor Sheet (Appendix D).

10.0 The following bone donor details are recorded in the Theatre Bone Ledger:

- Bone Bank Reference number;
- Patient details / patient identification label;
- Date of surgery;
- Consultant;
- Weight of femoral head (g);
- Blood group and rhesus status;
- Expiry date.

SOP: BB 7 Management of the Bone Freezers

Detail

1.0 All decisions in relation to the management of the freezers will be the responsibility of the Designated Individual.

2.0 The bone freezers are kept locked.

3.0 The Theatre Bone Ledger will be kept in the Bone Bank with a record of the stock of bone.

4.0 The freezers will operate at -80ºC. The freezers have a temperature control system set, chart recorder and digital temperature display.

5.0 The temperature is continuously monitored by a chart recording mechanism. All recordings are stored in the Bone Bank. Paper chart recording rolls are changed as necessary. The start and finish date for each chart recorder roll and any other events likely to cause a change in temperature will be marked and dated on the paper roll and stored for a minimum of 10 years.

6.0 The freezers will undergo annual maintenance. Details of the maintenance schedule will be held on file in the Bone Bank and dates recorded in the freezer diary.

7.0 The paper chart recording roll is battery operated. Battery and ink replacement is recorded in the Freezer Diary.

8.0 An audible alarm will be triggered if the freezer temperature rises above -70°C for longer than 10 minutes. The remote alarm, connected to telecommunications, ensures that the switchboard operator can then notify the theatre staff and Maintenance Department.

9.0 Each freezer has an independent supply of CO_2 available which is automatically initiated if the freezer temperature rises. The CO_2 supply for each freezer is continually monitored.

10.0 Bone not yet released for issue (in quarantine) will be stored in the Red Freezer which is marked ‘BONE NOT FOR IMPLANTATION’. Bone that has been released from quarantine will be stored in the Green Freezer marked ‘BONE FOR IMPLANTATION’.

11.0 The removal or transfer of bone from either freezer is logged and recorded on the stock sheet on each freezer door. These details are kept in the Bone Bank.

12.0 Bone stored for research purposes is stored in a separate freezer which is clearly labelled.

SOP: BB 8 Recall of Patients for blood tests following donation

Detail

1.0 Re-testing of donors for blood tests shall be performed over 180 days following tissue procurement.

2.0 The timing for second blood tests for donors will be identified from the Bone Bank Ledger.

3.0 Patient details will be available from the Bone Bank Ledger.

4.0 The patient will then be contacted post.

5.0 The Bone Bank Co-ordinator will then remind the patient that their bone has been stored following surgery and before their bone can made available for implantation, repeat blood tests for HIV 1 and 2, HTLV 1 and Hepatitis B and C will need to be performed with the patient's consent. If the patient declines, the bone will be discarded as per the relevant SOP BB13 (Discarding of Stored Bone).

6.0 The patient will be informed by letter of the times that phlebotomy services can be accessed.

7.0 If the Bone Bank Co-ordinator is unable to contact the patient by letter a further letter will be sent to the patient (Appendix G) asking the patient to contact the Bone Bank. If further attempts to contact the patient fail, the relevant bone will be disposed of as per SOP BB13 (Discarding of Stored Bone).

8.0 Following verbal consent blood will be taken for:

8.1 HIV 1 and 2 antibodies;

8.2 Hepatitis B Surface Antigen and Core Antibody;

8.3 Hepatitis C Antibody;

8.4 HTLV 1.

9.0 The request form will be completed as stating that the tests have been taken over 180 days following bone donation. The samples will be forwarded to the Microbiology Laboratory at New Cross Hospital.

10.0 The blood sample results will be returned and dealt with as per SOP BB 5 (Return of blood sample results).

SOP: BB 9 Standard Operating Procedure for the movement of bone for implantation out of quarantine

Detail

1.0 Moving the bone from the Red Freezer to the Green Freezer requires two personnel involved in the Bone Bank.

2.0 These staff will be present at the Bone Bank freezer in the theatre area and have the following information available:

- Theatre Bone Ledger;
- Patient documentation;
- All blood results and microbiology bone results relating to the donor.

3.0 The following information will be checked by the two members of staff:

- Patient identification i.e. name, date of birth and Bone Bank Reference number;
- Date of donation;
- Dates that blood samples were taken;
- Results of all bloods and bone samples;
- Culture results of all bone samples to be verified electronically.

