

The Tumour Bank

STANDARD OPERATING PROCEDURES

KIDS RESEARCH INSTITUTE, THE SYDNEY CHILDREN'S HOSPITALS NETWORK

Revised: December 2013



The Sydney
children's
Hospitals Network

care, advocacy, research, education

CONTENTS

1.0.....	3
ADMINISTRATION.....	3
2.0.....	4
PARTICIPANT AND RECRUITMENT MANGEMENT	4
02.01 Notification of Declined Consent	5
02.02 Patient Consent Information Flow	8
02.03 Patient Consenting Guideline.....	13
3.0.....	18
RECORDS AND DOCUMENTATION MANAGEMENT	18
03.01 Records and Documentation.....	19
03.02 Collation Of Clinical Data For Tumour Bank Applications	23
4.0.....	25
FACILITIES MANAGEMENT/ OPERATION	25
04.01 Tumour bank -80°C freezer failure procedure	26
04.02 Downloading -80°C Freezer Temperature Data From The Junior Escort Logger™	29
5.0.....	32
MATERIALS AND DOCUMENTATION	32
05.01 Sample Collection.....	33
05.02 Bone Marrow Aspirate and Trephine Sample Processing.....	37
05.03 Blood sample processing.....	40
05.04 Tissue Sample Collection and Processing.....	42
05.05 Constructing Tissue Microarrays.....	44
05.06 Obtaining Samples from Long Term Follow Up Patients.....	47
05.07 Obtaining Patient Peripheral Blood Samples from the Clinical Haematology Department	49
05.08 Banking Fresh Frozen Tissue (Tumour)	52
05.09 Collection of tissue from patients with neurofibromatosis and related conditions for storage in the Tumour Bank.....	55
05.10 DNA Extraction from OG-575 Saliva Self-Collection Kit	60
05.11 DNA Quantification Using Nanodrop 2000	63
05.12 DNA Quality Assessment	66
6.0.....	70
MATERIAL RELEASE	70
06.01 Responding to Requests for Specimens from the Children’s Hospital at Westmead Tumour Bank	71
06.02 Shipping and Transporting Samples to Researchers (as Dangerous Goods).....	93
06.03 TNT Shipment of Biological Samples on Dry Ice	97
7.0.....	100

PROJECT SPECIFIC OPERATIONS	100
07.01 Bone Marrow Sample Collection and Processing for Project Numbers 28 and 62	101
07.02 Processing Blood Samples for Project #57: C-Circle Assay and Alternative Lengthening of Telomeres (ALT) IN Cancer	105
8.0	109
EQUIPMENT USE.....	109
08.01 Scanscope Virtual Microscope Use	110
08.02 Immunohistochemistry Staining Using the Leica Bond-Max™ System	112

1.0

ADMINISTRATION

2.0

PARTICIPANT AND RECRUITMENT MANGEMENT

02.01 Notification of Declined Consent

Document Number: TB 02.01 Version: 002	Issue Date: 09/12/2013
Author: Oksana Markovych Title: Clinical Research Associate	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
01/08/2011	New Document		
11/10/2012	Annual Review	02.01.001	AR
09/12/2013	Annual review – notify Oncology CRA team of patients that have declined consent (Section 5 d and e); Proforma electronic location (Section 4)	02.01.002	OM

1. PURPOSE

The purpose of this document is to outline standardised procedures to follow when consent is declined for Tumour Bank (TB) in person, by telephone, by letter or by message via a third party.

2. SCOPE

This protocol covers all instances when consent is declined by a patient or the parent of a patient under the age of 18.

3. RESPONSIBILITIES

Any TB staff who are involved in taking receipt of information of a patient of Children's Hospital at Westmead (CHW) declining to consent to TB must ensure that this protocol is adhered to.

4. MATERIALS, EQUIPMENT AND FORMS

- Consent form, if relevant (http://chw.schn.health.nsw.gov.au/ou/oncology_research/resources/forms/consent_forms)
- 'Consent declined' proforma (Appendix 1) is located in G:\data\TumourB\Tumour CRA docs\Consents

5. METHOD

- a. Information regarding the decline of consent for a TB patient is received via the following routes:
 - “Consent declined” box checked on consent form
 - In person via the TB Clinical Research Associate
 - Via a telephone call from the patient or the patient’s parent/guardian
 - Via a telephone or pager message from a third party (eg. Haematology Staff)
- b. For methods other than written decline using the TB Consent form, TB staff must complete the ‘Consent declined’ proforma (Appendix 1).
- c. Place the completed proforma in the Administration Officer’s in tray for subsequent data entry and filing.
- d. On receipt of notification of a patient declining consent to TB, an email should be sent to:
 - The TB Project Officer (to remove any samples from the TB -80°C freezer)
 - The TB Administration Officer (to remove all associated clinical data from Biogenix, except the following data:
 - MRN
 - Patient name
 - Consent Status
 - Comments: discarded on [date]
 - ‘CC’ the TB CRA and Oncology CRA team
- e. Administration Officer will update “Consent Declined” patient list located in G:\data\TumourB\Tumour CRA docs\Lists

Note 1: See TB SOP 02.02 for a definition of ‘Consent Declined’ patients.

6. SAFETY

- Not applicable

7. APPENDIX

7.1 Appendix 1

the
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NOTIFICATION OF DECLINED CONSENT FOR TUMOUR BANK

NAME OF STUDY: *The Children's Hospital at Westmead, Tumour Bank*

NAMES OF INVESTIGATORS: Dr Luciano Dalla-Pozza, Dr Daniel Catchpoole, Dr Albert Chetcuti, Ms Amanda Rush

Method of notification:

- ☐ In person (via Tumour Bank Clinical Research Associate)
- ☐ Via telephone call from patient or patient's parent/guardian
- ☐ Via telephone call from patient or patient's parent/guardian

Comment:

NAME OF PATIENT:(Please print)

MRN OF PATIENT:(If known)

DOB OF PATIENT:(If known)

DATE OF DECLINE:.....

TUMOUR BANK STAFF MEMBER COMPLETING THIS FORM:

Emailed:

- ☐ Tumour Bank Project Officer
- ☐ Tumour Bank Database Administrator
- ☐ Tumour Bank Clinical Research Associate

02.02 Patient Consent Information Flow

Document Number: TB 02.02 Version: 005	Issue Date: 09/12/2013
Author: Oksana Markovych Title: Clinical Research Associate	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
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24/08/2010	New Document		
01/12/2011	Annual Review	02.02.001	AR
09/02/2012	Updates to consent categories	02.02.002	AR
10/10/2012	Addition of "Over 18 written consent"	02.02.003	AR
09/12/2013	Annual Review – addition of Powerchart set-up procedures in "5.1 Consenting" method	02.02.004	OM

1 PURPOSE

The purpose of this document is to outline a standardised procedure to follow when consent is obtained from patients at CHW, as well as via telephone and mail. In addition, consent definitions used in the Tumour Bank (TB) database are described.

2 SCOPE

This protocol covers the consenting process for all patients at CHW whose samples are stored at the TB. In accordance with the New South Wales (NSW) Human Tissue Act and the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Research Involving Humans, donations of human tissue must have written consent associated with them prior to being used for research purposes.

3 RESPONSIBILITIES

Any TB staff member who may be approaching oncology or non-oncology Children's Hospital at Westmead (CHW) patients for consenting in person, via telephone or mail for sample donation to the TB must ensure that these protocols are adhered to at all times during the process. In addition, the consent definitions are relevant to the TB Administration Officer.

4 MATERIALS, EQUIPMENT AND FORMS

TB consent information pack:

- TB information sheet and consent form
(http://chw.schn.health.nsw.gov.au/ou/oncology_research/resources/forms/consent_forms/cancer_and_leukaemia.pdf)
- TB newsletter (latest version)
- Reply paid envelope (ensure TB details are added)
- TB business card
- TB letter (G:\data\TumourB\Tumour CRA docs\Letters)

Appendix 1: Flow diagram of consenting process

Appendix 2: Timeline of changes to TB database

5 METHOD

5.1 Consenting

- The TB Clinical Research Associate (CRA) will check Powerchart each afternoon for any patients that are inpatients in Camperdown and Variety Wards, outlying wards or visiting the Oncology Treatment Centre (OTC) on the following day, and have not consented to TB.
- To view daily inpatient lists for the wards, initially set up individual ward tabs in Powerchart; this can subsequently be clicked on a daily basis to view a list of current inpatients.
- Follow the set-up procedure below:
 - Click on “Patient List” tab in Powerchart toolbar
 - Click on “List Maintenance” icon depicted as a wrench
 - “Modify Patient Lists” window will pop-up; click “New”
 - In “Patient List Type” window select “Location” and click “Next”
 - Expand “Locations” folder in the right-hand side field
 - Scroll down to “Royal Alexandra Hospital for Children” and expand the directory, then expand “Royal Alexandra Hospital” sub-directory to view locations
 - Select the location of interest e.g. “Camperdown Ward” by ticking the box next to it and click “Finish”
 - The location will appear in the “Available Lists” field on the left-hand side of the “Modify Patient Lists” window; select this location and move it to the “Active Lists” field by clicking on the blue arrow button
 - Click “OK”; a new tab will appear on your Powerchart screen
- To generate daily OTC visitors list:
 - Click on “Scheduling Appointment Book” tab in Powerchart toolbar
 - In “Scheduling: Scheduling Appointment” window click on “Appointment Report” icon depicted as a blue/yellow report
 - Click on “Location” tab in the “Schedule Report” window
 - Make the following field selections: “Report = Standard Appointment List”; “Location Type = Ambulatory”; “Location = Oncology OPD L2” and then select the appropriate appointment date to generate a list of patients coming to the OTC on that day
 - Click “View” to display “Schedule Report”
 - “Save As” the report in your personal directory and print lists as required.
- Cross check these lists against consent status in Biogenix, and approach those parents in person who have not consented, utilizing an interpreter where necessary. Mention the following during the consenting process:
 - introduction of self;
 - brief explanation of what the TB is;
 - what the TB does with samples;
 - researcher’s applications are vetted by ethics committee;
 - samples are de-identified;
 - research is voluntary- care in hospital is not affected either way (refer to TB SOP 02.03- Patient Consenting Guideline).
- If patients are not seen in person in the hospital, a letter is an alternative method of consenting. Approved letters are stored at
G:\data\TumourB\Tumour CRA docs\Letters\Current letter templates 020913

- g. The letter is followed up with a telephone call approximately one week later.
- h. Patients over the age of 18 must give consent themselves.

5.2 Consent Classification

Consents are classified into the following categories in the Biogenix database:

- a. Consent pending: Any patient of CHW (oncology or non-oncology), who may or may not have specimens available to the TB, and who has not been approached by the TB by each of the following three methods a) letter b) in person c) telephone call, or has been approached by all three methods and has not consented; however six months since last contact has not passed.
- b. Written consent: Any patient of CHW (oncology or non-oncology), who may or may not have specimens available to the TB, for whom the TB holds a signed *Consent Form for Tumour Bank*, irrespective of version number.
- c. Consent declined: Any patient of CHW (oncology or non-oncology), who has been approached by any method regarding consent for the TB, and has indicated that they do not wish/do not wish for their child to participate.
- d. Consent withdrawn: Any patient of CHW (oncology or non-oncology), who may or may not have specimens available to the TB, for whom the TB held a signed *Consent Form for Tumour Bank*, irrespective of version number, and subsequently indicated that they do not wish /do not wish for their child to participate.
- e. Consent not pursued: Any patient of CHW (oncology or non-oncology), who may or may not have specimens available to the TB, and has not been approached by the TB regarding consent due to perceived religious or cultural beliefs, personal reasons, or under instructions from their Senior Medical Officer.
- f. Passively declined: Any patient of CHW (oncology or non-oncology), who may or may not have specimens available to the TB, and who has been approached by the TB by each of the following three methods a) letter b) in person c) telephone call, and has not signed a *Consent Form for Tumour Bank* within six months of last contact.
- g. Lost to Follow Up: Any patient of CHW (oncology or non-oncology), who may or may not have specimens available to the Tumour Bank, and who is no longer contactable due to ethical or logistical reasons.
- h. HTA Exempt (incl. OT Consent): Any patient of CHW (oncology or non-oncology), who has paraffin blocks as their sole sample type in Biogenix eg. for TMAs or microscope slide sections, or who had samples collected prior to 1st November 2003. The Human Tissue Act does not operate so as to prohibit any tissue removed lawfully for medical purposes and stored in the form of a block to be used for scientific purposes; furthermore any tissue removed for medical or scientific purposes prior to the 1st November 2003 did not require specific patient/parent consent. Parents prior to 1st November 2003 may have signed an *Operating Theatre Consent* or *Children's Hospital at Westmead Admissions Form* that included consenting to residual samples being used for research purposes.
- i. >1 Consent status: Any patient of CHW (oncology or non-oncology), who has had changing consent statuses over time. The types of consent will be specified in the comments in Biogenix. For example, a participant may have samples that were HTA-Exempt (incl. OT Consent) until 1st November 2003 and then Written Consent was obtained for samples after that date.
- j. Over 18 written consent: Any patient of CHW (oncology or non-oncology), who may or may not have specimens available to the TB, for whom the TB holds a signed *Consent Form for Tumour Bank*, irrespective of version number and who has legally signed the consent form themselves, because they are over the age of 18 years.

Refer to Appendix 1 for a flow chart of the consenting process.

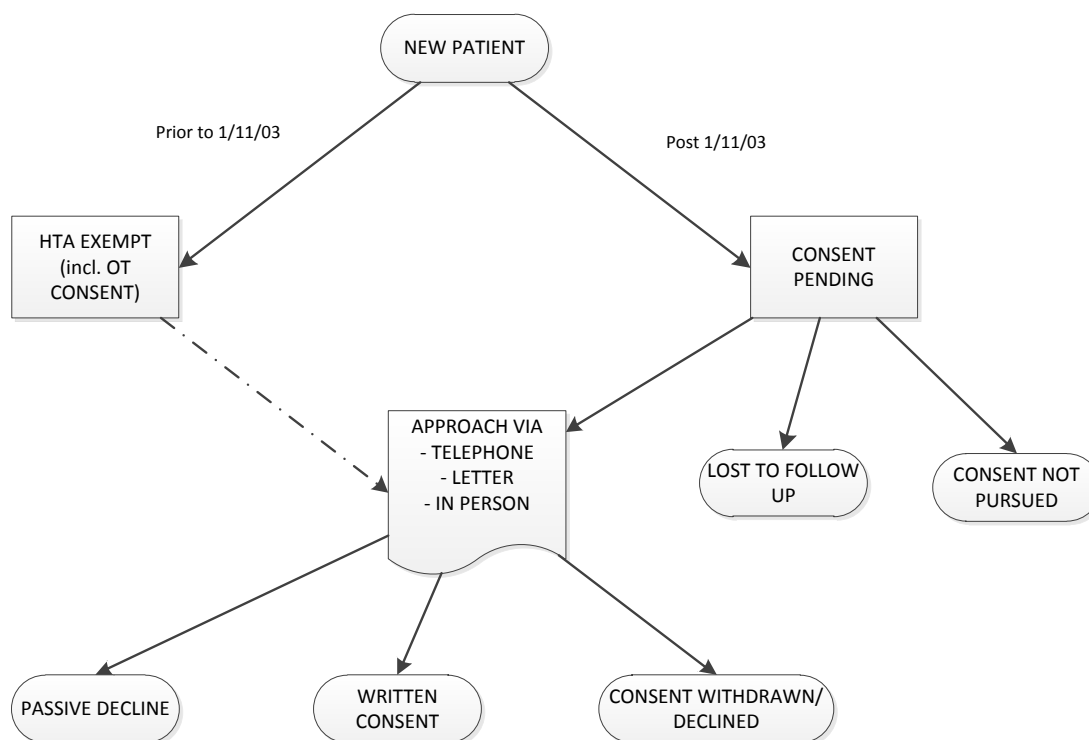
Refer to Appendix 2 for a timeline of changes to consent categories.

6 SAFETY

- Not applicable

7 APPENDIX
7.1 Appendix 1

Flow diagram of consenting process



7.2 Appendix 2

Timeline of changes to TB database (Consent Only)

Date	Amendment
09/08/10	<ol style="list-style-type: none"> Additional consent categories added to Biogenix <ul style="list-style-type: none"> 'Passive decline' 'Lost to follow up' All consent categories defined <p>Refer to SOP # 13 for definitions of all consent categories.</p>
20/10/11	<ol style="list-style-type: none"> Patients with paraffin blocks only had their consent status changed to 'HTA-Exempt' <p>Refer to SOP # 13 for definition of 'HTA Exempt'</p>
16/11/11	<ol style="list-style-type: none"> Samples between 1/11/03 and 1/1/06 sorted into three categories depending on rarity of sample and size of sample. Samples were divided into: <ul style="list-style-type: none"> 'Lost to Follow Up' 'Consent Pending' the samples were discarded, or moved to Box 401 in Histopathology (samples that do not have consent and cannot be used for research).
09/02/12	<ol style="list-style-type: none"> Remove category 'OT Consent' from Biogenix, and change 'HTA-Exempt' category to 'HTA-Exempt (incl. OT consent)' to include all samples prior to 1/11/03. Patients with all of their samples collected prior to 1/11/03 will be changed to 'HTA-Exempt (incl. OT consent)'; patients with samples that traverse this time will be coded '>1 Consent status'. <p>Refer to SOP # 13 Version 1.3 for expanded definition of 'HTA-Exempt (incl. OT consent)'.</p> <ol style="list-style-type: none"> Addition of category '>1 Consent status' to cover those participants with changing consent statuses. <p>NB. Patients whose consent statuses changed from 'OT consent' to '>1 consent status' because some of their samples were collected prior to 1/11/03, and some were collected post 1/11/03 (but prior to 1/1/06) appeared on the consent pending list and required sorting into 4 categories as per 16/11/11 point above ('Lost to Follow Up', 'Consent Pending', 'Discard' or 'Box 401').</p>

02.03 Patient Consenting Guideline

Document Number: TB 02.03 Version: 004	Issue Date: 09/12/2013
Author: Oksana Markovych Title: Clinical Research Associate	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
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21/09/2010	New Document		
01/12/2011	Annual Review	02.03.001	AR
10/10/2012	Annual Review	02.03.002	AR
09/12/2013	Annual Review – consent new patients 7 days post diagnosis (Section 5.2); consent patients in OTC Monday – Friday; utilise CAFAT interpreter (Section 5.5)	02.03.003	OM

1. PURPOSE

The purpose of this document is to outline a standardised procedure to follow when explaining and potentially obtaining consent from inpatients at Children's Hospital at Westmead (CHW), as well as via telephone and mail.

2. SCOPE

This protocol covers the consenting process for all patients at CHW whose samples are stored at the Tumour Bank (TB). In accordance with the New South Wales (NSW) Human Tissue Act and the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Research Involving Humans, donations of human tissue must have written consent associated with them prior to being used for research purposes.

3. RESPONSIBILITIES

This procedure is relevant to any TB staff member at CHW who may be approaching oncology or non-oncology CHW patients for consenting in person, via telephone or mail for sample donation to the TB. In addition, this procedure is relevant to Oncology Fellows who undertake TB consenting.

4. MATERIALS, EQUIPMENT AND FORMS

TB consent information pack:

- TB information sheet and consent form
(http://chw.schn.health.nsw.gov.au/ou/oncology_research/resources/forms/consent_forms/cancer_and_leukaemia.pdf)
- TB newsletter (latest version)
- Reply paid envelope (ensure TB details are added)
- TB business card
- TB letter (G:\data\TumourB\Tumour CRA docs\Letters\Current letter templates 020913)

TB SOP 02.02

Appendix 1: Flow chart of Tumour Bank consenting process

5. METHOD

Upon ascertaining a list of patients to be approached, the TB staff member and Oncology Fellow should be cognisant of the following when consenting.

5.1 Basic Information to Convey

- What is the TB?
- Why do we do research?
- Who may eventually use the samples
- How long the TB has been running for (approximately 12 years)
- What samples we store
- That the specimens are de-identified
- That researchers must apply to an ethics committee before samples are released
- That there are no needles or extra procedures
- That donation is voluntary and whether the parent/guardian consents or not makes no difference to their child's care in the hospital
- That families have a freedom to withdraw samples or retract consent at any time

5.2 Consenting in Camperdown and Outlying Wards

- Wait at least 7 days from initial diagnosis for families to settle into the ward and process their child's diagnosis
- Ask nurses at the ward front desk prior to approaching patients. This serves a number of purposes:
 - Nurses are aware of who you are and your purpose of visit
 - Patients may have been moved from the bed allocation listed on Powerchart
 - Nurses can inform you whether a parent or guardian is present at the time
 - Nurses can inform you whether the family is in a suitable emotional state to receive information about research
 - Nurses can inform you whether the family can speak fluent English
- Make use of the anti-bacterial hand rub both at the entrance to each ward, and at the entrance to each room
- Upon reaching the bedside, introduce self and explain that you are from the research arm of oncology
- Ask whether it is a good time to talk about research
- If so, explain the basic consent process as above
- Ask if the parent/guardian has any questions
- During the consenting process, use specific examples of their child's disease
- Use the child's name when talking about them
- Gauge the parent/guardian's emotional reactions when talking to them, and if necessary return at a more appropriate time
- If families are not ready to sign consent at the first visit, advise the parent/guardian to discuss the consent with their family and/or friends, then advise that you will return in a few days to check whether they have any further questions. Alternatively they can leave the form at the front desk of the Oncology Treatment Centre.