4.0 This will be recorded on the Checklist for the release of bone from quarantine (Appendix N).

5.0 Once the two members of staff agree that all of the above results are available and satisfactory the bone can then be moved from the Red to the Green freezer.

5.1 Prior to opening of freezers for transfer of bone, freezer temperatures are recorded in the bone bank diary and annotated on the freezer temperature recording rolls.

6.0 The two members of staff will then identify the bone and remove it from the Red Freezer.

7.0 The packaging will then be visually checked for signs of damage.

8.0 The red label indicating ‘BONE NOT FOR IMPLANTATION’ will be removed and a green label indicating ‘BONE FOR IMPLANTATION’ applied.

9.0 The container will then be placed in the Green Freezer indicating ‘BONE FOR IMPLANTATION’.

10.0 The transfer date will be recorded in the Theatre Bone Ledger. The stock sheet on the red and green freezer doors will then be updated.

SOP: BB 10 Information Given To Allograft Recipients

Detail

1.0 The Orthopaedic Surgeon, in the Outpatients Department, will identify potential recipients. This will be documented in the patients' health records and the waiting list card. Information leaflets are available for patients undergoing such orthopaedic surgery (Appendix H).

2.0 Prior to elective surgery the patient will be asked to attend the pre-assessment clinic. If the patient is likely to receive allograft bone the pre-assessment nurse will also offer an information leaflet (Appendix H).

SOP:BB 11 Procedure for the implantation of bone

Detail

1.0 The Theatre Bone Ledger and stock sheet on the green freezer record the bone available. Where possible, bone should be booked in advance.

2.0 When choosing bone the expiry date and size of the bone required should be considered. On the day of surgery, the required allograft will be identified from the Theatre Bone Ledger and the stock sheet on the green freezer. The bone is then identified by the reference number on the specimen container. Ideally the bone should be thawed for 1-2 hours. However, if use is uncertain it is possible to mill frozen bone. After removal from the green freezer an allograft can be left at room temperature for a maximum of 10 hours (based on local study 2009).

3.0 Bone will be removed from the freezer by 2 designated members of the theatre staff. Section A of the End-user form (Appendix L) will be completed and each member of staff must sign the Theatre Ledger. The Green Freezer stock list must also be updated.

4.0 Bone requested by Cannock or the Nuffield Hospital must be transported in a designated transport bag with an end user form. A label (Appendix M) must be completed and attached to the transport bag by the theatre staff. A security tag must be used to seal the zip on the bag. Bone must then be transported as per the relevant SOP BB18 (Transport of Allograft to Another Hospital).

5.0 Thawed, unused bone will be discarded as per the relevant SOP BB13 (Discarding of Stored Bone).

6.0 Bone to be implanted will be taken to the operating theatre by a designated member of staff, checked by the surgeon and removed from the container jar by the scrub practitioner and a surface swab taken. This specimen will be labelled with the recipient's details. The donor's reference number will also be added to the form by a designated member of the theatre staff.

7.0 A microbiology form will accompany the specimen to the Microbiology Laboratory at New Cross Hospital stating 'Bone Bank' as the return address. Culture and sensitivity tests will be requested on this specimen.

8.0 The recipient details, date of implantation and Consultant are entered into the Theatre Bone Ledger against the appropriate reference donor number. Section B of the End-user form (Appendix L) must be completed.

9.0 The Bone Bank Co-ordinator will be aware of allograft use by regular stock checks. These stock checks will take place following SOP BB 9 – Movement of bone for implantation.

SOP: BB 12 Procedure for the return of Recipient Swab Results

Detail

1.0 Recipient swab results will be returned to the Bone Bank via the internal mail system.

2.0 The Bone Bank Co-ordinator will check these results. If the test result is positive, the Bone Bank's Designated Individual and the patient's Consultant will be notified by the Bone Bank Co-ordinator. A copy of this result will be filed in the case-notes. Clinicians will liaise with medical specialists as appropriate.

3.0 The following information will then be recorded on the donor sheet:

- Recipient's name;
- Recipient's date of birth;
- Recipient's hospital number;
- Recipient's swab result;
- Lab reference number of above result;
- Date of results / surgery.

4.0 The Bone Bank Co-ordinator will then file the microbiology result in the recipient's health records.

5.0 All documents relating to the donor's and the recipient's microbiology result will be stored as per SOP BB 14 (Storage of Documents).