5.3 Upon Consenting in Wards

- Remove one of the small stickers with the child's identifying information (name, DOB, MRN) from the child's chart kept in the nurse's station
- Place at the top of the consent form
- Give the form to the TB Administration Officer for data entry into TB Database

5.4 Non-English Speaking Families

- Ascertain time periods that interpreters are available in the wards by asking the ward clerk/nurse in charge or looking on the print out at the front desk of each ward
- Ensure that the parent/guardian that you wish to speak to is available
- Liaise with other utilisers of the interpreter to ensure a suitable time for TB purposes within the time period. Tumour Banking explanations should take approximately 15 minutes per patient.
- If there is no interpreter booked and one is required urgently, book one via the Health Care Interpreter Service (Ph: 9912 3800; Name: CH Cancer Research Unit L4)
- Accompany the interpreter to the child's room, introduce yourself to the parent/guardian and ask whether they would mind coming to the interview room to talk about research; alternatively conduct the interview at bedside.
- Explain the TB as per *Consenting in Camperdown and outlying wards*, but with a pause every sentence or two to allow the interpreter to speak.

5.5 Consenting in the Oncology Treatment Centre

- Check daily the appointments scheduling for OTC using Powerchart as per the instructions outlined in TB SOP 02.02 5.1 b.
- Cross check this list as per TB SOP 02.02 5.1 e Attend OTC clinic daily to consent patients as required. Refer to the Patient Appointment List for scheduled appointment times TB SOP 02.02.5.1 d Liaise with OTC ward clerks regarding patient arrivals on the day of clinic. Provide ward clerks with the list of patients you are planning to see. The ward clerks can then page the TB CRA when these patients arrive.
- Utilising the check-in notice board at the front desk, as well as information from the ward clerks, ascertain which parents/guardians are available to speak to
 - The ward clerks can also inform you whether the family is in a suitable emotional state to receive information about research
 - The ward clerks can also inform you whether the family can speak fluent English
 - For French-speaking CAFAT patients utilise CAFAT interpreter who accompanies these patients on the day of clinic. (CAFAT interpreter can be paged on 6802)
- Call out the child's name, or ask the ward clerks to point out where the parents/guardian are seated
- Introduce self and explain that you are from the research arm of oncology
- Ask whether it is a good time to talk about research
- If so, explain the basic consent process as above
- Ask if the parent/guardian has any questions
- During this process, use specific examples of their child's disease
- Use the child's name when talking about them
- Gauge the parent/guardian's emotional reactions when talking to them, and if necessary return at a more appropriate time
- Advise the parent/guardian to discuss the consent with their family and/or friends
- Advise the parent/guardian that they can post the consent form using the reply paid envelope provided, or if they wish, they can leave the form with Donna in the Oncology Treatment Centre.

5.6 Letter/telephone Calls

- Divide the list of patients who require consenting into those who were diagnosed with a non-malignant condition, and those with a malignant condition
- Cross check the child's name, the parent/guardian name/s, types of sample/s against Biogenix and Powerchart
- Write standard letters (approved by HREC), completing details where necessary
- Send in batches of approximately 8
- Letters are followed up with a telephone call approximately one week later
- Patients over the age of 18 must give consent themselves
- Powerchart indicates under the 'Patient demographics' tab whether a family speaks English; if not, a letter should not be sent.

5.7 Recording consent

- When consents are returned to the TB CRA, the patient's name, DOB and MRN are written at the top of the form for identification by the Medical Records Department.
- All letters sent and interviews undertaken are recorded in an Excel sheet (G:\data\TumourB\Tumour CRA docs\Lists\Consenting), including whether the letter or interview resulted in a successful consent or not.
- The TB Administration Officer records the patient's consent status in the TB Database.

See Appendix 1 for a flow chart of the TB consenting process.

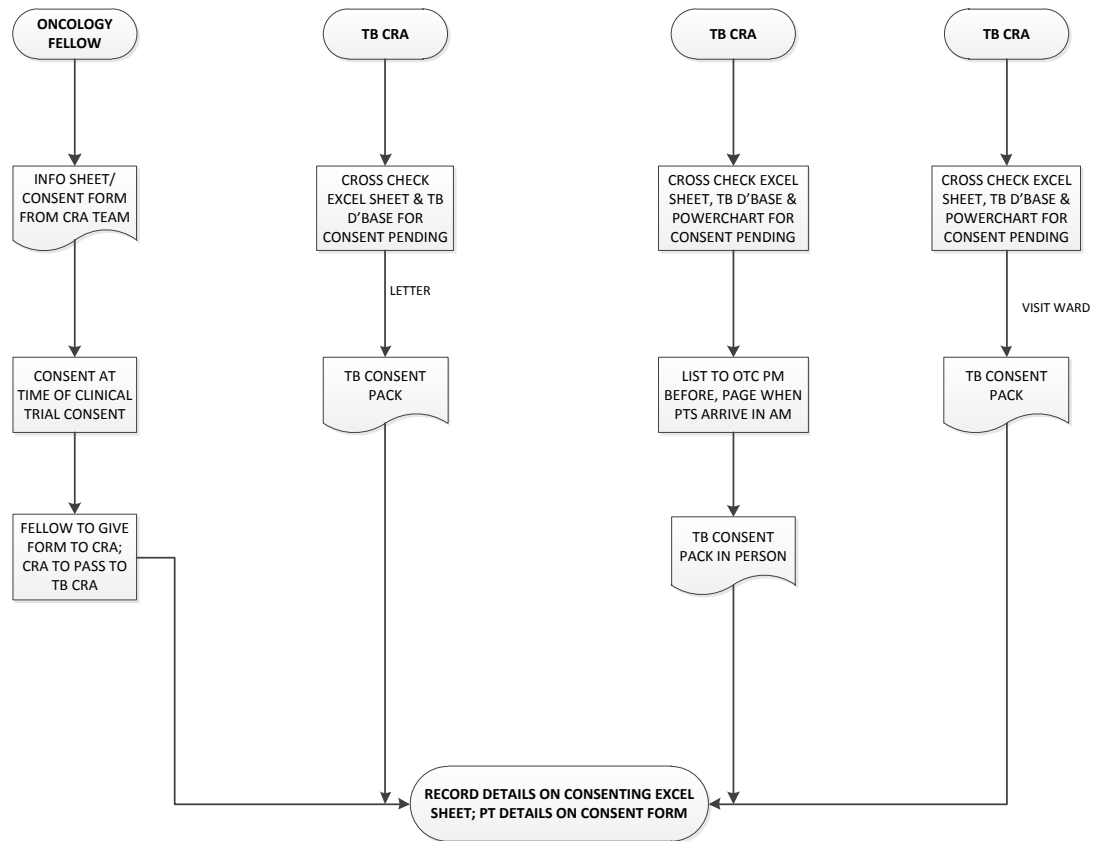
6. SAFETY

- Not applicable

7. APPENDIX

7.1 Appendix 1 The TB Consenting Process

The TB consenting process



3.0

RECORDS AND DOCUMENTATION MANAGEMENT

03.01 Records and Documentation

Document Number: TB 03.01 Version: 004	Issue Date: 16/09/2012
Author: Namrata Nath Title: Administration Officer Signature Date	Approved by: Daniel Catchpoole Title: Head of Tumour Bank Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
01/05/2009	New Document		
01/12/2011	Annual Review	03.01.001	KJ
19/09/2012	Annual Review	03.01.002	AR
16/9/2013	Annual Review – Amended 5.3 - “Tumour Bank Storage of TB Database” Added 7 - Appendix - “Timeline of Changes to TB Database”	03.01.003	NN

1. PURPOSE

The purpose of this document is to outline the principles that are used by the Tumour Bank (TB) to ensure that electronic and paper records and documents are generated and maintained with high quality standards.

2. SCOPE

This document applies to all records and documents that are generated and maintained as part of the operation of the tumour repository. The document covers written, original paper records, true copies such as photocopies, as well as electronic records and documents.

3. RESPONSIBILITIES

The TB Clinical Research Associate (CRA), Project Officer and Administration Officer must ensure that this protocol is adhered to at all times when generating, maintaining and handling paper and electronic records and documents as part of the operation of the TB.

4. MATERIALS, EQUIPMENT AND FORMS

The Children’s Hospital at Westmead Tumour Bank abides by, and is governed by three main laws that protect the privacy of individuals. These are:

- The Privacy and Personal Information Protection Act (1998) (NSW)
 - Sets privacy standards for dealing with personal information

- Provides information for all NSW public sector agencies in how they must manage personal information
- The Act includes 12 information protection principles (IPPs) that form the backbone of the Act and must be adhered to by all NSW public sector agencies. They can be grouped under 5 main headings- collection, storage, access and accuracy, use and disclosure.
- The Health Records and Information Privacy Act (2002) (NSW)
 - Sets privacy standards for dealing with health information
 - Governs the handling of health information in both the public and private sectors in NSW
 - The HRIP Act contains 15 health privacy principles (HPPs) which concern the collection, storage, access and accuracy, use, disclosure, identifiers and anonymity, and transferrals and linkage.
- The Federal Privacy Act (1988) (Commonwealth)
 - Sets privacy standards for dealing with personal information
 - Regulates with way the Commonwealth Government and ACT Government Agencies and some private sector organisations deal with personal information

The TB is also guided by The Sydney Children's Hospital Network's Code of Conduct (<http://chw.schn.health.nsw.gov.au/o/documents/policies/policies/2011-9004.pdf>).

- TB SOP 02.01 Notification of Declined Consent
- TB SOP 02.02 Patient Consent Information Flow
- TB SOP 02.03 Patient Consenting Guideline
- TB SOP 03.02 Collation of clinical data for Tumour Bank applications
- TB SOP 09.01 Responding to requests for specimens from the Children's Hospital at Westmead Paediatric Tumour Bank

5. METHOD

The following principles are to be used to further guide the TB in maintaining compliant records and documents.

5.1 Collecting demographic and clinical Information for TB database

- Information on patients is entered into the TB database when the TB receives a sample for that patient
- The Children's Hospital at Westmead's (CHW) patient management database, Powerchart is considered source data (original place of entry for all patient information), and this must be used to populate the TB database if at all possible
- The diagnosis should not be entered until it is confirmed by the relevant Pathology department ('not yet identified' should be used as an interim measure).

5.1.1 Consents

- The TB CRA will refer to the TB database to check the consent status of a patient, prior to seeking consent either in person or via post.
- The TB CRA will follow the protocol outlined in TB SOP 02.02 and TB SOP 02.03 when consenting patients, in order to obtain written consent for tumour banking.
- When a written consent for a patient is received, the TB Administration Officer will change the consent status of the patient in the TB database to 'written consent'.
- The written consent will be copied, and the copy will be taken to the Medical Records department on a monthly basis. The original will be filed.

5.1.2 Additional information requested by researchers

- Additional information requested by researchers is gathered as per TB SOP 03.02.

5.2 Retention of Data in the Case of Withheld or Revoked Consent

- a. The actions taken in the event of withheld or revoked consent are outlined in TB SOP 02.01.

5.3 Tumour Bank Storage of TB Database

5.3.1 TB Database

- a. The TB Database is password protected. The Head of TB, the Project Officer, the Administration Officer and the TB CRA are assigned 'Superuser' status, and can alter both data and aspects of the database per se.
- b. Separate usernames allow retrospective audit if required.
- c. The TB Database is backed up each night onto the local research server which is firewalled off from the main hospital. The back-up of the database on the research server is also password protected.

5.3.2 Consents

- a. Written consents are stored in a locked filing cabinet in the TB Office. The TB Office is also locked at night.
- b. Scanned copies of the TB consent are available on Powerchart, which is password protected.

5.3.3 Additional information requested by researchers

- a. Additional information requested by researchers is stored in Excel sheets on password protected computers that are backed up each night
- b. Emails pertaining to particular TB participants are also stored on password protected computers, and email subject lines do not contain patient names.

5.3.4 Biospecimens book

- a. The specimens book that lists all biospecimens received is locked each evening in the TB office. Only TB staff has access to this key. Completed specimen pages are stored in a locked filing cabinet in the TB office.

5.4 Access and accuracy of TB Database

- a. Access to the TB database is limited to the staff members of the TB
- b. The TB Administration Officer performs monthly audits on selected data points (name, DOB, diagnosis (incl. date), DOD if applicable, MRN, spelling in comments field, consent status, type of sample, collection date and split samples) within the TB Database to improve data accuracy. To avoid audit duplication, an Excel spreadsheet is used to mark off those cases that have been audited.

5.4.1 Additional information requested by researchers

- a. Refer to TB SOP 03.02 for an outline of monitoring for additional information requested.

5.5 Use and disclosure of Tumour Bank data; identifiers and anonymity

- a. TB samples and data are used solely for paediatric cancer research.
- b. They are provided to researchers and clinicians from CHW. Researchers must have their project reviewed and approved by the TB Committee (refer to TB SOP 09.01 for an outline of the application process).
- c. When samples are provided to a researcher, the TB Project Officer or Research Assistant will label the sample with the TB Biospecimens number only. This is a unique, database generated number.
- d. Data requested by the researcher to accompany the samples either at the time or after shipping will also be identified only by the TB Biospecimens number.

6. SAFETY

- Not applicable

7. APPENDIX

7.1 Appendix 7.1

Timeline of changes to TB database

Date	Amendment
09/08/10	<ol style="list-style-type: none"> Additional consent categories added to Biogenix <ul style="list-style-type: none"> 'Passive decline' 'Lost to follow up' All consent categories defined <p>Refer to SOP # 13 for definitions of all consent categories.</p>
20/10/11	<ol style="list-style-type: none"> Patients with paraffin blocks only had their consent status changed to 'HTA-Exempt' <p>Refer to SOP # 13 for definition of 'HTA Exempt'</p>
16/11/11	<ol style="list-style-type: none"> Samples between 1/11/03 and 1/1/06 sorted into three categories depending on rarity of sample and size of sample. Samples were divided into: <ul style="list-style-type: none"> 'Lost to Follow Up' 'Consent Pending' the samples were discarded, or moved to Box 401 in Histopathology (samples that do not have consent and cannot be used for research).
09/02/12	<ol style="list-style-type: none"> Remove category 'OT Consent' from Biogenix, and change 'HTA-Exempt' category to 'HTA-Exempt (incl. OT consent)' to include all samples prior to 1/11/03. Patients with all of their samples collected prior to 1/11/03 will be changed to 'HTA-Exempt (incl. OT consent)'; patients with samples that traverse this time will be coded '>1 Consent status'. <p>Refer to SOP # 13 Version 1.3 for expanded definition of 'HTA-Exempt (incl. OT consent)'.</p> <ol style="list-style-type: none"> Addition of category '>1 Consent status' to cover those participants with changing consent statuses. <p>NB. Patients whose consent statuses changed from 'OT consent' to '>1 consent status' because some of their samples were collected prior to 1/11/03, and some were collected post 1/11/03 (but prior to 1/1/06) appeared on the consent pending list and required sorting into 4 categories as per 16/11/11 point above ('Lost to Follow Up', 'Consent Pending', 'Discard' or 'Box 401').</p>
12/5/2013	Instead of using the status "Not available" for Jeremy Henson samples, use "Hold".
28/6/2013	<ol style="list-style-type: none"> 28/6/13: Box 401 could not be located in Histopathology, where it was being stored. Patients who only had samples stored in Box 401 were deleted. Patients who had samples both in Box 401 and elsewhere had samples from Box 401 only deleted.
8/7/2013	<ol style="list-style-type: none"> Created a new consent status for clinical trial patients' consent. This is called "Clinical Trial Service Provision" and is to be used for all clinical trial patients.
2/9/2013	<ol style="list-style-type: none"> Instead of using "Snap Frozen" for tumour samples, use "Frozen" for the preservation status.
12/9/2013	<ol style="list-style-type: none"> For each sample entered onto Biogenix, enter them as an aliquot (split), even if there is one split only.

03.02 Collation of Clinical Data for Tumour Bank Applications

Document Number: TB 03.02 Version: 002	Issue Date: 08/10/2012
Author: Amanda Rush and Albert Chetcuti Title: Clinical Research Associate/Project Officer <div style="display: flex; justify-content: space-around;"> Signature Date </div>	Approved by: Daniel Catchpoole Title: Head of Tumour Bank <div style="display: flex; justify-content: space-around;"> Signature Date </div>

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
12/10/2011	New Document		
08/10/2012	Annual Review	03.02.001	AC
16/9/2013	Annual Review – No changes made		NN

1. PURPOSE

The purpose of this document is to outline standardised procedures to follow when replying to researchers regarding their clinical data requests in a timely manner, and processes for accessing, collating and monitoring this data.

2. SCOPE

This protocol covers collation of all clinical data for successful Tumour Bank (TB) applications if requested by the applicant. Care should be taken to assure accuracy of this collated data, by using primary data sources to obtain the data and subsequent monitoring mechanisms to check for errors.

3. RESPONSIBILITIES

The TB Clinical Research Associate (CRA), TB Project Officer and Administration Officer must ensure that these protocols are adhered to at all times when collating clinical data for applicants.

4. MATERIALS, EQUIPMENT AND FORMS

- None

5. METHOD

5.1 Response to Tumour Bank Applicants

- a. On receipt of clinical data request from an applicant, a response is to be made within 1 business day by the TB Project Officer.

- b. This should include advising the time period in which they can expect the data (usually 3-4 weeks depending on the number of samples).

5.2 Accessing and Collation of Clinical Data

- a. Clinical data associated with the TB samples can include demographinc/epidemiological data and data from Haematology, Histopathology, Cytogenetics, Molecular Genetics, Imaging studies, surgery and clinical trials.
- b. This data is stored in various databases within the hospital, and each source requires checking and cross checking to ensure data accuracy.
- c. Sources for clinical data include:
 - Power Chart: The main clinical database for The Children's Hospital at Westmead (CHW) and contains all data on patients from 1995 onwards.
 - Oncology Database: An Access database managed by the Oncology CRA team and contains detailed records of all Oncology patients admitted under the Oncology Department since 1986.
 - PathNet: A DOS-based database used by the Histopathology Department to record details of samples processed by Histopathology.
 - Acute Lymphoblastic Leukaemia (ALL) Excel spread sheet: Created and up kept by TB Research Assistants, this spread sheet contains some clinical information on most ALL patients at CHW since 2008.
 - AREV: This system pre-dates PathNet (pre-1997), and is still active in the Histopathology department for old cases (access is gained via the Head of Histopathology or the Secretary of Histopathology).

5.3 Monitoring of Collated Data

The TB Project Officer and/or the TB CRA have to monitor the data for accuracy and completeness once the TB Administration Officer has collated all the clinical data.

5.4 Forwarding Data to Researcher

Once the monitoring is completed, the TB Project Officer is to forward the checked data to the researcher.

6. SAFETY

- Not applicable

4.0

FACILITIES MANAGEMENT/ OPERATION

04.01 Tumour Bank -80°C Freezer Failure Procedure

Document Number: TB 04.1 Version: 005	Issue Date: 30/10/2013
Author: Aedan Roberts Title: Research Assistant Signature Date	Approved by: Daniel Catchpoole Title: Head of Tumour Bank Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
06/07/2009	New Document		
01/12/2011	Annual Review	04.01.001	AC
03/04/2012	Revision of text	04.01.002	KJ
21/09/2012	Annual Review	04.01.003	AC
30/10/2013	Annual Review – Change of contacts	04.01.004	ARo

1. PURPOSE

The purpose of this document is to outline a standardised procedure to follow if the Tumour Bank's (TB) -80°C freezer were to fail (i.e., unable to keep the contents of the freezer below -60°C long term).

2. SCOPE

This protocol covers any occasions when the freezer may fail (including power failures). The TB's -80°C freezer contains more than 25,000 samples collected over 13 years. The contents of the TB's -80°C freezer must be maintained at less than -60°C to ensure the long-term viability of samples. The reason why the freezer has failed will determine the short-term and long-term action(s) required to address the problem. The freezer may fail because of:

- Short- or long-term power failure of the whole or part of the building
- Complete failure of the freezer, i.e., mechanical compressor failure

3. RESPONSIBILITIES

The TB will be responsible for management of the freezer in co-ordination with the Laboratory Manager.

4. MATERIALS, EQUIPMENT AND FORMS

- Depending on what action is required.

5. METHOD

5.1 Person to Contact

If the TB -80°C freezer alarm goes off and the freezer is unable to return to less than -65°C, DO NOT OPEN THE FREEZER DOOR. Keep the freezer door closed until one or more of the following persons are contacted.

First Contact

Laboratory Manager	(Mobile)	0418 283 427
Mark Ornatowski	(Work)	9845 3091
	(Pager)	6489

Second Contact

Dan Catchpoole	(Mobile)	0408 297 594
	(Work)	9845 1205
	(Pager)	6809
	(Home)	(02) 4753 6553

or

Li Zhou	(Mobile)	0432 634 562
	(Work)	9845 3028
	(Pager)	6692

or

Aedan Roberts	(Mobile)	0421 778 363
	(Work)	9845 3028
	(Pager)	6692

It will be the role of these persons to determine the problem that has caused the alarm to be triggered, and thus the short- and long-term course of action required.

5.2 Course of Action

5.2.1 Freezer CO₂ backup system

The TB -80°C freezer is connected to a CO₂ backup. If the temperature inside the freezer rises above -60°C, CO₂ gas will be pumped into the freezer slowly. This will maintain temperature of the contents at around -60°C to -65°C.

5.2.2 Short- and long-term power failure

If the freezer is in working order, but part or the whole of the building is experiencing power failure, then the freezer's CO₂ back up system will maintain the temperature inside the freezer at around -60°C to -65°C. The CO₂ back-up system should be maintained and checked to keep the freezer cold. Monitor and manage the CO₂ gas level only at this stage. If the CO₂ system fails, then the procedure for "*Complete freezer failure*" should be followed.

5.2.3 Complete freezer failure

If it has been determined that the freezer has malfunctioned (i.e., the freezer compressor has failed), then a process of transferring the contents to the backup -80°C freezer, located next to the TB freezer, should begin. The CO₂ backup should still be working and monitored during the transfer procedure. The transfer procedure should follow these steps:

- The failed -80°C freezer should be opened and only the top 5 racks of samples (all the freezer racks on the top shelf) should be removed from the failed freezer and immediately transferred to the back-up freezer.
- Both freezers should be allowed to settle and cool-down for 60 min.
- The next shelf (5 racks of samples) should then be quickly transferred between freezers.
- This should be repeated until all samples are transferred.

6. SAFETY

- Thick gloves (large orange) should be worn to transfer material from one -80°C freezer to another -80°C freezer.

04.02 Downloading -80°C Freezer Temperature Data From The Junior Escort Logger™

Document Number: TB 04.02 Version: 003	Issue Date: 10/10/2012
Author: Amanda Rush Title: Clinical Research Associate Signature Date	Approved by: Daniel Catchpoole Title: Head of Tumour Bank Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
02/06/2011	New Document		
01/12/2011	Annual Review	04.02.001	AR
10/10/2012	Annual Review	04.02.002	AR
16/9/2013	Annual Review – No changes made		NN

1. PURPOSE

The purpose of this document is to outline standardised procedures to follow when downloading temperatures from the Tumour Bank's (TB) -80°C freezer by the Junior Escort Logger.

2. SCOPE

This protocol covers all monthly downloads of the Junior Escort Logger which is used to ensure that the storage of samples is maintained at less than -60°C. The download should occur on the 1st of every month (or on the next work day if the 1st falls on a weekend or public holiday).



3. RESPONSIBILITIES

The TB Administration Officer or TB CRA must ensure that this protocol is adhered to at all times when downloading temperatures from the Junior Escort Logger.

4. MATERIALS, EQUIPMENT AND FORMS

- Junior Escort Logger™ installed in the TB's -80°C freezer
- Junior Escort Logger™ downloading software, installed on the TB Administration Officer's computer in the TB office
- Cradle interface and starter magnet
- Appendix 1: Screen shot of Escort Console Pro interface

5. METHOD

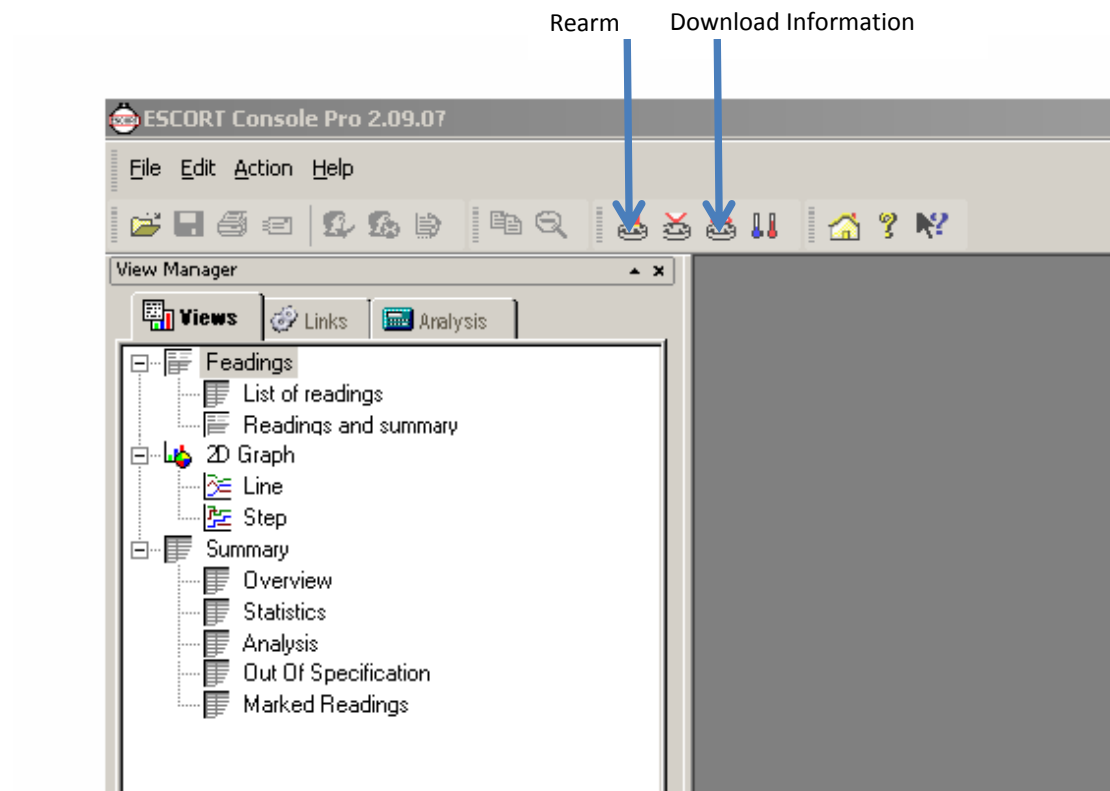
- a. Carefully separate the circular temperature logger (“puck”) from the recording wire that lies inside the freezer cavity, taking care not to damage the points on the end of the wire.
- b. Connect the cradle interface (stored in the TB office) to the TB Administration Officer’s computer via the lower USB port.
- c. Place the circular temperature logger in the cradle, ensuring that the gold electrodes of the cradle and the logger touch.
- d. Double click on the “Escort Console” icon on the desktop of the Database Administrator computer.
- e. Ensure that “Communications Port (COM4)” is ticked on the left hand side of the page.
- f. Click on the “Download Information” icon  (12th icon from the left- see Appendix 1)
- g. Click “Next”, then “Download”, then “Next”
- h. Leave the radio button set to “Do not upload any new start conditions to the logger”
- i. Click “Finish”
- j. Save the data as a .csv file in G:\Data\TumourB\My Logger Data. This will automatically open in Excel format on the Admin Officers computer.
- k. Generate a line graph of the temperatures using Excel to check for any temperature deviations; there is no need to save this graph.
- l. Save file as “yymmdd(start date)-yymmdd(finish date)”.csv
- m. Click the “Rearm” icon  (10th icon from left- see Appendix 1)
- n. Follow the steps till “Finish”.
- o. Disconnect the cradle interface from the computer
- p. Remove the circular temperature logger from the cradle
- q. Re-connect the temperature logger to the recording wire sitting outside the -80°C freezer
- r. Swipe the starter magnet (in drawer in Tumour Bank office) to re-start the temperature logger.

6. SAFETY

- Not applicable

7. APPENDIX

7.1 Appendix 1



5.0

MATERIALS AND DOCUMENTATION

05.01 Sample Collection

Document Number: TB 05.01 Version: 002	Issue Date: 09/12/2013
Author: Oksana Markovych Title: Clinical Research Associate	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
02/09/12	New Document		
09/12/13	Annual Review – all peripheral bloods ordered by TB staff can be retrieved from the box labelled "Tumour Bank" located in Pathology department (Section 5.1)	05.01.001	OM

1. PURPOSE

The purpose of this document is to outline standardised procedures to follow when collecting samples for the Tumour Bank (TB) from departments across The Children's Hospital at Westmead (CHW). This will maximise the number and quality of samples collected, which in turn will maximise translational research gains for investigators at CHW and their collaborators.

2. SCOPE

This protocol covers all bone marrow aspirate, trephine, blood, bone marrow slides and solid tissue samples collected from oncology or non-oncology patients at CHW.

3. RESPONSIBILITIES

The TB Clinical Research Associate (CRA), Project Officer, Administration Officer and Research Assistants must ensure that these protocols are adhered to at all times when retrieving samples from CHW departments.

4. MATERIALS, EQUIPMENT AND FORMS

- Blank yellow outpatient request forms, with pre-filled instructions for blood collection signed by the Head of Oncology
- Blank green outpatient request forms, with pre-filled instructions for blood collection signed by the Head of Oncology
- White inpatient request forms, with pre-filled information pertaining to Project #57
- Blank white inpatient request forms, with pre-filled instructions for blood collection signed by the Head of Oncology

- CRA SOP BSM 001 Requesting and Managing Bone Marrow Aspirate Samples for Oncology Patients Attachment 1.
- CRA SOP BSH 006 Collection of Tumour/Tissue for Research
- TB SOP 05.06 Obtaining Samples From Long Term Follow Up Patients
- TB SOP 05.07 Obtaining Patient Peripheral Blood Samples from the Clinical Haematology Department
- Appendix 1: Flow chart of blood samples across CHW
- Appendix 2: Flow chart of bone marrow and solid samples across CHW

5. METHOD

5.5 Peripheral blood ordering and retrieval

5.5.1 Oncology Treatment Centre (OTC)

- The TB CRA/Research Assistant will complete patient details on blank yellow outpatient request forms, using the General Anaesthetic (GA) folder located in OTC.
- Request forms are to be completed on Friday and Wednesday afternoons, for sample collection on the following Monday and Thursday, respectively.
- Give completed yellow forms to the ward clerks at the OTC front desk
- Only patients undergoing a Bone Marrow Aspirate (BMA) are to have bloods ordered.
- TB staff can retrieve bloods from the red box labelled “Tumour Bank” located in the Pathology department

5.5.2 Clinical Haematology department

- Refer to TB SOP 05.07 for details of new and relapsed oncology patients who have had bloods collected for the purpose of a full blood count, and can have this EDTA tube subsequently banked in the TB.

5.5.3 Specimen reception- pathology

- Blood sample requests specifically for the TB written by either the TB CRA or doctors throughout the CHW are labelled ‘Do not send sample to pathology; please page Tumour Bank on 6692’.
- Occasionally these samples arrive at pathology specimen reception.
- The TB will be paged to retrieve them; they can be collected from pathology specimen reception, in the Clinical Haematology laboratory.

5.5.4 Blood collection- pathology

- Refer to TB SOP 05.06 for details of Long Term Follow Up (LTFU) patients with blood request forms who present to CHW’s blood collection room in the Pathology department.
- Blood samples can be retrieved from the box labelled “Tumour Bank” located in the Pathology department

5.5.5 Camperdown Ward

- Bloods for newly diagnosed patients (who don’t have a suitable sample available in clinical haematology) or patients at specific treatment timepoints, who have been admitted to Camperdown Ward can be requested via the Camperdown Ward in-tray for either morning (am) or afternoon (pm) collections.
- Bloods can be picked up that day (am collection) or the next day (pm collection) from the TPN fridge.

5.6 Bone marrow aspirate/trephine ordering and retrieval

5.6.1 Bone Marrow Aspirates

- Bone marrow aspirates (and trephines if sufficient aspirate cannot be obtained) are ordered by the CRA team and/or Haematology registrar, according to the schedule outlined in the CRA SOP BSM 001.

- b. The Haematology registrar will page the TB when samples are ready to collect.
- c. Samples are to be collected from the designated TB receptacle in the Haematology registrar's office.

5.6.2 Bone Marrow Slides

- a. Haematology registrars routinely make bone marrow slides for clinical investigations.
- b. Additional research slides are stored in slide drawers provided by the TB CRA.
- c. When the drawer is full, the haematology registrar will contact the TB.
- d. The TB CRA will collect the drawer and replace it with an empty drawer.

5.3 Solid tissue retrieval

- a. Malignant and non-malignant tissue excised by CHW surgeons is triaged via the Histopathology department as per the CRA SOP BSH 006.
- b. Tissue for the TB is allocated to a 'Postie Box' receptacle in Histopathology's -80°C freezer.
- c. On a monthly basis, the TB Project Officer retrieves samples from the 'Postie Box' in Histopathology.

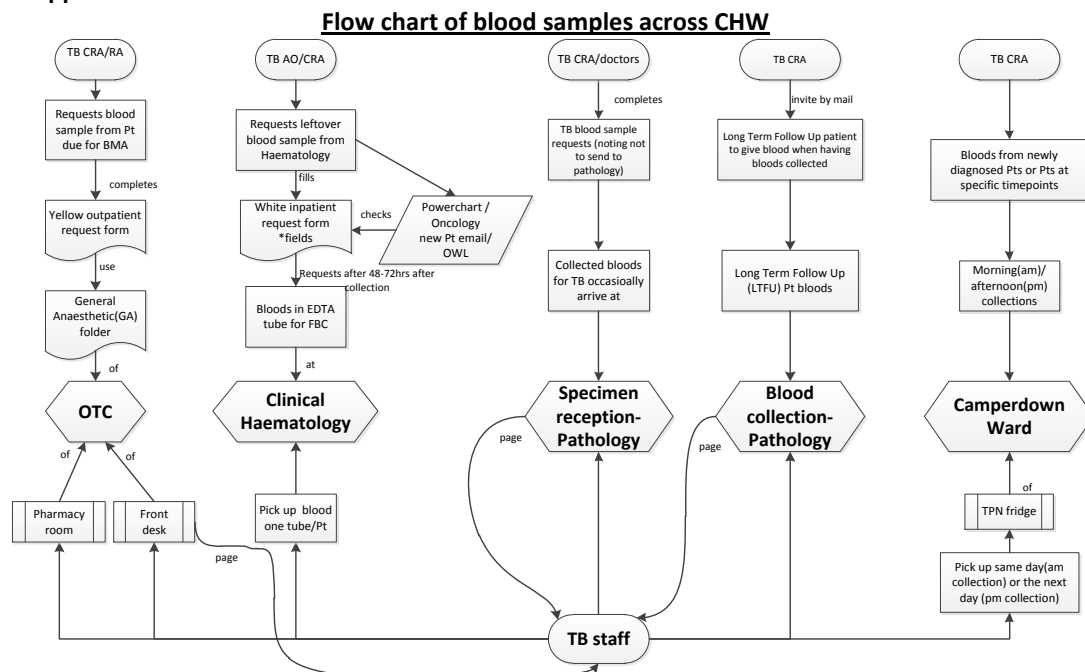
Refer to appendix 1 for a flow chart of all samples across CHW.

6. SAFETY

- Adhere to all local biological, chemical and sharps policies.

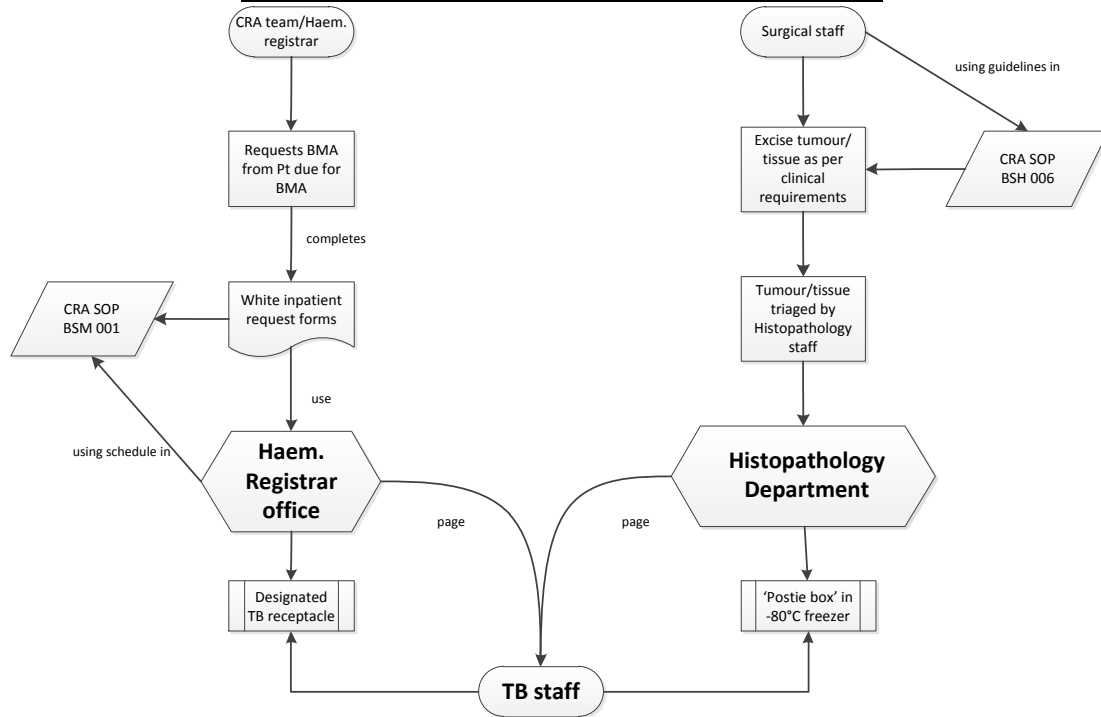
7. APPENDIX

7.1 Appendix 1



7.2 Appendix 2

Flow chart of bone marrow and solid samples across CHW



05.02 Bone Marrow Aspirate and Trephine Sample Processing

Document Number: TB 05.02 Version: 004	Issue Date: 19/09/2012
Author: Amanda Rush Title: Clinical Research Associate	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
01/05/2009	New Document		
30/06/2010	Annual Review	05.02.001	AR
01/12/2011	Annual Review	05.02.002	AR
19/09/2012	Annual Review	05.02.003	AR
23/10/2013	Annual Review – No changes made		AY

1. PURPOSE

The purpose of this document is to outline standardised procedures to follow when snap freezing bone marrow samples in order to provide maximum benefit to the end users.

2. SCOPE

This protocol covers all bone marrow samples collected from oncology or non-oncology patients at The Children's Hospital at Westmead (CHW), for whom the Haematology department has residual samples, and subsequently contacts the Tumour Bank (TB) for processing and storage.

3. RESPONSIBILITIES

The TB Clinical Research Associate (CRA), Project Officer and Research Assistants (RA) must ensure that these protocols are adhered to at all times when processing and storing bone marrow samples.

4. MATERIALS, EQUIPMENT AND FORMS

- 2.0mL Cryovials – with clear lid
- Cryovial lid inserts – white
- Disposable plastic transfer pipettes
- Racks to hold tubes while processing
- Tongs

- Freezer storage boxes
- Laboratory Bench Sample Record Sheet form
- Permanent waterproof marker
- Metal cup for aliquotting liquid nitrogen into
- 4 decimal place balance
- Label printer
- Small dewar for liquid nitrogen transportation
- Personal protective equipment - gowns, gloves, safety glasses

5. METHOD

5.7 Sample Processing and Labelling

Aliquot and snap freeze bone marrow aspirate and/or trephine samples as soon as possible after retrieval.

5.1.1 Bone Marrow Aspirate

- Aliquot (into cryovials with clear lid) the BMA sample into 2.0mL lots using a disposable plastic transfer pipette.
- Place a white insert into the lid.
- Label the side of the cryovial with the following information using a label printer (use font size 10pt):
 - CHWTB number
 - Date of collection
 - Type of specimen (BMA)
- Label the insert of the lid with the following information
 - Volume of sample in millilitres

5.1.2 Bone Marrow Trephine

- Using the 4 decimal place balance in the chemical room, weigh an empty cryovial with yellow lid. Record the weight.
- Place bone marrow trephine sample into the cryovial which has been weighed and replace lid.
- Reweigh the cryovial containing bone marrow trephine sample.
- Record the weight of the tube with a yellow lid plus the bone marrow trephine sample.
- Subtract the weight of empty cryovial from the weight of the cryovial plus sample. Record the weight.
- Place a white insert into the lid.
- Label the side of the cryovial with the following information using a label printer (use font size 10pt):
 - CHWTB number
 - Date of collection
 - Type of specimen (trephine)
- Label the insert of the lid with the following information
 - Volume of sample in grams

5.8 Sample Freezing and Storing

- Decant liquid nitrogen from the large dewar (in the liquid nitrogen store room on Level 3) into a small dewar and transport to laboratory.
- In the laboratory, aliquot liquid nitrogen into a metal cup.
- Using tongs, immerse cryovial containing sample into liquid nitrogen for approximately 15 seconds or until sample changes colour.
- Record the volume of each cryovial on request form.
- Place frozen cryovial containing sample in next available freezer box space in Tumour Bank freezer.
- Record box number, row and column position on request form.