SOP: BB 13 Procedure for the discarding of stored bone from the freezer

Detail

1.0 Bone will be discarded in the presence of two members of the Bone Bank Staff.

2.0 All relevant documents will be available:

- Donor sheet;
- Donor consent form and checklist;
- All bone bank microbiology results;
- Bone Bank Ledger;
- Theatre Ledger.

3.0 The identity of the patient and the bone sample will be cross-referenced in the above documents by two members of staff.

4.0 The bone will then be identified and removed from the freezer.

5.0 The reason for bone being discarded will be recorded on the donor sheet. The two members of staff will sign and their names to authorise that the bone has been discarded. Alternatively, if the patient has given written consent suitable bone may be stored in the research freezer.

6.0 The bone and containers will then be disposed of as per the local Prevention of Infection Policy or retained in the quarantine freezer for research purposes.

7.0 The patient's documents will then be stored as per SOP BB 14 (Storage of Documents).

8.0 If bone has to be discarded for any unforeseen reason by theatre staff e.g. damage to the packaging or labelling etc. it is the responsibility of the member of staff removing bone from the freezer to notify the Theatre Coordinator. The Bone Bank Co-ordinator must then be informed to ensure that the relevant documentation is completed.

SOP: BB 14 Procedure for the storage of Bone Bank Documents

Detail

1.0 This SOP relates to the storage of all Bone Bank patient documentation and ledgers.

2.0 Patient records will be held in separate, individual files.

3.0 Donor documentation will only be released from the Bone Bank when the patient is admitted for hip replacement surgery. It is the responsibility of the Bone Bank staff to ensure that these documents are returned following surgery.

4.0 All patient records will be stored for a minimum of 30 years after the expiry date of the tissue irrespective of whether the Bone Bank activities have terminated.

5.0 Any destruction of records will be carried out under the Trust Preservation, Retention and Destruction of Records Policy.

SOP: BB 15 Change of Procedure or Documentation Detail

1.0 Any member of staff involved in the process of bone donation may request a change of procedure or documentation. This may also be carried out within the review or audit process.

2.0 Requests for changes in procedure or documentation must be submitted in writing to the Designated Individual using the appropriate form (Appendix I).

3.0 The Designated Individual will then liaise with the appropriate individuals before authorising the change. The Bone Bank Co-ordinator is responsible for amending documentation and circulating it to the appropriate areas.

4.0 All amendments must be recorded on an amendment form (Appendix J).

SOP: BB 16 Dealing with Complaints, Incidents and Risks

Detail

1.0 Any complaints, incidents or risks occurring must be dealt with as per the local Complaint, Incident or Risk Management Policy and the Designated Individual notified as soon as practicably possible.

2.0 An Incident Report Form must be completed electronically for each incident, by the member of staff involved.

3.0 The incident is then dealt with as per the local Risk Management Reporting system.

4.0 Risk assessments are carried out for key activities and reviewed at least annually.

5.0 All complaints and incidents are monitored by the Designated Individual and action taken as required.

6.0 All complaints, incidents and risks will be reviewed at the Bone Bank Meetings.

7.0 Amber or red incidents must be reported to the Human Tissue Authority by the Designated Individual within 24 hours. These might be a serious adverse event e.g. fire or theft or a serious adverse reaction, e.g. an acute, serious related illness of the recipient following implantation. In the absence of the Designated Individual the duty of reporting to the HTA will be delegated to the Bone Bank Co-ordinator, Pre-operative Assessment Co-ordinator or the Theatre Co-ordinator.

The contact details for the HTA are:

Human Tissue Authority
151 Buckingham Palace Road
Victoria
London
SW1W 9SZ

Telephone 020 7269 1900

SOP: BB 17 Procurement of Autograft that is to be stored

Detail

1.0 Patients that require bone to be procured for autograft use will be identified from the health records.

2.0 At the pre-assessment appointment an assessment of the patient's medical / behavioural history is not required. However, the minimum set of biological blood tests must be performed as per SOP BB 3 (Preparation of Donor Blood Samples).

3.0 Consent will be taken using the Consent Form for Autograft (Appendix O).

4.0 The Donor sheet will be prepared as per SOP BB 4 (Preparation of Donor Documents). The nurse entering the details into the Bone Bank Ledger will add that the bone is for autograft use.

5.0 The admissions clerical staff will be notified by the pre-assessment nurse that the patient is an autograft donor. This information will then be added to the theatre list.