5.9 Sample Recording

Record the following details of sample in the Tumour Bank Laboratory Bench Sample Record Sheet form for entry into the TB database.

- Patient MRN
- Surname and first name
- Date of birth
- Sample type
- Date of sample collection
- Number and weight/volume of sample
- Freezer box number and position
- Any additional notes

6. SAFETY

- Adhere to all local chemical and sharps policies.
- Dispose empty bone marrow tubes, pipette tips and soiled gloves in accordance with local regulations for handling of potentially infectious biological material.

05.03 Blood Sample Processing

Document Number: TB 05.03 Version: 005	Issue Date: 23/10/2013
Author: Aysen Yuksel Title: Clinical Research Associate	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
01/05/2009	New Document		
01/07/2010	Annual Review	05.03.001	KJ/AR
01/12/2011	Annual Review	05.03.002	AR
20/02/2012	Expansion of blood collection methods	05.03.003	AR
19/09/2012	Annual Review	05.03.004	AR
23/10/2013	Annual Review-Use of label printer	05.03.005	AY

1. PURPOSE

The purpose of this document is to outline standardised procedures to follow when snap freezing blood samples in order to provide maximum benefit to the end users.

2. SCOPE

This protocol covers all blood samples collected from oncology or non-oncology patients at The Children's Hospital at Westmead (CHW), for there are residual samples, and the Tumour Bank (TB) is subsequently contacted for processing and storage.

3. RESPONSIBILITIES

The TB Clinical Research Associate (CRA), Project Officer and Research Assistants (RA) must ensure that these protocols are adhered to at all times when processing and storing blood samples.

4. MATERIALS, EQUIPMENT AND FORMS

- 2.0ml Cryovials with red lids
- Cryovial lid inserts – white
- Disposable plastic transfer pipettes
- Racks to hold tubes while processing
- Tongs

- Freezer storage boxes
- Laboratory Bench Sample Record Sheet form
- Permanent waterproof marker
- Metal cup for aliquotting liquid nitrogen into
- Label printer
- Small dewar for liquid nitrogen transportation
- Personal protective equipment - gowns, gloves, safety glasses

5. METHOD

5.1 Sample Processing and Labelling

After retrieval, aliquot and snap freeze blood sample as soon as possible.

- If there are any delays in processing, store the sample in the TB 4°C refrigerator.
- Aliquot (into red cryovials) the blood sample into 2.0mL lots using a disposable plastic transfer pipette.
- Place a white insert into the lid.
- Label the side of the cryovial with the following information using a label printer (use font size 10pt)
 - CHWTB number
 - Date of collection
 - Type of specimen (blood)
- Label the insert of the lid with the following information
 - Volume of sample in millilitres

5.2 Sample Freezing and Storing

- Decant liquid nitrogen from the large dewar (in the liquid nitrogen store room on Level 3) into a small dewar and transport to laboratory.
- In the laboratory, aliquot liquid nitrogen into a metal cup.
- Using tongs, immerse cryovial containing sample into liquid nitrogen for approximately 15 seconds or until sample changes colour.
- Record the volume of each cryovial on request form.
- Place frozen cryovial containing sample in next available freezer box space in Tumour Bank freezer.
- Record box number, row and column position on request form.

5.3 Sample Recording

Record the following details of sample in the TB Laboratory Bench Sample Record Sheet form for entry into the TB database.

- Patient MRN
- Surname and first name
- Date of birth
- Sample type
- Sample Source
- Date of sample collection
- Number and volume of sample
- Freezer box number and position
- Any additional notes

6. SAFETY

- Adhere to all local chemical and sharps policies.
- Dispose empty bone marrow tubes, pipette tips and soiled gloves in accordance with local regulations for handling of potentially infectious biological material.

05.04 Tissue Sample Collection and Processing

Document Number: TB 05.04 Version: 004	Issue Date: 24/09/2012
Author: Albert Chetcuti Title: Project Officer	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
26/05/2009	New document		
22/09/2010	Change of protocol	05.04.001	NM/AC
01/12/2011	Annual Review		AC
03/04/2012	Revision of text	05.04.002	KJ
24/09/2012	Annual Review	05.04.003	AC
23/10/2013	Annual Review – no changes made		AY

1. PURPOSE

The purpose of this document is to outline standardised procedure to be followed during the transportation, processing and storage of frozen tissue/tumour samples from CHW Histopathology Department to provide maximum benefit to the end users.

2. SCOPE

This protocol covers tissue and tumour samples collected from CHW patients for whom the CHW Histopathology Department has residual samples which they have frozen. Subsequently the Tumour Bank (TB) will bank and store the samples after patients have consented.

3. RESPONSIBILITIES

The TB Clinical Research Associate (CRA), Project Officer and Research Assistant (RA) have to ensure that these protocols are adhered to at all times when processing and storing tissue samples.

4. MATERIALS, EQUIPMENT AND FORMS

- 2 mL blue lid cryovials with insert (Greiner bio-one)
- Appropriate racks to hold tubes while processing
- Stainless steel tongs
- Sartorius micro-balance (4 decimal place) in chemical/radiation room (Level 4)
- Freezer Storage boxes
- Lab Bench Sample Record Sheet
- Personal protective equipment - gowns, gloves and safety glasses
- Liquid nitrogen

5. METHOD

Residual fresh tumour sample following diagnosis is deposited in the TB's Postie Box located in the Histopathology Department -80°C upright freezer.

A TB staff member is to check and empty the Postie Box located in Histopathology -80°C upright freezer on a monthly basis using the following procedure.

- Empty all cryovials from the TB's Postie Box into a dewar containing liquid nitrogen.
- Bring the dewar back up to the TB specimen reception desk.
- Transfer cryovials individually from the dewar into a 10X10 freezer storage box sitting in liquid nitrogen.
- Record the information on each cryovial on the Lab Bench Sample Record Sheet under appropriate headings (record BX number under "Notes").
- If the biopsy number bopsy number (BX-##-####) is the only information recorded on the cryovial, check the pathology database (PathNet) to obtain patient's full name, DOB, collection date and MRN. The hospital database (PowerChart) may also be used to find details about the sample.
- Weigh the cryovial containing tumour sample using the 4 decimal place balance in the chemical room. Record the total weight of the cryovial and subtract from the following to determine the approximate weight of the tissue in the cryovial.
 - blue lid cyrovial with white cap insert = 2.1223g
 - blue top cyrovial without white cap insert = 1.9713g
- Record the weight of the tissue in the cryovial on the Lab Bench Sample Record Sheet.
- Label cryovial with patients CHWTB number, sample type (e.g. 'TUMOUR' or 'TISSUE') and collection date.
- Place sample in the next available freezer box space in TB freezer, and record box number and position (row, column) on the Lab Bench Sample Record Sheet.
- Use the information from Lab Bench Sample Record Sheet to prepare a detailed MS Excel spread sheet of the samples collected. Add an extra column titled "Diagnosis" and fill in. You can find the diagnosis of sample in either PathNet or PowerChart.
- Forward this MS Excel spread sheet to the TB's Administration Officer.
- The TB's Administration Officer is to record the information from the Lab Bench Sample Record Sheet on to the TB database.
- The TB's Administration Officer is to update the consent status on the MS Excel spread sheet and forward it to the TB CRA.

6. SAFETY

- Caution should be used when dealing with liquid nitrogen.
- Personal protective equipment should be used, including latex gloves, lab gown, safety glasses.
- Soiled gloves should be disposed of in accordance with local regulations for handling of potentially infectious biological material.

<h2 style="margin: 0;">05.05 Constructing Tissue Microarrays</h2>			
Document Number: TB 05.05 Version: 004		Issue Date: 21/09/2012	
Author: Aysen Yuksel Title: Research Assistant		Approved by: Daniel Catchpoole Title: Head of Tumour Bank	
Signature	Date	Signature	Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
26/05/2009	New Document		NM
22/09/2012	Annual Review	05.05.001	NM
13/12/2011	Annual Review	05.05.002	AC
21/09/2012	Annual Review	05.05.003	AY
21/10/2013	Annual Review – No changes made		AY

1. PURPOSE

The purpose of this document is to outline standardised procedures to be followed when locating, collecting and sampling tissue; and annealing and sectioning a constructed tissue microarray (TMA).

2. SCOPE

This protocol covers all TMA's constructed by the Tumour Bank (TB). Prior to constructing/planning a TMA, every core of tissue should be assessed and approved for use by a member of the Histopathology Department.

3. RESPONSIBILITIES

TMA's will be constructed by the TB's Histopathology Research Assistant (RA) under guidance by the TB Project Officer.

4. MATERIALS, EQUIPMENT AND FORMS

- Diagnostic/donor tissue block together with matching H&E slide and report
- Paraffin wax recipient block or Unitma Pre-made recipient block
- Large embedding (eyeball) mould
- Superfrost plus slides

- MTA-1 Beecher Manual Tissue Arrayer
- Automated H&E stainer
- Microtome
- Water bath
- Incubator
- Automated Immunohistochemical stainer (Leica BOND-max)
- Histopathologist Block Screening form- for pathologist to complete and sign
- To be approved list form –for RA to complete

5. METHOD

5.1. Tissue selection and donor block preparation

- Pull all the cases to be included in the TMA together i.e. blocks, slides and report.
- If the blocks have been previously cut for other clinical or research purposes, a fresh H&E slide may be obtained to ensure that the slide is representative of the block.
- Complete the “Histopathologist Block Screening form” and “To be approved list form”.
- Place the completed “Histopathologist Block Screening form” together with the case.
- Deliver case to a Histopathologist to review all the slides and they will mark areas of interest. It is useful to mark multiple areas from more than one block, as blocks may be depleted or misplaced.
- Areas to be sampled/cored (tumour, normal) should be identified.

5.2. The recipient block

- Prepare the recipient block by melting paraffin wax and dispensing it into a deep eyeball size mould.
- Place a cassette on top of the liquid paraffin and wait until the wax has solidified.
- Remove recipient block from mould.
- Check block for any holes or cracks that may have risen during the block preparation.
- Ensure that the block surface is flat and parallel to the underside of the cassette by facing off or trimming the block surface on a rotary microtome.
- Take care not to introduce scores or nicks in the paraffin recipient block.
- Or, you may use a ready to use Unitma pre-made recipient block.

5.3. TMA construction

- Use the smaller core to make a hole in the recipient block where the donor tissue will be positioned.
- Place the donor paraffin blocks under a low wattage lamp before coring. This makes the donor blocks softer, less likely to crack and easier to punch.
- Use the larger core to extract tissue from the donor block.
- Tissue cores are to be deposited in a grid pattern in the recipient block to form a “tissue microarray”.

5.4. Annealing of the TMA Block

- Place block facing upward in slide oven at 64°C for 10 minutes (1st Round).
- Use a clean glass microscope slide to level the face of the block by placing a glass slide on top of the block, applying even pressure to push all the cores on the array to the same level.
- Let block cool at room temperature for 10 minutes.
- Place block facing upward in slide oven at 64°C for 10 minutes (2nd Round).
- Use a clean glass microscope slide to level the face of the block by placing a glass slide on top of the block, applying even pressure to push all the cores on the array to the same level.
- Let block cool at room temperature for 10 minutes.
- Place block facing upward in slide oven at 64°C for 10 minutes (3rd Round).
- Use a clean glass microscope slide to level the face of the block by placing a glass slide on top of the block, applying even pressure to push all the cores on the array to the same level.

- i. Let block cool at room temperature for 10 minutes.
- j. Place block facing upward in slide oven at 64°C for 10 minutes (4th Round)
- k. Use a clean glass microscope slide to level the face of the block by placing a glass slide on top of the block, applying even pressure to push all the cores on the array to the same level.
- l. Let block cool at room temperature for 10 minutes.
- m. After annealing the block, allow block to settle overnight before sectioning.
- n. Take a digital photo of the tissue microarray block before sectioning.

5.5. Sectioning of the Array Block

- a. Note the depth of the block and adjust the microtome distance accordingly.
- b. Use a new disposable blade. Section a blank wax TMA block to blunt the knife slightly before trimming the TMA.
- c. Trim block.
- d. Put on ice for 20 minutes.
- e. Serial Section Block.
- f. Float out ribbon on 42°C water bath.
- g. Use Superfrost Plus slides to pick up sections, don't waste any sections, pick up every section including those with folds or bubbles.

5.6. Possible Sectioning Problems

- When moving the knife to new part, always blunt blade slightly on a new blank wax block to avoid discs (cores) rolling.
- If discs are rolling onto themselves then the blade is probably too sharp or wax needs to re-anneal around the cores.
- Put in slide oven (64°C) for 1 minute (max), then let block cool on ice.

5.7. Refer to the following manuals for further technical instructions

- Manual Tissue Arrayer Technical Manual Version 1
- Manual Tissue Arrayer MTA-1 Beecher Instruments Instruction Manual

6. SAFETY

- All local chemical and sharps policies must be adhered to.
- Safety equipment required includes latex gloves, lab gown, safety glasses and oven mitt.

05.06 Obtaining Samples from Long Term Follow Up Patients

Document Number: TB 05.06 Version: 005	Issue Date: 09/12/2013
Author: Oksana Markovych Title: Clinical Research Associate	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
	New Document		
30/06/2010	Annual Review	05.06.001	AR
01/12/2011	Annual Review	05.06.002	AR
19/09/2012	Annual Review	05.06.003	AR
09/12/2013	Annual Review – Changes to 5 - Method	05.06.004	OM

1. PURPOSE

The purpose of this document is to outline standardised procedure to follow when obtaining consent and blood specimens from patients attending the Children's Hospital at Westmead (CHW) Oncology Department's Long Term Follow Up (LTFU) Clinic.

2. SCOPE

This protocol covers all consent and sample collection of patients attending the Long Term Follow Up Clinic, usually 5 years off treatment plus subsequent visits.

3. RESPONSIBILITIES

This document is relevant to the Tumour Bank (TB) Clinical Research Associate (CRA), who obtains consent and collects blood specimens from the CHW Pathology Department, and also the TB Research Assistants (RAs) and the TB Project Officer.

4. MATERIALS, EQUIPMENT AND FORMS

TB Long Term Follow Up consent information pack:

- TB Long Term Follow Up Information Sheet and Consent Form (consent form printed on green paper)

(http://chw.schn.health.nsw.gov.au/ou/oncology_research/resources/forms/consent_forms/long_term_follow_up_patients.pdf)

- TB newsletter (latest edition)
- Reply paid envelope (ensure stamped TB details are added)
- TB business card
- Pathology request form with details of TB request copied on green paper
- TB LTFU letter (G:\data\TumourB\Tumour CRA docs\Letters\Current letter templates 020913)
- TB SOP 05.03 Blood Sample Processing

5. METHOD

- a. The LTFU secretaries will email the TB CRA each invitation to attend an upcoming LTFU clinic.
- b. The TB CRA is to check the TB database to see whether the patient or patient's parents have given consent for TB, and if the TB has a suitable blood sample stored .
- c. If there is no consent, the TB CRA is to consent patient at the upcoming clinic in person. Alternatively, send out the TB LTFU consent information pack.
- d. If there is an existing consent, the TB CRA is to send out the TB LTFU letter, a blood request form, TB business card and a TB newsletter only.
- e. If the patient agrees, they will bring the green consent form and/or request form only to the pathology blood collectors on the day of their LTFU blood collection tests.
- f. A number of patients may have their routine blood collections done the day of the clinic. This information can be found on LTFU clinic list distributed via an e-mail from LTFU clinical staff. In this instance, complete green blood request form a day before the clinic and leave it with the front desk receptionist in Pathology Collection room. Blood samples can be then collected from Tumour Bank designated red box located in Pathology.
- g. The TB CRA will process the blood as per TB SOP 05.03.

6. SAFETY

- Not applicable

05.07 Obtaining Patient Peripheral Blood Samples from the Clinical Haematology Department

Document Number: TB 05.07 Version: 004	Issue Date: 09/12/2013
Author: Oksana Markovych Title: Clinical Research Associate	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
14/03/2011	New Document		
01/12/2011	Annual review	05.07.001	AR
10/10/2012	Annual Review	05.07.002	AR
09/12/2013	Annual Review – minor amendments to Section 5.1 and 5.2	05.07.003	OM

1. PURPOSE

The purpose of this document is to outline standardised procedures to follow when obtaining blood samples from the clinical Haematology department.

2. SCOPE

This protocol covers all patients with a suspected malignancy at the Children's Hospital at Westmead (CHW), who has consented to be part of the bank and have agreed to donate blood.

3. RESPONSIBILITIES

The Tumour Bank (TB) Clinical Research Associate (CRA), Project Officer, Administration Officer and Research Assistants must ensure that these protocols are adhered to at all times when retrieving samples from CHW departments.

4. MATERIALS, EQUIPMENT AND FORMS

- Appropriate rack for blood tubes
- Completed request form for each patient with suspected malignancy (Appendix 1)

5. METHOD

5.1 Searching for Suitable Bloods

- 5.1.1 The TB CRA and the generic TB email address (tumourb@chw.edu.au) are sent details of any patient with a suspected malignancy (either leukaemia or solid tumour).
- 5.1.2 Upon receiving an email notification of a new suspected malignancy, the TB CRA or TB Administration Officer will check the patient's details in PowerChart to ascertain if and when they have had blood taken for a full blood count and differential.
- 5.1.3 This is done by:
 - a. Clicking the 'Results' tab on the list of hyperlinks on the left hand side of PowerChart
 - b. Clicking 'FBC' from the pale blue list on the left hand side of PowerChart
 - c. Using the bottom scroll bar to find any full blood counts that have been performed at the Haematology Department within the last 3 days
 - d. Full blood EDTA samples are kept in Haematology Department for maximum 7 days after collection after which time they are routinely discarded.

5.2 Retrieving bloods from the Clinical Haematology Department

- a. If there is a suitable blood to collect from the clinical Haematology Department, double click on the full blood count result to display a macro window.
- b. From the window, record the following information on a clinical Haematology request form (see Attachment 1 for an example):
 - MRN
 - Name
 - DOB
 - Sex
 - Collection date
 - Collection time
 - Lab accession number
- a.
- c. Take the request form to the clinical Haematology Department at approximately 14:30 (this is a less busy time of the day), and explain that you are TB staff and would like to retrieve a patient sample if they have completed clinical testing.
- d. If the sample is available, process as per TB SOP 05.03 and if relevant TB SOP 07.02, ensuring that the snap delay time is recorded under "Notes" in the Laboratory Bench Sample Record Sheet form.

6. SAFETY

- Transport the samples in a suitable rack.
- All local chemical and sharps policies must be adhered to.

7. APPENDIX
b. 7.1 Appendix 1

**THE CHILDREN'S HOSPITAL AT WESTMEAD
PATHOLOGY REQUEST FORM - INPATIENTS (APA)**

<p>*MRN </p> <p>*NAME _____</p> <p>ADDRESS _____</p> <p>*DOB _____ *SEX _____</p>	<p>Lab Number <small>OFFICE USE ONLY</small></p> <p>Ward</p> <p>Request Date</p> <p>AMO</p> <p>Provider No.</p> <p>Requesting Doctor</p> <p>Doctor's Signature</p> <p>Page / Ext No.</p>
<p>PATIENT STATUS AT THE TIME OF SERVICE OR WHEN THE SPECIMEN WAS COLLECTED:</p> <p>Hospital Patient in a recognised hospital <input type="checkbox"/></p> <p>Private Patient in a recognised hospital <input type="checkbox"/></p> <p>Private Patient in an approved day hospital facility <input type="checkbox"/></p> <p>Research Patient <input type="checkbox"/></p> <p>Ineligible Patient (Overseas) <input type="checkbox"/></p> <p>Compensable - Transcover Pre July 1989 <input type="checkbox"/></p> <p>Compensable - Motor Accident Authority, from July'89 <input type="checkbox"/></p> <p>Compensable - Other <input type="checkbox"/></p>	
<p>Collection Date _____ Collection Time _____ Received in Lab. _____</p>	
<p>Tests Requested:</p> <p>Clinical haematology samples: Peripheral blood in EDTA tube for Project # 57, and any residual for standard tumour banking.</p>	
<p>Specimen Type:</p> <p>Peripheral blood, EDTA tube</p>	
<p>Clinical Notes (Include Relevant Medication):</p> <p>CHWTB - Lab accession #</p>	

The Children's Hospital at Westmead
Onr Hawkesbury Road & Hainsworth Street, Westmead
Locked Bag 4001 Westmead NSW 2145

05.08 Banking Fresh Frozen Tissue (Tumour)

Document Number: TB 05.08 Version: 003	Issue Date: 08/10/2012
Author: Albert Chetcuti Title: Project Officer	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
07/04/2011	New Document		
03/04/2012	Revision of text	05.08.001	KJ
08/10/2012	Annual Review	05.08.002	AC
21/10/2013	Annual Review – No changes made		AY

1. PURPOSE

The purpose of this document is to outline standardised procedures to follow when collecting fresh tissue/tumour samples throughout the hospital, and processing and storing them.

2. SCOPE

This protocol covers all patients who have consented to be part of the bank and have agreed to donate tissue.

3. RESPONSIBILITIES

The TB Clinical Research Associate (CRA), TB Project Officer, and Research Assistants must ensure that these protocols are adhered to at all times when processing and storing fresh tissue samples.

4. MATERIALS, EQUIPMENT AND FORMS

- 2 mL blue lid cryovials with insert
- Carbon Steel Surgical Blade (Swann-Morton size 20)
- Surgical Blade handle
- Appropriate racks to hold tubes while processing
- Sartorius micro-balance (4 decimal place) in chemical/radiation room (Level 4)
- Stainless steel tongs
- Freezer storage boxes
- Liquid nitrogen
- 90 mm petri-dish (Lab 8 cabinet)
- Lab Bench Sample Record Sheet

- Label using Brady LabXpert printer
- Metal cup measure for aliquotting liquid nitrogen into
- Personal protective equipment - gowns, gloves and safety glasses

5. METHOD

5.1 Fresh Tissue (or Tumour)

- Fresh tissue or tumour will be collected by a surgical team at CHW or from an external hospital/laboratory.
- If coming from an external hospital/laboratory, the TB will be notified by email or phone of the expected delivery day and time of fresh tissue. The tissue should be shipped to CHW on dry-ice.

5.2 Sample Processing and Storage

Depending on the size of the tissue sample, either split the sample into small pieces or bank as a whole piece (smaller <100 mg).

5.2.1 Sample to be banked as a whole

- Print label with CHW TB number, sample type (e.g. 'TUMOUR' or 'TISSUE') and collection date and place on blue-lid 2 mL cryovial tube.
- Place the tissue in the labelled cryovial.
- Using tongs, snap freeze by.
- Immersing cryovial into liquid nitrogen for approximately 15 seconds or until the sample stops boiling.
- Check for next available freezer box space in TB freezer, and store specimens in row and column order, recording box number and position on request sheet.

5.2.2 Sample to be split

- Label as many blue-lid 2 mL cryovials as necessary with patients CHW TB number (together with tube number e.g. S1, S2, S3, S4, etc.), sample type (e.g. 'TUMOUR' or 'TISSUE') and collection date.
- Weigh each labelled empty tube individually with the Sartorius micro-balance (4 decimal place) in chemical/radiation room on level 4 and record the weight (empty weight).
- Place fresh tissue/tumour sample on a 90 mm petri-dish. Using a sterile surgical blade cut the tissue (while covering it with the petri-dish lid).
- Place each piece of tissue in a separate labelled cryovial.
- Record the total weight of each tube (using the same balance) and subtract from the empty weight to determine approximately the weight of the tissue in the tube.
- Snap freeze by submersion in liquid nitrogen (see step 5.2.1 c).
- Place sample in the next available freezer box space in TB freezer, and record box number and position (row, column) on request sheet.

5.2 Sample Recording

Record the following details of sample in the Tumour Bank Laboratory Bench Sample Record Sheet form for entry into the TB database.

- Patient MRN
- Surname and first name
- Date of birth
- Sample type
- Date of sample collection
- Number and weight/volume of sample
- Freezer box number and position
- Any additional notes

6. SAFETY

- All local chemical and sharps policies must be adhered to.
- Used surgical blades should be placed in sharps bin.
- Empty tubes/container and soiled gloves should be disposed of in accordance with local regulations for handling of potentially infectious biological material.

05.09 Collection of Tissue from Patients With Neurofibromatosis and Related Conditions for Storage in the Tumour Bank

Document Number: TB 05.09 Version: 003	Issue Date: 9/12/2013
Author: Oksana Markovych Title: Clinical Research Associate	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
25/05/2012	New Document		
11/10/2012	Annual Review	05.09.001	AR
9/12/2013	Annual Review – CHW Contact details (7.1 Appendix 1)	05.09.002	OM

1. PURPOSE

The purpose of this document is to outline standardised procedures for tissue allocation from all relevant patients of the Children's Hospital at Westmead (CHW) undergoing surgery, and tissue collection/transport from all relevant patients from hospitals other than CHW. The procedures ensure that fresh or frozen tissue with a probable or definitive diagnosis of neurofibromatosis or related condition is made available, whenever possible for research.

2. SCOPE

This protocol covers all CHW neurofibromatosis and related conditions research and clinical staff, all Histopathology staff, and all Tumour Bank (TB) staff. If surgery is performed at CHW, the fresh tissue must be triaged via Histopathology. The steps taken to subsequently bank blood and tissue into the TB are described in TB SOP 05.03 and SOP TB SOP 05.04 respectively.

3. RESPONSIBILITIES

This procedure must be adhered to by the TB CRA, the TB Project Officer, the TB Administration Officer, all members of the INMR-NF group, and surgeons excising tissue from probable and definitive neurofibromatosis patients.

4. MATERIALS, EQUIPMENT AND FORMS

- Tumour Bank Laboratory Bench Sample Record Sheet
- Appendix 1: Contact details and transport details for samples collected at hospitals other than CHW

- Appendix 2: Proforma to accompany neurofibromatosis specimens

5. METHOD

5.3 Notification to TB by Institute of Neuroscience and Muscular Research – Neurofibromatosis group (INMR-NF) (Head: Dr Simone Ardern-Holmes)

- Once aware of impending surgery at any hospital, a member of the INMR-NF group will email the Tumour Bank's Clinical Research Associate and Project Officer with:
 - patient name
 - date of surgery
 - approximate time of surgery (if known)
 - hospital where surgery is occurring

5.1 Surgical collections at hospitals other than CHW

- A member of the INMR-NF group will liaise with the Tumour Bank to check who will be available to receive the samples. Instructions should be given to the addresser to mark the package of samples clearly to the attention of that Tumour Bank personnel.
- Arrangements should be made for packages to arrive during business hours at the Tumour Bank.
- Samples should be accompanied by a signed Tumour Bank consent form (http://chw.schn.health.nsw.gov.au/ou/oncology_research/resources/forms/consent_forms/normal_samples_-_non_malignant.pdf). If this is not possible, consent must be obtained by a clinical member of the INMR-NF group as soon as possible after the samples have been banked.
- Ideal sample collection and transport are as follows:
 - 5 – 8 mL blood in EDTA tube, labeled with patient details and date of collection. Transport immediately at ambient temperature, or store at 4°C and transport at ambient temperature.
 - 1 x specimen of tissue collected into sterile urine pot, labeled with patient details and date of collection. Transport immediately on dry ice (or wet ice if dry ice is not available), or store at -80°C and transport on dry ice (or wet ice if dry ice is not available).
- Transport samples using the details supplied in Appendix 1 with a completed proforma (Appendix 2) and signed consent form.

5.2 Surgical Collections at CHW

- It is the responsibility of a clinical member of the INMR-NF group to ensure both 'Histology' and 'Tumour Bank' are requested to ensure that the Histopathology team triages tissue to TB where possible.
- A second request form should request 5 – 10 mL blood in EDTA (purple top) tube, for Tumour Bank.
- The blood can be arranged to be delivered immediately to TB by a INMR-NF group member, as this is a specific research request.
- Blood samples should be accompanied by a signed TB consent form (http://chw.schn.health.nsw.gov.au/ou/oncology_research/resources/forms/consent_forms/normal_samples_-_non_malignant.pdf). If this is not possible, consent must be obtained by an INMR-NF clinical member as soon as possible after the blood samples have been banked.
- Solid samples will be obtained from the Histopathology 'Postie Box' by the TB Project Officer once per month, if there was adequate tissue for research.

5.3 Tumour Bank Receipt of Samples

- TB will email the neurofibromatosis team to inform them of receipt of
 - Tissue and blood samples received and banked from hospitals other than CHW
 - Blood received and banked from CHW
 - Relevant tissue collected and banked on a monthly basis from the Histopathology Department

- Relevant outstanding patient consents

5.4 Tumour Bank Laboratory Procedures

- a. Bank blood and tissue as per TB SOP 05.03 and TB SOP 05.04 respectively.

6. SAFETY

- All local chemical and sharps policies must be adhered to.
- Empty blood tubes and pipette tips should be disposed of in accordance with local regulations for handling of potentially infectious biological material.

7. APPENDIX

7.1 Appendix 1

Contact details and transport details for samples collected at hospitals other than CHW

Delivery address:

The Children's Hospital at Westmead Tumour Bank
Attention: Oksana Markovych
Laboratory 7, Level 4
Kerry Packer Research Building
The Children's Hospital at Westmead
Corner Hawkesbury Rd and Hainsworth St
Westmead
NSW 2145

Telephone: 02 9845 1214

Pager: 6692

Email: oksana.markovych@health.nsw.gov.au

	Immediate transport	Delayed transport (will not arrive at Tumour Bank on same day as surgery)
Blood	Transport at ambient temperature	Store at 4°C; transport at ambient temperature next business day
Tissue	Transport on dry ice (or wet ice if no dry ice available)	Store at -80°C. Transport on dry ice (or wet ice if no dry ice available)

7.2 Appendix 2

Proforma to accompany neurofibromatosis specimens

Date: _____

Dear Tumour Bank staff,

Thank you for storing these samples:

☐ Blood

☐ Tissue (detailed on following lines)

☐ Consent form enclosed

Patient name: _____

Patient MRN: _____

Hospital: _____

Date of collection: _____

Time of collection: _____

Collected by: _____

Doctor's name: _____

05.10 DNA Extraction from OG-575 Saliva Self-Collection Kit

Document Number: TB 05.10 Version: 002	Issue Date: 30/10/2013
Author: Aedan Roberts Title: Research Assistant	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
17/10/2012	New Document		GN
30/10/2013	Annual Review – Minor text change	05.10.001	ARo

1. PURPOSE

The purpose of this document is to outline how to extract the DNA from Saliva Self-Collection Kits that have been returned to the Tumour Bank (TB).

2. SCOPE

This protocol covers the process of all DNA extractions from returned Saliva Self-Collection Kits and the long-term storage of DNA within the TB. As a part of the operation of the TB, it is sometimes difficult to collect samples for DNA from patients when in the hospital. To address this issue, sometimes it is appropriate to send out Saliva Self-Collection Kits (OG-575 supplied by DNA Genotek) when the sample is required for studies (appropriateness to be assessed by the Clinical Research Associate).

3. RESPONSIBILITIES

The TB Research Assistants must ensure that these protocols are adhered to at all times when extracting DNA using Saliva Self-Collection Kits (or other sources).

4. MATERIALS, EQUIPMENT AND FORMS

- Microcentrifuge capable of running at 15,000 x g
- 1.5 mL microcentrifuge tubes (autoclaved) capable of handling 15,000 x g
- Water bath at 50°C
- 95-100% ethanol at room temperature
- 70% ethanol at room temperature (made up with Milli-Q water)
- DNA storage buffer: TE (1.0 mM Tris-HCl, 1 mM EDTA, pH 8.0) or similar. As EDTA can make it difficult to perform some downstream applications a buffer such as FG3 from the QIAGEN Flexigene DNA Kit (1.0 mM Tris-HCl) would be preferred.
- PT-L2P buffer

- Ice in small esky/foam container
- Pipettes (1000 µL and 5-40 µL sizes) and blue and yellow pipette tips.
- Paper towels/Kimwipes
- Cryovials
- Permanent Marker

5. METHOD

- Make sure that the water bath is turned on and is stable at 50°C for 10 minutes before proceeding with methods.
- Label the tube from the Saliva Self-Collection kit that contains the patient saliva with the MRN using a permanent marker in 2 places.
- Gently mix the sample in the collection tube by inversion and shaking for a few seconds to ensure viscous samples are properly mixed.
- Incubate the sample tubes at 50°C in the water bath for at least 1 hour. Make sure that the fluid within the tube is submerged under the water, but also make sure the top of the tube is above the water line to make sure no water can leak into the sample. The heat treatment is essential to ensure that DNA is adequately released and nucleases are permanently inactivated. The sample may be incubated at 50°C overnight.
- Label 1.5 mL microcentrifuge tubes with patient MRN using a permanent marker. Generally with the OG-575 three 1.5 mL tubes are sufficient but it will depend on the amount of saliva collected.
- Aliquot 500 µL sample from the original collection tube into labelled 1.5 mL microcentrifuge tubes.
- To 500 µL samples add 20 µL PT-L2P and mix by vortexing for a few seconds. If sample volume in tubes is less than 500 µL then add the appropriate volume of PT-L2P (1/25th the volume of sample aliquot in tube).
- Incubate on ice for 10 minutes.
- Centrifuge at room temperature for 15 minutes at 15,000 x g. If time is short the centrifugation step may be reduced to as low as 5 minutes, but the 15 minute spin is beneficial for reducing the turbidity and achieving purer DNA.
- While samples are being centrifuged label fresh 1.5 mL microcentrifuge tubes with patient MRNs (equal number of tubes as used in steps 5-7).
- Carefully transfer the clear supernatant from centrifuged samples into the fresh labelled 1.5 mL microcentrifuge tubes. Be careful not to disturb the pellet while transferring. If the pellet is disturbed you will need to re-centrifuge the samples (step 9). Otherwise discard pellets.
- To the 500 µL of supernatant add 600 µL of room temperature 95-100% ethanol. If less than 500 µL of supernatant add the appropriate amount of 95-100% ethanol using 5 parts supernatant:6 parts ethanol. Mix gently by inversion 10 times.
- Centrifuge the 1.5 mL microcentrifuge tube at room temperature for 2 minutes at 15,000 x g. Make sure you know the orientation of the tube so that you know where the pellet will form (in case it is too small to see).
- Carefully remove the supernatant and discard it. Take care not to disturb the DNA pellet.
- Carefully add 250 µL of room temperature 70% ethanol to wash the pellet. Add ethanol slowly so as to not disturb pellet and incubate at room temperature for 1 min. If you disturb the pellet when washing then re-centrifuge at 15,000 x g at room temperature for 5 minutes
- Remove the ethanol from the pellet. If the pellet is secure invert the tube onto a paper towel and allow ethanol to evaporate for 7 minutes.
- Add 100 µL of TE buffer (or buffer used) to dissolve the DNA pellet (if the pellet is smaller than usual than you can dissolve in smaller volumes to increase concentration).
- Incubate DNA solution at 50°C for 1 hour with occasional vortexing to ensure complete hydration of DNA in buffer. May be incubated for longer, including overnight.
- While DNA is hydrating (dissolving) in buffer at 50°C, label two cryovials with yellow tops for each patient.
 - MRN
 - "DNA Saliva"
 - Date

- Buffer (i.e. “TE buffer” etc.)
- t. After DNA has dissolved combine all the aliquots from a patient together and mix gently by inversion. Once mixed take a 12 µL aliquot for quality control (see Tumour Bank SOP 05.12, “DNA Quality Assessment”) which should be stored at 4 °C. The rest of the DNA can be aliquoted evenly between the two cryovials.
- u. Fill in the details of the patient and samples into the Tumour Bank specimen folder. In the notes section write that the sample is from a Saliva Self-Collection kit and the buffer the DNA is dissolved in. Place the cryovials into the correct position in the freezer box and place in the Tumour Bank -80°C freezer.

6. SAFETY

- All local Chemical and Sharps policies must be adhered to.
- Empty blood tubes, pipette tips etc. should be disposed of in accordance with local regulations for handling of potentially infectious biological material.
- Saliva should be considered potentially harmful and appropriate personal protective equipment should be used including gloves, laboratory coat and safety glasses.

Note: This SOP is adapted from the PrepIT™•L2P Manual purification protocol handbook from DNAGENOTEK (<http://www.dnagenotek.com/ROW/pdf/PD-PR-006.pdf>). It contains many comments and hints that may help if experiencing difficulty with this SOP or if a kit other than the OG-575 is used.

05.11 DNA Quantification Using Nanodrop 2000

Document Number: TB 05.11 Version: 001	Issue Date: 21/10/2012
Author: Guy Nelmes Title: Research Assistant Signature Date	Approved by: Daniel Catchpoole Title: Head of Tumour Bank Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
21/10/2012	New Document		GN
01/11/2013	Annual Review – No changes made		ARo

1. PURPOSE

The purpose of this document is to outline how to quantify DNA extracted from Saliva Self-Collection Kits (or other sources).

2. SCOPE

This protocol covers the process of quantifying DNA extracted from returned Saliva Self-Collection Kits (or other sources). As a part of the operation of the Tumour Bank (TB), it is sometimes necessary to extract and store DNA rather than storing the original tissue sample. Before freezing and storing long term it is essential to check the quantity and quality of the DNA extracted so that its usefulness for researchers is known without having to repeatedly thaw samples. This SOP is designed to be used in conjunction with SOP 05. 10, "DNA Extraction from OG-575 Saliva Self-Collection Kit", but can be used to assess the quality of any DNA sample dissolved in a known buffer.

3. RESPONSIBILITIES

The TB Research Assistants must ensure that these protocols are adhered to at all times when quantifying DNA extracted from Saliva Self-Collection Kits (or other sources).

4. MATERIALS, EQUIPMENT AND FORMS

- 2 µL sample of DNA (or less if DNA concentration is sufficient)
- Buffer that DNA is dissolved in, minimum 2 µL (e.g. TE buffer or QIAGEN's FG3 buffer)
- Pipettes (0.5-10 µL size)
- Pipette tips
- Ice in small foam container

- USB thumb drive or lab book (both is better)
- Kimwipes
- Milli-Q Water

5. METHOD

- The first step in assessing the quality of extracted DNA is to quantify it. This is done using the Nanodrop 2000 on level 3. Keep DNA on ice during this process. Turn on computer attached to Nanodrop and open the “Nanodrop 2000” software using the shortcut on the desktop.
- Wipe the two measurement pedestals using a kimwipe dampened with Milli-Q water as shown below and then lower the sampling arm.



- Select the ‘Nucleic Acid’ button on the home screen of the Nanodrop 2000 software
- Press “OK” at the “Wavelength verification” prompt if you have lowered the sampling arm already. Next make sure the “Add to Report” option is ticked near the top left of the screen (otherwise you will need to write down the results as you go).
- Pipette 2 μL of the buffer used to dissolve the DNA onto the lower measurement pedestal as shown below.



- Select “Blank” near top left corner of the screen.
- After the blank has been sampled (the machine will make noises for a few seconds and then stop), lift up the sampling arm and wipe away the blank buffer using a kimwipe.
- Type in the name of the sample (MRN or other identifier) into the “Sample ID” field in the top right of the screen. Also make sure that the “DNA” option is selected in the “Type” field.
- Pipette 2 μL of the sample onto the lower measurement pedestal and select “Measure” near the top left of the screen.

- j. Save the file/report in a known location (either on a USB thumb drive or a labelled folder on the C:/ drive) and note the results of the concentration, the A260/280 and A260/230 readings, and then wipe the Nanodrop clean.
- k. Repeat the steps h-k for all samples to be analysed.
- l. If the sample is to be analysed for quality of DNA using agarose gels then proceed to SOP 05.12, "Quality Control of Genomic DNA using Agarose Gel Electrophoresis", leaving the DNA on ice (or keep at 4 °C overnight).

6. SAFETY

- All local Chemical and Sharps policies must be adhered to.
- This method should be considered potentially harmful and appropriate personal protective equipment should be used including gloves and laboratory coat.

05.12 DNA Quality Assessment

Document Number: TB 05.12 Version: 002	Issue Date: 31/10/2013
Author: Aedan Roberts Title: Research Assistant	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
21/10/2012	New Document		GN
31/10/2013	Annual Review – Minor text changes	05.12.001	ARo

1. PURPOSE

The purpose of this document is to outline how to assess the quality of extracted DNA from Saliva Self-Collection Kits (or other sources) where the concentration of DNA is known.

2. SCOPE

This protocol covers the process of quantifying DNA extracted from returned Saliva Self-Collection Kits (or other sources). As a part of the operation of the Tumour Bank (TB), it is sometimes necessary to extract and store DNA rather than storing the original tissue sample. Before freezing and storing long term it is essential to check the quantity and quality of the DNA extracted so that its usefulness for researchers is known without having to repeatedly thaw samples. This SOP is designed to be used in conjunction with Tumour Bank SOP 05.10, "DNA Extraction from OG-575 Saliva Self-Collection Kit" and is a continuation of SOP 05.11, "DNA Quantification using Nanodrop 2000", but can be used to assess the quality of any DNA sample of known concentration.