6.0 The Donor Sheet and microbiology forms will accompany the patient to theatre.

7.0 Bone will be harvested as per SOP BB 6 (Bone Donation During Surgery). The container will also be labelled with a yellow sticker stating: AUTOGRAFT FOR THE SOLE USE OF……

8.0 The member of theatre staff will then write the patient's name and unit number on this sticker. The bone will be documented for auto graft use in the Theatre Ledger.

9.0 The bone will be stored and remain in the Red Freezer, segregated from bone available to be used, until it is required. The auto graft stock sheet on the red freezer door must then be updated.

10.0 If the bone is stored for over 180 days the minimum biological blood tests will be performed as per the relevant SOP BB8 (Recall of Patients For Second Blood Tests).

SOP: BB 18 Transport of allograft to another hospital

Detail

1.0 Where possible, bone should be booked in advance.

2.0 The allograft will be removed from the green freezer as per the relevant SOP BB18 (Transport of Allograft to Another Hospital).

3.0 The allograft with an end-user form must be transported in a designated bag immediately. A label (Appendix M) must be completed and attached to the transport bag by theatre staff. A security tag must be used to seal the zip on the transport bag.

4.0 Transport must be arranged by the receiving hospital (if the Nuffield) or placed on Hospital transport between New Cross and Cannock sites.

5.0 The allograft removed from the bone freezer and placed at room temperature must be implanted within 10 hours (based on local study 2009).

SOP: BB 19 Recall procedure for allograft released for use

Detail

1.0 This SOP should be used in the event of the need for a recall e.g. quarantine bone being incorrectly released for use or a bone container found to be unsterile.

2.0 In the event that an allograft has to be recalled, the initial responsibility is with the member of staff at New Cross Hospital discovering the problem.

3.0 Immediate action must be taken to inform the end user. The surgeon due to implant the bone must be informed.

4.0 If appropriate, transport should be arranged by New Cross Hospital to return the allograft to Wolverhampton Bone Bank.

5.0 A senior member of the Bone Bank Designated Individual or Bone Bank Co-ordinators) must be informed. A decision will then be made as to whether the allograft should be tested, retained for research purposes or appropriately disposed of.

6.0 If a senior member of staff cannot be contacted the allograft must be appropriately disposed of as per SOP BB13 (Discarding Of Stored Bone).

7.0 The end user form must be completed to record that the allograft has not been used and the reason why.

8.0 An incident form must be completed as per SOP BB16 (Dealing With Complaints, Incidents and Risks) and the HTA informed, if appropriate, within 24 hours by the Designated Individual. In the absence of the Designated Individual the duty of reporting to the HTA will be delegated to either the Bone Bank Co-ordinator or the Theatre Co-ordinator.
The contact details for the HTA are:

Human Tissue Authority
151 Buckingham Palace Road
Victoria
London
SW1W 9SZ

Telephone 020 7269 1900

SOP: BB 20 Termination of Bone Bank Activities

Detail

1.0 Termination of activities is likely to occur either as a result of planned closure or a major adverse event.

2.0 A planned closure will occur with agreement of the Designated Individual and Licence Holder. Bone donation will then cease and existing bone stored in the bone bank will either be processed and used locally or be transferred to another licensed establishment. The records and raw data would be transferred with the bone.

Prior to transfer to another tissue establishment an audit will be carried out to ensure any discrepancies are resolved. Records of the Designated Individual and any third parties will be included.

3.0 Bone in the research freezer will be disposed of as per the relevant SOP BB13 (Discarding of Stored Bone).

4.0 Termination of activities as a result of a sufficiently major adverse event would not allow continued use or processing of bone or transfer to another licensed establishment. In this situation all bone would be disposed of as per SOP BB13 (Discarding of Stored Bone).

5.0 In the event of termination of activities the Designated Individual would notify the HTA and include a copy of any audit reports.

6.0 All records would be retained as per the relevant SOP BB14 (Storage of Documents).

SOP: BB 21 Procedure for freezer failure

Detail

1.0 In the event of a freezer failure, the alarm will be activated within the hospital switchboard, who will then contact the orthopaedic theatre office.

2.0 Bone in the affected freezer will need to be moved into the empty standby freezer.

3.0 Bone contained in the freezer will be identified by the reference numbers logged on the outside of the affected freezer.

4.0 Each bone reference number needs to be accounted for on removal from the affected freezer by two members of theatre staff and must also be accounted for on entry to the standby freezer.

5.0 Freezer failure will then need reporting to the Theatre coordinator and appropriate action taken (freezer repair or replacement).