3. RESPONSIBILITIES

The TB Research Assistants must ensure that these protocols are adhered to at all times when assessing the quality of extracted DNA from Saliva Self-Collection Kits (or other sources).

4. MATERIALS, EQUIPMENT AND FORMS

- Agarose I
- Milli-Q Water
- Laboratory bottle (500 mL)
- Ethidium Bromide-contaminated conical flask
- Microwave
- Agarose Gel casting equipment (Gel caster, combs and mini or wide gel tray; see diagram in Appendix 1)

- Agarose gel electrophoresis equipment (power pack, correct size agarose gel electrophoresis tank for gel used and lid)
- 1x TAE Buffer (50x recipe: Appendix 1)
- 6x Loading buffer (recipe: Appendix 1)
- Ethidium Bromide
- Large heat proof gloves
- Cytogenetic waste bin and sharps bin
- Pipette and pipette tips (0.5-10 μ L)
- 1.5 mL microcentrifuge tubes
- Invitrogen 1Kb Plus DNA ladder (Catalogue Number 10787-018)
- Ethidium Bromide-contaminated container for transporting agarose gels

5. METHOD

- Determine the total number of samples to be assessed. If 14 or less a “mini” agarose gel can be used, if more then a “wide” agarose gel must be used.
- Make up the required volume of 0.7% agarose solution by combining 0.42g of Agarose I with 1x TAE buffer to a final volume of 60 mL for a “small” agarose gel, or 1.54g of Agarose I with 1x TAE buffer to 220 mL for a “wide” gel, in a 500 mL laboratory bottle.
- Place the 500 mL laboratory bottle into the microwave and unscrew the lid. Leave the lid sitting on the top of the bottle. Set the microwave on high and run for 2 minutes (or longer if required). The solution will need to approach boiling before the agarose will dissolve so it will be necessary to adjust the length of time the agarose is in the microwave until the agarose has dissolved. Remove the bottle from the microwave using the large black heat resistant gloves next to the microwave and allow to cool in a safe place for at least 20 minutes.
- While the agarose solution is cooling set up the gel casting equipment (see Appendix 2). This is done by placing the gel tray within the gel casting tray and sealing before adding the 2 gel combs required (which will depend on the number of samples). For a mini gel it should be 2 x 8 well combs and for a wide gel 2 x 15 well combs.
- When the agarose solution has cooled (but not started to set) add the Ethidium Bromide. **Caution: Ethidium Bromide is a carcinogen and all work with Ethidium Bromide should be performed within a fume hood using full Personal Protective Equipment.** Working in the fume hood, slowly pour the agarose solution into the Ethidium Bromide-contaminated conical flask (found labelled next to the agarose gel electrophoresis equipment). While pouring it is safer to use the black heat resistant gloves as the agarose may still be hot despite the cooling period.
- Pipette the required volume of Ethidium Bromide into the solution and mix by gentle swirling. For a mini gel with volume of 60 mL add 3 μ L and for a wide gel with a volume of 220 mL add 11 μ L. Dispose of pipette tip into cytogenetic sharps waste bin.
- Place the set up agarose gel casting equipment into the fume hood and make sure it is level. Gently pour in agarose solution, but make sure it doesn’t get above the level of the wells on the combs, and allow to set for 40 minutes. Any agarose not used should be poured into a weigh boat and allowed to set in the fume hood. Once set, the weight boat containing the agarose should be disposed of in a cytogenetic waste bin.
- While gel is setting prepare the DNA for electrophoresis. Label 1.5 mL microcentrifuge tubes with MRN or other sample identifier. Load 0.5 μ g of DNA and adjust volume to 10 μ L using Milli-Q water. Add 2 μ L of 6x gel loading buffer to the sample.
- Once the gel is set remove the combs from the gel gently to expose the wells. The gel can now be removed from fume hood and placed in the agarose electrophoresis tank. The wells need

to be closer to the black electrode as DNA will move through the gel from the black (negative) electrode to the red (positive) electrode. Fill the electrophoresis tank with TAE buffer until at the level indicated.

- j. Load the first lane of both combs with 1 µL of Invitrogen 1Kb Plus DNA ladder (if 2 rows of wells are required). Load DNA samples into the other wells slowly so as to not mix DNA samples (one well per sample).
- k. Electrophorese at 40V for 3 hours. This step can be sped up by increasing voltage to near 100V. It is imperative to not let the dye front travel off the gel or through the wells of the second comb so it is important to keep an eye on the gel throughout the electrophoresis. Once complete dispose of TAE buffer according to local chemical policies.
- l. Once gel has finished running, visualise on the UV transilluminator on level 3, lab 2, known as the Alpha Imager. Take down the gel (still on its gel tray) using the Ethidium Bromide-contaminated container for transporting gels (located next to microwave on level 4, lab 8).
- m. To scan the gel, place it in the Alpha Imager. Open the "Alpha Imager" software from the desktop of the attached computer (**always use gloves while using this computer**) and select "acquire". Focus the camera onto your gel manually. Close the Alpha Imager, turn on the UV transilluminator and select "expose preview". If happy with the focus and quality of the displayed image then select "acquire image". On the captured image it is then possible to edit the contrast, gamma readings etc. to make the bands more defined. Once the image is ready, save the image and print out a copy.
- n. Turn off the UV transilluminator and dispose of the gel into the cytogenetic waste. Wipe down the bench with 70% Ethanol and Kimwipes.

6. SAFETY

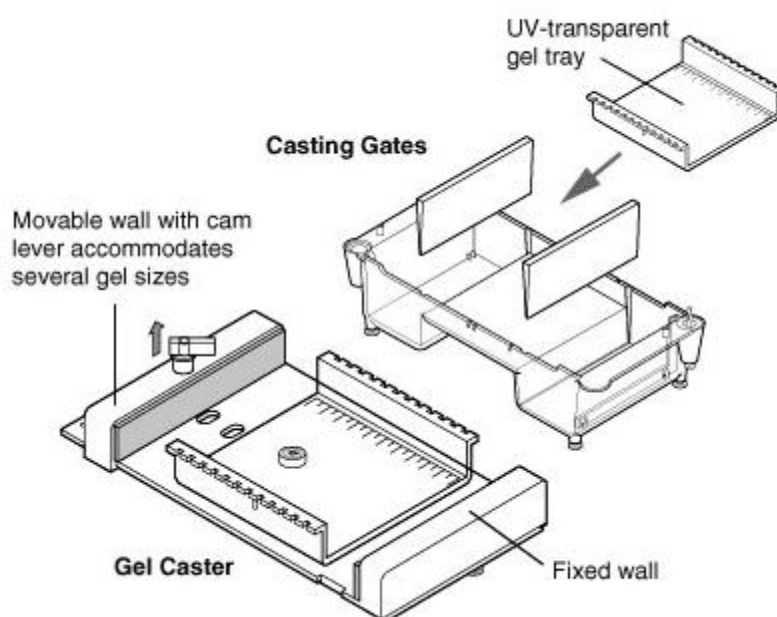
- All local Chemical and Sharps policies must be adhered to.
- Ethidium Bromide is a known carcinogen. Always handle with care and familiarise yourself with the MSDS before using Ethidium Bromide. In particular, don't add Ethidium Bromide to agarose when it is still hot and steam is being produced.
- This method should be considered potentially harmful and appropriate personal protective equipment should be used including gloves, laboratory coat and safety glasses. Fume hoods should be used for Ethidium Bromide work.

7. APPENDIX

7.1 Appendix 1 - Reagent Recipes

Reagent	Recipe
50 x TAE Buffer	242 g Tris base 57.1 mL Glacial acetic acid 100 mL EDTA, pH 8.0 Make up to 1 L with Milli-Q water and store at room temperature
6 x Gel Loading Buffer	0.25% Bromophenol Blue (25 mg) 0.25% Xylene Cyanol FF (25 mg) 40% (w/v) sucrose (4 g) Make up to 10 mL using Milli-Q Water

7.2 Appendix 2 – Diagram of gel casting equipment



(Adapted from <http://www.bio-rad.com/prd/en/AU/LSE/PDP/bec92fc8-9963-42b2-82cd-9381acce8a3/Mini-Sub-Cell-GT-Systems>)

6.0

MATERIAL RELEASE

06.01 Responding to Requests for Specimens from the Children's Hospital at Westmead Tumour Bank

Document Number: TB 06.01 Version: 005	Issue Date: 19/9/2012
Author: Albert Chetcuti Title: Project Officer	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
01/05/2009	New Document		AC
07/07/2010	Annual Review	06.01.001	AR
07/07/2012	Update to "Materials, Equipment & Forms"	06.01.002	AR
01/12/2011	Addition to "Project Progress Reports"	06.01.003	KJ
19/09/2012	Annual Review	06.01.004	AC
11/12/2013	Annual Review – No changes made		LZ

1. PURPOSE

The purpose of this document is to outline the Tumour Bank's(TB) response to a researcher's request to obtain specimens from the TB.

2. SCOPE

This protocol covers all tumour, bone marrow, blood and cerebrospinal fluid (CSF) samples collected from patients at The Children's Hospital at Westmead (CHW), for whom the Haematology and Histopathology departments have residual specimens.

3. RESPONSIBILITIES

The TB Project Officer has to ensure that these protocols are adhered to at all times when responding to a researcher's request to obtain samples.

4. MATERIALS, EQUIPMENT AND FORMS

- Tumour Bank Application Form (Appendix 1)
- Tumour Bank Project Update Form (Appendix 2)

- Tumour Bank Request Form (Appendix 3)

5. METHOD

5.1 External Researchers Applications

5.1.1 Initial Contact

- Upon receiving an email from an interested researcher, the Tumour Bank Administration Officer will search TB to establish the number of samples the bank has in storage which are suitable for the researcher.
- Send a reply email to the researcher detailing the number and type of samples held by the TB.
- Provide details of the application process to the researcher and attach the current tumour bank application form (Appendix 1).

5.1.2 Receipt of Tumour Bank Application

- Check application form to see that all components of the application form are attached.
These include the following
 - Application form
 - Ethics approval
 - Evidence of funding
 - Any additional scientific information
- Depending on when the application is received, it may be appropriate to email the application form with its components to the members of the Tumour Bank Committee who are then given two weeks to review the application. If a Tumour Bank Committee meeting is to be held within 6 weeks of receiving the application, then this should be reviewed at the next TB Committee meeting.
- Tabulate any issues or concerns raised by the committee.
- Perform an updated search of the TB database while the application is being reviewed by the committee if a significant amount of time has elapsed.

5.1.3 Applications Not Approved

- If an application is rejected by the TB Committee, email a letter to the applicant outlining the concerns raised by the TB Committee and why their application was rejected.
- On the letter, indicate that the TB will be happy to review an amended application that addresses the issues and concerns raised.

5.1.4 Applications Approved

- When an application is approved, notify the applicant by email and ask to forward details of their World Courier account number to facilitate delivery of the samples (if applicable).
- If the applicant is a local researcher, arrange for samples to be collected directly from the CHW TB.
- If the samples are to be shipped internationally by World Courier, make arrangements to have the World Courier come to the TB and collect samples for shipment (usually done on dry-ice).
- Shipment should preferably be done on Monday or Tuesday to ensure the sample does not arrive at the destination on the weekend (also check for any national public holidays in the relevant destination country).
- Send an email to the receiver acknowledging that the samples have been sent and asking to inform the TB when they are received (with the WC tracking number).

5.1.5 Requests for Clinical Data

- a. If clinical data is requested by researchers via email, the TB Administration Officer will collate the data.
- b. Prior to sending the data to the relevant researcher, the data will be sent to another TB staff (usually the Clinical Research Associate or Project Officer) for checking for quality assurance purposes.

5.1.6 Project Progress Reports

- a. Once a successful applicant has received samples from the TB, send them an email requesting a progress report on the samples received with the Project Update form (Appendix 2).
- b. Completed update forms are to be returned via email or post to the TB Administration Officer at the following time points:
 - 12 months after sample shipment
 - 12 months following until project completion
- c. Track issuing and receiving completed update forms using the research applications tracking sheet. (G:/Tumour B/ TB Management/ Research applications tracking sheet).
- d. The TB Administration Officer is to co-ordinate project updates.
- e. Any unused specimens are to be returned to the Tumour Bank.

5.2 Internal Clinician Requests

5.2.1 Initial Contact

- a. A clinician from the CHW or their representative contacts the TB CRA to request for samples stored at the TB.
- b. The CRA is to then triage the sample urgency according to the purpose of the request.
- c. The requests can be for diagnosis and treatment decisions which are treated as urgent or for quality assurance (QA) purposes which are not treated as urgent.

5.2.2 Diagnosis and Treatment Decisions

- a. These sample requests are urgent.
- b. The CRA has to check for availability of the sample in the TB storage.
- c. If the sample is available, the CRA contacts the clinician and sends them the sample as soon as possible.
- d. The CRA has to ensure the clinicians have filled in a TB Request Form (Appendix 3) retrospectively.
- e. The completed forms are used to update the TB database and filed in the filing cabinet.

5.2.3 Quality Assurance Purpose

- a. Samples which are requested for QA purposes are not treated as urgent.
- b. The CRA is to ensure the clinicians have filled in a Tumour Bank Request Form prior to checking for availability of samples.
- c. Once the form is received, the CRA has to check for availability of the sample and send them to the clinician when it is available.
- d. The completed forms are used to update the TB database and filed in the filing cabinet.

6. SAFETY

- Not applicable

7. APPENDIX

7.1 Appendix 1 Tumour Bank Application Form



Tumour Bank Application Form

IMPORTANT:

Please read the attached '*Conditions of Use for Tumour Bank Samples*' prior to completing this application form.

For further information please contact:

Tumour Bank
Children's Cancer Research Unit
The Children's Hospital at Westmead
Locked Bag 4001
Westmead NSW 2145
AUSTRALIA
TEL: +61-2-9845-3028
FAX: +61-2-9845-3078
Email: daniel.catchpoole@health.nsw.gov.au

Please submit completed form by email (preferred) or fax.

Investigator Details

Name of Investigator(s):

Department and Institution:

Address:

Delivery Address (if different from above):

Telephone (including area code):

Facsimile (including area code):

Email Address(es):

Project Description

Project Title:

5.4 Lay Description of Project

5.5 Project Description

On separate pages, please provide details about the project (up to 4 pages maximum)

- 1) Introduction
- 2) Aims and hypotheses
- 3) Research Plan (including methods to be used)
- 4) Samples required (type, clinical/pathological staging, number of specimens)
- 5) Preliminary results
- 6) Significance of the research
- 7) Relevant Publications

5.6 Institutional Ethics Committee Approval.

Before samples can be released the Tumour Bank Committee requires evidence that the specific project has been adequately peer-reviewed by a scientific body. Consequently, please send a copy of the Ethic Committee Approval letter covering the proposed project with this application.

Date received: __/__/__.

Project Funding

Please indicate the source of funding for this project:

Pending Grant Application (date notification expected __/__/__)
or Grant Application approved. (include approval letter)
or Institutional Funding (Provide Statement from Institution Head)

☐
☐
☐

Scientific Review

Please indicate in which manner the project has been independently peer-reviewed by internal or external means (e.g. publications, successful grant, formal scientific review board etc).

Duration of Project:

Proposed Commencement Date:

Tumour Specimens Requested

Type of Samples and Specific Disease

(please indicate blood, bone marrow, fresh tissue, FFPE and disease)

Indicate the number of samples required.

Justification of sample numbers – why do you require this number?

How will the data be analysed?

The Children's Hospital at Westmead Tumour Bank

Conditions of Use for Tumour Bank Samples

Conditions of Use

Samples from The Children's Hospital at Westmead Tumour Bank are provided free of charge with the intention of facilitating research into cancer or a related field. The samples must be used in the manner described in the application as provided to the Tumour Bank Committee. Any change in the project direction must be communicated in writing to the Tumour Bank Committee who reserves the right to withdraw support. Written permission must be obtained from the Tumour Bank if the investigator wishes to share the samples with another researcher with their host institute.

Tumour Bank Samples

The Tumour Bank samples are provided without revealing the patient's name or date of birth. No attempts should be made by the Investigator to identify the patient or to determine other patient information. If additional clinical information is required, it should be requested through the Tumour Bank.

Whilst the majority of tumours are easily distinguished from surrounding normal tissue, this is often not so for the small round cell tumours such as the soft tissue sarcomas. All care is taken by Pathologists to select tumour tissue, however the Tumour Bank and the Histopathology department of The Children's Hospital at Westmead will not accept any responsibility for the inadvertent provision of incorrect tissue. In addition, whilst an attempt is made to freeze the samples as rapidly as possible, the Tumour Bank does not guarantee that high quality RNA will be obtained from samples.

Samples are provided in compliance with the NSW Human Tissue and Anatomy Legislation Amendment ACT 2003 and the NH&MRC National Statement on Ethical Conduct in Human Research.

Research Support

At the request of the investigator and following approval by the Tumour Bank Committee, the Tumour Bank can be of assistance with preparation of high quality DNA, total RNA or protein from blood, bone marrow or tissue samples. Preparation of DNA, total RNA or protein will depend on the amount of each sample available and the specific requirements of each project, and will be performed on a case-by-case basis.

The Tumour Bank in collaboration with the Histopathology department also has the facility to prepare sectioned tissue on microscope slides (paraffin embedded and fresh frozen tissue) and preparation of small scale tissue microarrays (TMA). The preparation of TMAs is very time consuming and each application for production will be assessed on a case by case basis. The preparation of sectioned paraffin-embedded tissue and TMAs requires the Tumour Bank to obtain permission from the Histopathology department. A request for production of a TMA may not be possible because of restrictions accessing sufficient tissue to prepare TMA cores.

The Tumour Bank has several research tools to assist in tissue based research. These include a virtual microscope suite, laser capture microdissection microscope and automated immunohistochemistry system. The Tumour Bank has a Aperio ScanScope CS that can digitally scan microscope slides up to 83X magnification and perform high-resolution digital image analysis to quantify gene expression from IHC/ISH. With use of a PALM Laser Capture Microdissection microscope, the Tumour Bank can isolate specific cell populations from a tissue section. DNA, RNA or protein can then be isolated for further downstream molecular analysis. The Tumour Bank has a Vision Bio-Systems Bond-X IHC system capable of performing specialised high quality immunohistochemistry. This system uses commonly utilised detection chemistries and is suited to researchers requiring large scale screening of samples for research and diagnostic applications. For further information about virtual microscopy, TMAs, LCM, or Bond-X IHC, please contact the Tumour Bank directly.

Sample Safety

While samples are not stored from patients with known HIV, Tuberculosis or Hepatitis B, the screening of patients for the presence of such pathogens is not routinely performed. All samples should be handled with the utmost care to prevent infection with pathogens. No responsibility will be taken by the Tumour Bank for injury or illness that may occur to investigators handling the samples.

Commercialising and Intellectual Property

Samples must not be given or sold to other investigators, nor used to produce commercial products. Although the Tumour Bank supplies samples to the investigator, the investigator has full intellectual property over any discoveries derived from using Tumour Bank samples. The Tumour Bank assumes no intellectual property over any samples given to the investigator.

Sample Preparation Cost

Australian law prohibits trade in human tissues. Tissue may be provided to the investigator at no charge but in many cases considerable work and expense is involved in processing and preparing samples for dispatch, and some cost recovery might be necessary. Any cost recovery fees will be discussed with the investigator beforehand.

Courier Cost

The cost of packaging and shipment of the samples will be borne by the investigator/institution requesting the samples and NOT by the Tumour Bank. Please be aware that a substantial cost may be involved in sending samples within Australia or overseas.

Sydney Based Investigators

For investigators based in Sydney (or nearby), it is possible for samples to be collected directly from the Tumour Bank laboratories at The Children's Hospital at Westmead. Successful investigators will be directly notified when samples will be

ready for collection. The Children's Hospital at Westmead also has a courier service available to deliver samples free of charge within the Sydney metropolitan area.

Interstate and International Investigators

The Tumour Bank has chosen to only transport samples using the courier services of World Courier PTY LTD (www.worldcourier.com). This company has offices in major cities around the world and to date have provided us with very professional service. The investigator is requested to establish an account with World Courier so that the cost of sample shipment can be directly invoiced to the investigator's institute. The investigator is also responsible for complying with appropriate customs regulations for the importation of human tissue from foreign countries. The Tumour Bank will not be held responsible if samples fail to pass customs at the port of entry in a foreign country. Successful investigators are requested to provide the Tumour Bank with a World Courier account number prior to shipment of the samples. Samples will be shipped by air and delivery is usually made within 2-3 days of departure from Sydney. Under no circumstance is it possible for the Tumour Bank to pay for shipping and then be reimbursed by the investigator. The Tumour Bank may choose to use the services of an alternative courier service only under exceptional circumstances.

Application Requirements

Scientific Review

The investigator(s) are required to show evidence that the proposed project has been reviewed scientifically by independent means. This could include a successful grant application, peer-reviewed publication relating to the project in which the investigator is a co-author, a letter from an internal review board (IRB) or scientific advisory committee (SAC) or from an independent scientist not related to the project and not within the same program/department as the investigator. Approval from the investigators institutes' human ethics committee does not represent an independent scientific review of the proposed project using Tumour Bank samples.

Ethics Approval

The investigators are required to obtain ethics approval from their institute prior to submission of an application form. Applications will be rejected without ethics approval. A copy of the ethics approval letter from the investigator's host institute will need to be forwarded with the application form.

Project Funding

Investigators are required to indicate the funding source for the proposed project using Tumour Bank tissue. This may include a successful grant application letter, or a letter from the investigator's institute indicating funding for the project.

Application Assessment

Application for samples from the Tumour Bank will be assessed on an individual basis by the Children's Hospital at Westmead Tumour Bank Committee. This committee meets every 3 months and includes Tumour Bank scientific staff,

pathologists, oncology surgeons and other senior scientific staff within the Children's Cancer Research Unit.

The Tumour Bank committee will evaluate each application based on the following criteria:

Scientific Approach

Are the conceptual framework, hypothesis, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Is this a justified and efficient use of the tissue resource? Does the application acknowledge potential problem areas and consider alternative tactics?

Significance and Applicability

Does this study address an important problem in the study of cancer? If the aims of the application are achieved, how will scientific knowledge be advanced?

Investigator

Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers?

Funding

Does this proposal have specific funding? Is this funding adequate to perform the work?

Tissue Availability

Does the Tumour Bank have sufficient tissue (cases and numbers) to allow the project to have adequate statistical power.

Following assessment of each application by the Tumour Bank Committee, the investigator will be informed if their application is successful. If the committee identifies any questions in regards to an application, the investigator will be asked to respond to the committee's questions in writing.

Progress Reports and Publications

The investigator(s) are required to provide a report 12 months following receiving samples and also a report following completion of the project. These reports should indicate the percentage of samples that have provided useful information, whether the study is still continuing, and the anticipated date of study completion. You will NOT be requested to reveal the results of the study in this report. At study completion, any remaining samples should be returned to the Tumour Bank for use by others.

A copy of all publications (peer-reviewed manuscripts and conference abstracts) resulting from use of Tumour Bank samples should be forwarded to the Tumour Bank upon acceptance by the conference/journal committee.

Study Completion

At study completion, all remaining material should be returned to The Children's Hospital at Westmead Tumour Bank for use by others. The cost of shipping the samples back to the Tumour Bank will be covered by the investigator.

Acknowledgement and Collaborations

The investigator(s) will be required to acknowledge the Tumour Bank in all publications or presentations resulting from research using Tumour Bank samples. Depending on the level of support given, the investigator may also be required to acknowledge the appropriate Tumour Bank staff member as co-author on resulting publications resulting from Tumour Bank samples. Failure to recognise the Tumour Bank in this manner will render the individual and/or the institution ineligible for future Tumour Bank applications. The following statement needs to be signed by the Principal Investigator.

I, (Principal Investigator) will be recognised as a collaborator in this project and, as such, will be given the opportunity to review any drafts prepared for publication, and will appear as a co-author on any publications.

Agreement Statement and Signatures

By signing this document, I
(principal investigator) have read the "Conditions of Use for Tumour Bank Samples"
and hereby agree to follow these conditions outlined below:

1. That I will use the specimens provided by The Children's Hospital at Westmead Tumour Bank only in the manner detailed in my application. I will not give or sell samples to a third party, or use samples for commercial gain.
2. I, as the principal investigator acknowledge that these samples have not been screened for potential pathogens and therefore may result in severe illness or even death if not handled properly. The responsibility for the correct handling of the samples lies solely in the investigator and is not the responsibility of The Children's Hospital at Westmead Tumour Bank. Any illness resulting from the mishandling of these samples is not the responsibility or liability of The Children's Hospital at Westmead Tumour Bank.
3. I, as the principal investigator will be responsible for the full cost of shipping samples from the Tumour Bank to my institution. In addition, also cover the full cost (if necessary) to transport any remaining samples back to the Tumour Bank upon completion of the project.
4. Have obtained ethics approval for the use of human tissue from my host institute Human Ethics Review Committee (or equivalent).
5. To acknowledge The Children's Hospital at Westmead Tumour Bank in all publications and presentations resulting from samples supplied.
6. That I will not attempt to identify the patients from whom samples were obtained from, nor will I attempt to gain any personal information regarding these patients other than that obtained through written requests to the Tumour Bank.
7. Provide details for the funding of the project to the Tumour Bank.
8. Provide progress reports detailing the use of samples provided when requested.

Signature of Principal Investigator

Full Name (printed)

Date.....

Signature of Co-Investigator

Full Name (printed)

Date.....

Signature of Institutional Head

Full Name (printed)

Date.....

Institution Name

Address

.....

.....

.....

Contact Information

Mailing Address:

Tumour Bank
Children's Cancer Research Unit
The Children's Hospital at Westmead
Locked Bag 4001
Westmead NSW 2145
AUSTRALIA

Email Address: albert.chetcuti@health.nsw.gov.au (Albert Chetcuti)

Facsimile: (02) 9845 3078 - Address document to the Tumour Bank

Website: <http://tumourbank.chw.edu.au/>

Checklist

- ☐ Application Form
- ☐ Ethics Approval
- ☐ Confirmation of Project Funding
- ☐ Evidence of external scientific review
- ☐ Acknowledgment and collaboration (if necessary)
- ☐ Agreement Statement and Signatures

Office Use Only.

TB Specimen Availability:

.....

.....

.....

.....

TB Committee Recommendation:

.....

.....



Tumour Bank Project Update Form

When provided with samples from The Children's Hospital at Westmead Tumour Bank, the applicant is required to provide a project update report 12 months following receipt of samples. In this report, you should summarise your progress to date using samples provided. The template below has been designed to assist in providing this.

Name of Applicant(s):

--

Institution:

--

Details:

Telephone #:

Facsimile #:

Email:

Project Title:

--

Date of Project commencement: _____

Number and Type of Specimens Received

--

Was the delivery and quality of the samples received satisfactory?

--

Once the samples were analysed, did they yield data suitable for your experimental purposes? Please explain.

--

Would you like the Tumour Bank to assist you further with other tissue handling support, for example, more samples, different samples or application of novel technologies (eg virtual microscope, Tissue Microarrays)?

--

Has the data generated from the samples allowed you to complete your study?

Yes ☐ No ☐

If Yes, has it lead to publications and/or presentations (e.g. journal articles, abstracts, Thesis, book chapters)? Please provide details.

If No, when is the anticipated completion date of your project?

Please return this completed Project update form by post or email –

By Mail to: Tumour Bank
Children's Cancer Research Unit
The Children's Hospital at Westmead
Locked Bag 4001
Westmead, NSW 2145 Australia.

By Email to: TumourB@chw.edu.au



Tumour Bank Request Form

Retrieval of Specimens from Storage
For Patient Diagnostic Purposes
at The Children's Hospital at Westmead

Name of Investigator(s):

Department:

Address:

Telephone: _____

Facsimile: _____

Email Address: _____

Pager Number: _____

In signing this request form you indicate that you have read and agreed to the 'Conditions of Tumour Bank Sample Use' as outlined at the end of this document.

Signature:

Date: / /

Tumour Specimens Requested

5.7 Patient Details

MRN No: _____

AMO: _____

Name: _____

a. Date of Birth: ____/____/____

Date of Diagnosis: ____/____/____

Diagnosis

Type of Specimen Requested

Sample Collection Date: ____/____/____

- ☐ Blood
- ☐ Bone Marrow
- ☐ Control Tissue
- ☐ Solid Tumours (Histopathology Number: BX-____-____)

5.8 Reason For Request

OFFICE USE ONLY

Sample CHWTB: _____

Location: Box: _____

Position: _____

Date Stored: ____/____/____

Date Supplied: ____/____/____

Volume/Wt: _____

Conditions of Use of Tumour Bank Samples

1. The specimens provided by The Children's Hospital Westmead Tumour Bank will be used only in the manner detailed in my request. I will not give or sell them to a third party, nor will I use them for commercial gain.
2. These samples have not been screened for potential pathogens and therefore may result in severe illness or even death if not handled properly. The responsibility for the correct handling of the samples lies solely in my hands and is not the responsibility of The Children's Hospital at Westmead Tumour Bank. Any illness resulting from the mishandling of these samples is not the responsibility or liability of The Children's Hospital at Westmead.
3. Whilst the majority of tumours are easily distinguished from surrounding normal tissue, this is often not so for some tumour types. All care is taken by Pathologists to select tumour tissue, however the Tumour Bank will not accept any responsibility for the inadvertent provision of incorrect tissue. In addition, whilst an attempt is made to freeze the samples as rapidly as possible, the Tumour Bank does not guarantee that mRNA will be obtained from samples.
4. The costs of packaging and transport of the specimens will be borne by the individual/institution requesting the samples and not by the Tumour Bank.
5. The Investigator/s are requested that, at completion of the analysis, any remaining samples should be returned to the Tumour Bank.

Contact Information

- **Mailing Address**

Tumour Bank
The Children's Hospital at Westmead
Locked Bag 4001
Westmead, NSW 2145

- **Email Address**

albert.chetcuti@health.nsw.gov.au

- **Facsimile**

(02) 9845 3078 - Address document to the Tumour Bank

- **Website**

<http://tumourbank.chw.edu.au>

06.02 Shipping and Transporting Samples to Researchers (as Dangerous Goods)

Document Number: TB 06.02 Version: 005	Issue Date: 01/11/2013
Author: Aedan Roberts Title: Research Assistant	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
01/05/2009	New Document		
01/05/2010	Annual Review	06.02.001	KJ
01/12/2011	Annual Review	06.02.002	KJ
19/09/2012	Annual Review	06.02.003	AC
01/11/2013	Annual Review – Addition of approved shippers for dangerous goods	06.02.004	ARo

1. PURPOSE

The purpose of this document is to outline a standardised procedure to follow when shipping samples to researches nationally and internationally in such a way that the samples meet the needs of the end users, and for quality control purposes.

2. SCOPE

This protocol covers all samples that are to be shipped to researchers both nationally and internationally. Human Biological Materials are a precious and delicate resource and care should be taken to maintain and protect sample integrity at all times. An established and tested shipping procedure is essential, as inadequate shipping procedures may lead to the loss of the samples and additional costs for repeat shipments.

3. RESPONSIBILITIES

Shipments can only be prepared and authorised by approved Dangerous Goods shippers. Currently the approved shippers in the Tumour Bank are Aedan Roberts and Aysen Yuksel.

4. MATERIALS, EQUIPMENT AND FORMS

- Customs Declaration form
- United States Department of Agriculture (USDA) Statement form (for US shipments only)

5. METHOD

5.1 Procedure

The safe and legal transport of patient specimens is based on the following mandated activities:

- Classification and naming of the material to be shipped.
- Selection of packaging that will contain the contents if the package is damaged.
- Packing the shipment correctly.
- Placing appropriate markings and labels onto the outer package.
- Documenting relevant aspects of each package and its contents.

5.2 Appropriate Packaging and Shipping Conditions

- a. Packaging must be appropriate for the transportation of perishable goods. Contents of the package may be categorised as being dangerous or biohazardous and so packaging must conform to International Airway Transportation Authority (IATA) regulations.

IATA has defined a “patient specimen” as material collected directly from human or animals for diagnostic, treatment, prevention, investigational or research purposes. Patient specimens have to be categorized as Biological Substance, Category A or Category B, or Exempt Specimens.

A **Biological Substance, Category A** substance is "an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, or life threatening or fatal disease to otherwise healthy humans or animals".

A **Biological Substance, Category B** substance is "an infectious substance which does not meet the criteria for inclusion in Category A". Typical clinical or patient specimens being shipped for routine culturing or other testing for a non-Category A infectious microorganism or suspected of containing a non-Category A infectious microorganism are examples of Category B substances.

Exempt human or animal specimens are those for which there is "minimal likelihood there are pathogens present".

- b. Ship all frozen products in cryovials and frozen sections (in slide shippers) on dry ice.
Dry ice is classified as a dangerous substance and needs to be sent in a double-insulated shipper (styrofoam container in fitted cardboard box). Dry ice must NEVER be placed into a tightly sealed container (explosion hazard); the packaging must allow the release of CO₂.
- c. Ship all refrigerated products on frozen gel packs in insulated shippers.
- d. Ship paraffin blocks and slides with paraffin sections at room temperature.
- e. To prevent damage during shipping and ensure leak-proof conditions, cryovials must be inserted in cardboard or plastic vial shippers. Glass slides must be inserted in slide shipping cassettes to prevent breakage and damage.
- f. The quantity of samples to be shipped will affect the size of the packaging. Add sufficient refrigerant to maintain the desired temperature throughout the shipping cycle.
Use sufficient dry ice to ensure that the sample will remain frozen even if delayed in transit for 48-72 hours.
- g. Tape and seal the packaging securely to prevent condensation of refrigerant and provide additional security for the contents.
- h. Affix appropriate labels required to comply with shipping regulations and to ensure timely and proper shipping protocol, e.g. dry ice declaration sticker, “Keep Frozen” sticker, etc.
The service provided by World Courier takes care of all dry ice, packaging and labelling requirements.

5.3 Appropriate Supporting Documentation

- a. Contact the courier to establish what supporting documentation is needed to ship the sample to the specified destination. For international shipments, research any new regulations that may have been adopted, or special permits.
- b. Complete a Customs Declaration (to provide contact information and to declare nature of contents to customs and regulatory agencies) and an itemised list of contents (Tumour Bank Transport Receipt form).

For shipments to the United States, include a letter to the USDA to declare the presence or absence of possible contamination with any pathogenic agents if relevant.

- c. Dry Ice is a Class 9 Dangerous Good, and requires completion of a shipper's declaration. (This is usually completed by World Courier).

5.4 Appropriate Courier

World Courier is our chosen courier for International Shipments and **TNT** is generally our chosen Courier for Domestic Shipments.

We use these companies based on the following characteristics -

- Reliability
- Experience with and ability to routinely ship human biological materials.
- Ability to provide online tracking of shipments.
- Knowledge about relevant transportation regulations and permits.
- Existence of established, standardised paperwork accompanying shipments.
- Efficient customer service ensuring that unforeseen delays and deviations are tracked and communicated to relevant personnel.
- Customer service agents capable of troubleshooting and expediting shipments in accordance with temperature and time sensitivity of the samples.
- Willingness to “top up” dry ice in the package in the event of a delay in transit.

5.5 Shipping Procedure

(When using TNT as the chosen courier, refer to TB SOP 06.03, “TNT Shipment of Biological Samples on Dry Ice”, for specific details)

- a. The day before the shipment is to go out, contact shipper to schedule package pick-up. Request that World Courier provide all required packaging components, including dry ice, as well as a consignment note. Verify that all shipping information, contacts and required documents are accurate and complete.
- b. It is optimal to specify to whose attention the shipment is being delivered. This measure should prevent the shipment from arriving and being held in the receiving department for too long.
- c. When the World Courier representative arrives in the laboratory, retrieve samples from storage.
- d. Use appropriate safety procedures when handling dry ice or when retrieving samples from liquid nitrogen containers.
- e. Once samples have been dispatched, advise the Tumour Bank Administration Officer who will record this information in Biogenix.
- f. Contact (call or e-mail) consignee to provide them with the tracking number and inform them that the package has been shipped. Give them an estimated delivery time so that they can anticipate arrival of the sample.
- g. Track delivery using the online tracking capability of the courier to monitor shipment and expedite sample if delayed by customs or regulatory agencies.

Timing of shipping (to prevent delays in-transit):

- Schedule pick-up early in the day so that the package goes out on the earliest flight available.
- Schedule pick-up for early in the week (Monday or Tuesday) to prevent delays in shipment or delivery due to weekend schedules.

- Do not ship just before a holiday long weekend as it usually translates into delays in transit. Be aware of public holidays in the province or country of destination to plan for optimal shipping dates.

6. SAFETY

- Not applicable

06.03 TNT Shipment of Biological Samples on Dry Ice

Document Number: TB 06.03 Version: 005	Issue Date: 21/9/2012
Author: Albert Chetcuti Title: Project Officer	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
06/07/2009	New Document		
07/07/2010	Annual Review	06.03.001	AC
01/012/2011	Annual Review – Addition of appendix	06.03.002	AC
03/04/2012	Revision of text	06.03.003	KJ
21/09/2012	Annual Review	06.03.004	AC
01/11/2013	Annual Review – No changes made		ARo

1. PURPOSE

The purpose of this document is to outline a standardised procedure to follow when shipping biological samples that are classed as Biological Substance, Category B (UN3373), to a domestic location in Australia on dry ice using TNT.

2. SCOPE

This protocol covers all samples that are to be packaged and sent on dry ice, using the domestic courier services of TNT, through the hospital's Transport Department.

3. RESPONSIBILITIES

This shipment can only be authorised by an authorised Dangerous Goods shipper. Current authorised shippers in the Tumour Bank are Aedan Roberts and Aysen Yuksel.

4. MATERIALS, EQUIPMENT AND FORMS

- Large foam box with a cardboard box of equal size (e.g. Invitrogen Box)
- Labels (consignee + shipper) – Appendix 1
- Hazardous material Class 9 (Miscellaneous) Label (for Dry Ice)

- UN3373 Label (for Biological Substance, Category B materials)
- Hospital Cost Code account number
- Authorised shipper with current licence

5. METHOD

- a. Samples to be transported are to be packed as per the current Dangerous Goods regulations.
- b. Place the sample within a primary and secondary container with absorbent material in between.
- c. Bury the samples in 3-4 kg of dry ice (obtained from Level 3 freezer).
- d. Place dry ice in a large foam box with lid.
- e. Place a hole in the top of the lid to allow any build-up of carbon dioxide gas to be released.
- f. Place the foam box in a cardboard box with a breathing hole.
- g. Record the weight of the box.
- h. Label the box with shipper and consignee details, and UN3373 and Class 9 (Miscellaneous Goods) labels see (Appendix 1).

6. SAFETY

- The box containing dry ice should have ventilation holes.

7. APPENDIX

7.1 Appendix 1

UN3373 BIOLOGICAL SUBSTANCE, CATEGORY B

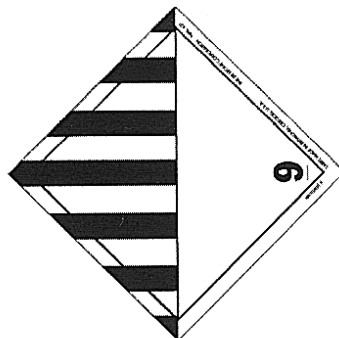
UN1845, DRY ICE, Net Weight _____ kg

SHIPPER:

Children's Cancer Research Unit
The Children's Hospital at Westmead
Loading Dock 5, Redbank Road
NORTHMEAD NSW 2152
Contact Person: Dr Albert Chetcuti
Contact Phone: 02 98453028

CONSIGNEE:

1st Name Surname
Department
Institute
1 Noname Street
Town State ???
Phone: area-code ???-???
Fax: area-code ???-???



7.0

PROJECT SPECIFIC OPERATIONS

07.01 Bone Marrow Sample Collection and Processing for Project Numbers 28 and 62

Document Number: TB 07.01 Version: 006	Issue Date: 1/11/2013
Author: Aedan Roberts Title: Research Assistant	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
01/05/2009	New Document		
30/06/2010	Annual Review	07.01.001	AR
19/10/2010	Addition of pertinent information	07.01.002	AR
01/12/2011	Annual Review	07.01.003	AR
20/09/2012	Annual Review	07.01.004	AR
16/05/2013	Review of discard/return procedures	07.01.005	AR
1/11/2013	Annual Review - Addition of 5.2 – Generation of a TB Biospecimen Number	07.01.006	ARo

1. PURPOSE

The purpose of this document is to outline a standardised procedure to follow when contacting the researcher, or processing, storing and tracking samples for the project 'CXCR4 antagonists in ALL in NOD/SCID mice' (Project 28) and 'Stem-like cells and relapse in ALL' (Project 62).

2. SCOPE

This protocol covers all samples that are from newly diagnosed and relapsed ALL patients from the Children's Hospital at Westmead (CHW) who have an appropriate RPMI tube prepared in the Haematology Department, and the Tumour Bank (TB) are subsequently notified.

3. RESPONSIBILITIES

The TB Clinical Research Associate (CRA), the TB Research Assistants (RAs), the TB Project Officer and the TB Administration Officer must ensure that these protocols are adhered to at all times when carrying out the above procedure.

4. MATERIALS, EQUIPMENT AND FORMS

- Lab Bench sample record sheet
- Blank label (stored in Lab Bench Sample Record folder)
- Personal protective equipment - gowns, gloves and safety glasses
- Labelling pen
- CRA SOP BSM 001 Appendix 1: Requesting and Managing Bone Marrow Aspirate Samples
- Appendix 1: Sample to be destroyed/ returned to Tumour Bank

5. METHOD

5.1 Bone Marrow collection and Preparation

- a. Bone marrow will be collected, at specified treatment timepoints (as per BSM 001), by qualified staff in the Haematology Department within CHW.
- b. Bone marrow will be collected in flow (cell culture) RPMI media, capped with a yellow or black screw top.
- c. Batches of tubes containing RPMI and heparin are supplied by the Linda Bendall research group to TB, for distribution to Haematology when requested.
- d. The TB will be notified that samples are ready for collection via pager or by telephone.
- e. A TB staff member will pick up the sample as soon as possible from the Haematology Department.
- f. Label the sample as per instructions below and store in the small TB refrigerator until collection by the Linda Bendall research group.
- g. Remove the patient MRN and all other identifying information from the tube with a suitable solvent and replace with a single unique Tumour Bank Biospecimen number.
- h. Write the number on a cryoprotective label stuck on to the side of the tube.
- i. Keep the specimen in its own specimen bag and remove the request form from the bag.

5.2 Generation of a TB Biospecimen Number

5.2.1 For new patients

- a. Log on to the Biogenix database
- b. Click the 'Search' button within the 'New Search' box
- c. Click 'Add new patient' box
- d. Fill in patient ID/MRN, patient's first name, surname, DOB
- e. Click 'Save' button
- f. Click on 'Episode' tab and fill in an episode date. Click on the 'Select diagnosis' button and select a diagnosis from the Diagnostic codes drop down menu (tick box). If the diagnosis is unknown at this point, use 'not yet identified' located towards the bottom of this list. This information is editable and does not need to be accurate to generate the biospecimens number.
- g. Click the 'Submit' button at the bottom of the list, followed by the 'Add' button when the system returns you to the previous screen.
- h. Follow steps in 5.2.2 below for new samples.

5.2.2 For existing patients

- a. Click on the 'Biospecimens' tab followed by 'Add new biospecimen'
- b. You only need to fill in the type of biospecimen, from the drop down menu, followed by the 'Save' button and the system will provide you with the CHWTB number for that sample.

5.3 Collection by Linda Bendall Research team

- a. Store the sample in the Tumour Bank refrigerator until collection.

- b. Record sample details including the CHWTB number and 'Linda Bendall' in the Tumour Bank specimens log book.
- c. Notify a member of Linda Bendall's research group (ext 59075) at the Westmead Millenium Institute that a sample is ready for collection. If there is no answer, call Linda Bendall's office (ext 59069), and if no answer there then email Linda Bendall (linda.bendall@sydney.edu.au) and inform her that there is a sample ready for collection.
- d. File the request form in the specimens log book with a note stating that the sample was allocated to Linda Bendall's research group.

5.4 Notification to Linda Bendall team (for Project 62 samples only)

- a. As soon as the below information becomes apparent, the TB Administration Officer or TB CRA will email Linda Bendall (linda.bendall@sydney.edu.au).
- b. If all information is not immediately available, an initial email with treatment stage should be sent, followed by the remaining information when it comes to hand:

Clinical Information	Source of Information
Treatment stage of specimen	Sample request form
Definitive diagnosis	Bone marrow haematology section of Powerchart
Linked specimen numbers (CHW TB #)	Biospecimen tab of TB Database

5.5 Samples to discard or return to the Tumour Bank

- a. The TB Database Administrator will email Linda Bendall the Discard/Return Form (Appendix 1) if a sample requires discard or return to the Tumour Bank. The Database Administrator will complete the top section of the form, and then attach it to an email that requests Linda Bendall to return the form when completed.

6. SAFETY

- All local Chemical and Sharps policies must be adhered to.
- Empty bone marrow tubes and pipette tips should be disposed of in accordance with local regulations for handling of potentially infectious biological material.

7. APPENDIX
7.1 Appendix 1

Sample to be destroyed/returned to Tumour Bank

For completion by Tumour Bank staff:

Dear Linda

The following sample is no longer suitable for your research project:

CHWTB # _____
for the following reason:

- a) ☐ Parent/patient has withdrawn consent
- b) ☐ Final diagnosis is not ALL
- c) ☐ Other

Could you please:

- a) ☐ Destroy the sample
- b) ☐ Arrange for the sample/sample's extracts to be returned to the Tumour Bank

as soon as possible?

For completion by Linda Bendall or designee:

CHWTB # _____

Sample discard date _____ OR Sample return date _____

After discard or return, please email this form to tumourbankchw.schn@health.nsw.gov.au

Office use only	
Date form received	
Data entered into database	

07.02 Processing Blood Samples for Project #57: C-Circle Assay and Alternative Lengthening of Telomeres (ALT) IN Cancer

Document Number: TB 07.02 Version: 005	Issue Date: 01/11/2013
Author: Aedan Roberts Title: Research Assistant Signature Date	Approved by: Daniel Catchpoole Title: Head of Tumour Bank Signature Date

REVISION HISTORY			
Date	Amendment Details	Superseded version	Revised by
10/02/2011	New Document		
13/12/2011	Additions/Changes	07.02.002	AC
08/10/2012	Annual Review	07.02.003	AC
01/11/2013	Annual Review	07.02.004	ARo

1. PURPOSE

The purpose of this document is to outline standardised procedures to follow when processing and storing blood samples for the C-Circle Assay and ALT project (Project #57 – Jeremy Henson).

2. SCOPE

This protocol covers all oncology patients at the Children's Hospital at Westmead (CHW) who have agreed to donate blood and/or have blood taken by a staff member of a department within CHW.

3. RESPONSIBILITIES

The Tumour Bank (TB) Clinical Research Associate (CRA), the TB Research Assistants (RAs) and the TB Project Officer must ensure that these protocols are adhered to at all times when processing and storing samples from CHW departments.

4. MATERIALS, EQUIPMENT AND FORMS

- Lab Bench Sample Record Sheet
- 1.5 mL microcentrifuge tubes
- Benchtop microcentrifuge (Level 3 cold room)
- 200-1000 µL pipette with blue tips
- Lab timer
- Personal protective equipment - gowns, gloves and safety glasses

- Appropriate racks to hold tubes while processing
- Tongs
- Freezer storage boxes

5. METHOD

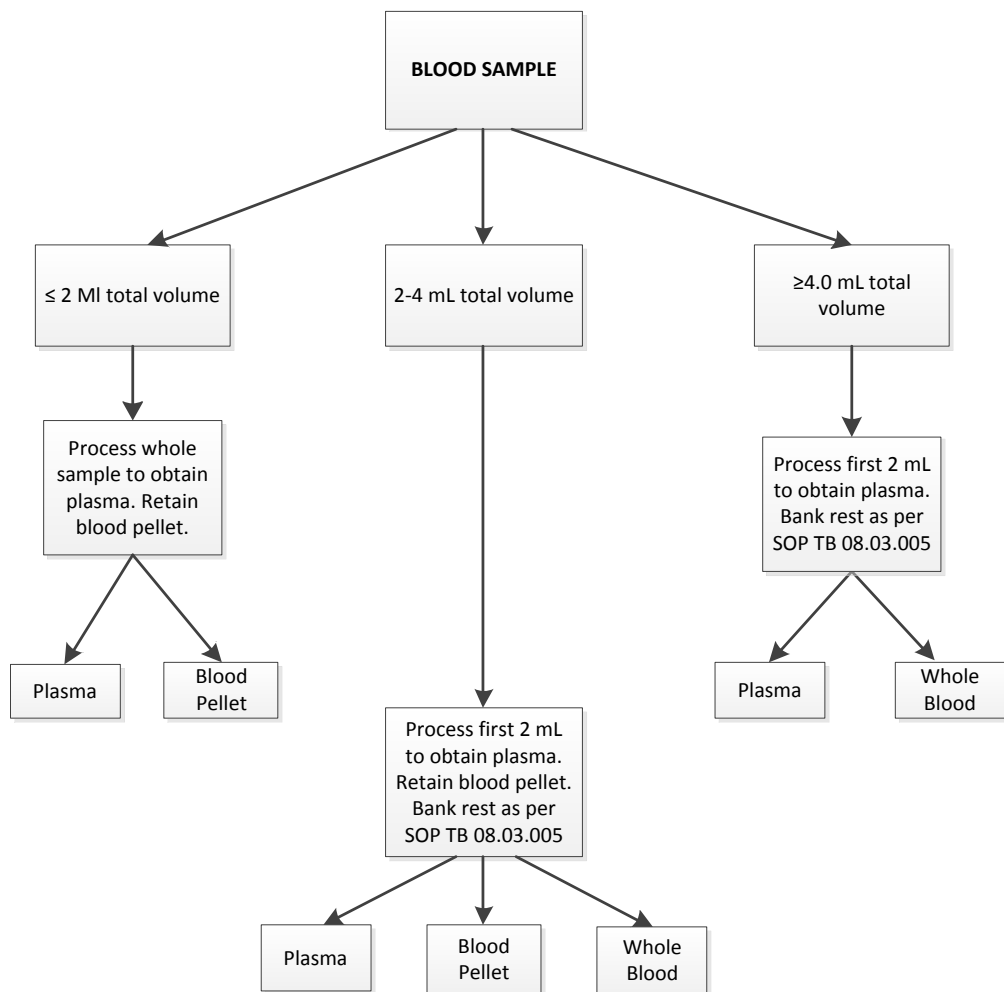
5.1 Blood Collection

- The TB will be notified when the samples are ready for collection via the TB pager or phone, or the samples will be left at pick up points in the Oncology Treatment Centre (OTC) or Camperdown Ward (CW).
- The sample should be picked up as soon as possible and stored in the TB 4°C refrigerator until ready for processing. Alternatively, samples left over from clinical tests may be picked up from the Clinical Haematology department by arrangement with their staff. Refer to TB SOP 05.07 "Obtaining Patient Peripheral Blood Samples from the Clinical Haematology Department" for details on how to obtain these samples.

5.2 Sample Volume Allocation Between Tumour Bank and Project #57

The procedure for processing blood samples will depend on the total volume of blood obtained (see diagram below).

- For blood samples with a volume of ≤ 2.0 mL, process the whole sample to obtain plasma according to Section 5.4. Retain the blood pellet(s) following the first spin and bank as per TB SOP 05.03, "Blood Sample Processing".
- For blood samples with a volume of 2-4 mL, process the first 2mL to obtain plasma according to Section 5.4. Retain the blood pellet(s) following the first spin and bank as per TB SOP 05.03, "Blood Sample Processing". Bank the remaining blood volume (< 2.0 mL) as per TB SOP 05.03, "Blood Sample Processing".
- For blood samples with a volume of ≥ 4.0 mL, process the first 2mL to obtain plasma according to Section 5.4. Bank the remaining blood volume (up to a total of 6 mL) as TB SOP 05.03, "Blood Sample Processing".



5.3 Biospecimen Number Generation and Tube Labelling

- Allocate a biospecimen number (CHWTB) for each sample according to the next available number on the current Lab Bench Sample Record sheet, using the details provided on the request forms.
- If a new CHWTB number needs to be generated, follow the procedure outlined in TB SOP 07.01, "Bone Marrow Sample Collection and Processing for Project Numbers 28 and 62".
- Label 3 autoclaved microcentrifuge tubes with the patient's MRN for each sample.
- Label a yellow-topped 2 mL Greiner Bio-One cryovial with the sample type (PLASMA), the allocated sample CHWTB number, and the collection date, using the label printer.
- Arrange each separate patient tube(s), corresponding microcentrifuge tubes and cryovial in vertical lines down the rack to minimise sample mixing.

5.4 Blood Processing

- Aliquot 2.0 mL of whole blood (1.0 mL of blood per 1.5 mL eppendorf tube) into two labelled microcentrifuge tubes using a 200-1000 µL pipette set to 1000 µL and a new blue tip for each sample.
- Spin at 4°C for 10 minutes at 4,200 RPM (1,600g) in the Level 3 Cold Room (4°C) benchtop centrifuge.
- Using 200-1000 µL pipette, transfer the upper plasma layers into a single new 1.5 mL microcentrifuge tube for each patient sample using a new disposable blue tip for each sample.

- d. Retain the blood pellet if the total volume of blood received is ≤ 4.0 mL. To do this, combine the blood cell pellets into a new red-topped 2 mL Greiner Bio-One cryovial and labelled appropriately (CHWTB number, "PELLET" and collection date on a printed label from the label printer on the tube, volume on lid).
- e. Spin the single microcentrifuge tube containing the plasma again at 4°C for 10 minutes at 13,200 RPM (16,000g).
- f. Using 200-1000 μ L pipette, pipette the plasma and place in the labelled yellow-topped 2 mL Greiner Bio-One cryovial according to the instructions below, and record the volume on the lid.
- g. Aliquot the total plasma volume using the following protocol. Bank the first 500 μ L of plasma into a separate tube. For volumes < 500 μ L, the entire volume should be banked in a single yellow top cryovial. For plasma volumes > 500 μ L, the first 500 μ L should be banked in a single tube (labelled as CHWTB-?????-s-1, PLASMA, collection date) and the rest (irrespective of the volume) should be banked in a second cyro-vial (labelled as CHWTB-?????-s-2, PLASMA, collection date).
- h. In between spins, process rest of the blood samples as per TB SOP 05.03, "Blood Sample Processing".
- i. Snap freeze all samples in liquid nitrogen and store in the next available spot in the TB -80°C freezer.
- j. Record all sample details (including the volume of whole blood/blood pellet/plasma and any time delay in processing) on the Lab Bench Sample Record sheet.
- k. The TB Administration Officer should then enter the data from the Lab Bench Sample Record sheet into the TB database.

5.5 Transfer of Samples to Researcher

- a. Approximately every 3 months the TB will notify Jeremy Henson (jhenson@cmri.org.au or 96872800) that samples are ready for collection.
- b. The TB Administration Officer should prepare an MS Excel sheet detailing the samples collected over the past 3 months (MRN, patient name, collection date, CHWTB number, diagnosis, treatment phase, consent status, location, volume, infection status, process delay).
- c. The TB Administration Officer should check the consent and infectious status (HIV, Hep B, TB) of each patient prior to dispatching samples.
- d. The TB CRA and/or the TB Project Officer should perform a data check of any clinical information regarding the project sent to the researcher.
- e. Prepare a transport receipt for each 3 month batch of samples given to Jeremy Henson.
- f. The TB Project Officer should make arrangements with Jeremy Henson for collection of samples when the above steps have been completed.

6. SAFETY

- All local biohazard, chemical and sharps policies must be adhered to.
- Empty blood tubes, pipette tips and gloves should be disposed of in accordance with local regulations for handling of potentially infectious biological material.

8.0

EQUIPMENT USE

08.01 Scanscope Virtual Microscope Use			
Document Number: TB 08.01 Version: 004		Issue Date: 23/10/2013	
Author: Aysen Yuksel Title: Research Assistant		Approved by: Daniel Catchpoole Title: Head of Tumour Bank	
Signature	Date	Signature	Date

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1. PURPOSE

The purpose of this document is to outline a standardised procedure on how to scan a microscope slide using the Tumour Banks' (TB) Aperio ScanScope CS virtual microscope and how to access the images using the Aperio Spectrum server.

2. SCOPE

This protocol covers all microscope slides that are to be scanned at very high resolution. Slides can be scanned at 20X, 40X, and 83X (oil scanning) magnification. The high resolution images can be used to capture snapshots of tissue histology and can be used for performing digital quantitative analysis.

3. MATERIALS, EQUIPMENT AND FORMS

- Coverslipped microscope slides

4. METHOD

4.1 Booking the Scanner

You will be provided with log in details after a training session on use of scanner. To use the scanner, a booking must be made via www.cmri.org.au/ppms. Once you are in the web site

- Click KRI Microscope Facility
- Enter user name or find your name in the 'list of PPMS accounts'.
- Enter password and login

This also allows the TB to keep track of the scanners use.

4.2 Switching the Scanner On

- a. Ensure that the doubler is pulled out (20X) before the scanner is turned on.
- b. Turn on the scanner (before the computer) via the small switch on the back of the scanner near the power cord.
- c. Boot the computer by pressing the round bottom on the front of the computer tower.
- d. Turn on the external light source by the switch on the back (near power cord).

4.3 Slide Holder

- a. Place up to 5 slides in the slide holder.
- b. Place the slide label to the left side.
- c. Sit the slides flat in the holder with the spring-slide-holder pushing the corner of the slide.
- d. Place the slide holder flat in the scanner.

4.4 Snapshots and Scanning

- a. Double click on the SSConsole icon on the desktop.
- b. Click on the 'Start' tab.
- c. Right click on the highlighted slides and click 'Get snapshots'.
- d. Click the 'Scan Area' tab.
- e. Reduce the size of the green boarder to scan the area of interest (click on the edge of the green line).
- f. Place the blue calibration blue diamond on a clear area (no tissue) of the slide.
- g. Select the magnification required (20X with doubler pulled out, 40X with doubler pushed in).
- h. Click the 'Focus Points' tab.
- i. Click the 'Auto Select' button.
- j. Click the 'Auto Focus' if possible.
- k. Click the 'Calibrate' tab and click the 'Calibrate' button.
- l. Click the 'Scan' tab and click 'Start Scan'.
- m. Once the scan is finished, click 'View Slide' button and ImageScope software will launch and the scanned slide will appear (log onto ImageScope may be necessary).

4.5 Accessing Images on the Spectrum Server

- a. To access the images scanned on the Aperio Virtual Microscope, obtain a user name and password from the Aperio Administrator (TB).
- b. The scanned images on the spectrum server can be accessed at the URL:
<http://vmskids.chw.med.usyd.edu.au/Login.php>.

4.6 Data Backup Process

Once over 200 images have been scanned and not accessed on a regular basis, images are removed off the Aperio server and burnt onto DVD or transferred to external hard drives.

5. SAFETY

- Not applicable

08.02 Immunohistochemistry Staining Using the Leica Bond-Max™ System

Document Number: TB 08.02 Version: 001	Issue Date: 21/11/2012
Author: Aysen Yuksel Title: Research Assistant	Approved by: Daniel Catchpoole Title: Head of Tumour Bank
Signature Date	Signature Date

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21/11/2012	New Document		
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1. PURPOSE

The purpose of this document is to describe the procedure for immunohistochemistry (IHC) staining of specimens mounted on microscope slides using the Leica Bond-max™ system. The Bond-max™ system is a fully automated advanced staining process including IHC and chromogenic in situ hybridization (ISH).

2. SCOPE

This protocol is applicable to an immunohistochemistry technique on sections obtained from a variety of normal and tumour tissues.

The adopted procedure is to identify the location of the target receptor within the tissue together with an indication of receptor density. The current SOP is based on the use of a polymer detection system supplied by Leica Microsystems (the system is biotin-free).

3. RESPONSIBILITIES

It is the responsibility of person(s) performing this procedure to be familiar with Leica Bond-max™ system and use of laboratory safety procedures. The interpretation of results must be done by a person trained in the procedure and familiar with such interpretation.

4. MATERIALS, EQUIPMENT AND FORMS

- Ancillary Reagents/Consumables;
 - Bond Wash Solution (Cat. No. AR9590)
 - Bond Epitope Retrieval Solution 1 (Cat. No. AR9961)
 - Bond Epitope Retrieval Solution 2 (Cat. No. AR9640)
 - Bond Dewax Solution (Cat. No. AR9222)
 - Bond Universal Covertiles (Cat. No. S21.2001.110)
 - Bond Open Containers 7 mL (Cat. No. OP79193)
 - Bond Open Containers 30 mL (Cat. No. OP309700)

Bond Universal Slide Labels (Cat. No. S21.2011.110)
 Bond Universal Printing Ribbon (Cat. No. S21.1912.110)
 Bond Slide trays (Cat. No. S21.0304.110)
 Bond Reagent trays (Cat. No. S21.1003.110)
 Bond Polymer Refine Detection (Cat. No. DS9800)
 Bond Primary Antibody Diluent (Cat. No. AR9352)
 Primary Antibody of choice (source: mouse or rabbit)
 Coverslips
 Mounting Media
 Ethanol
 Xylene

- Equipment;
 - Bond-max™ Processing Module
 - Computer
 - Handheld ID scanner
 - Slide labeller (TLP3742)
- Personal protective equipment - gown, gloves, safety glasses

5. METHOD

5.1 Booking the BOND-max

- a. Online booking web address is www.cmri.org.au/ppms
- b. Click on KRI Microscope facility. Enter username or find your name in the “List of PPMS accounts”. Enter password and login.
- c. Click on “Schedules” box in the top menu bar
- d. Select “BOND-MAX(TumourBank)” in the “Jump to a system” menu.
- e. Click on “Book this system”
- f. Click on the day and time you wish to use the system.
- g. Click on “Book the selected sessions”

5.2 Log into the system on PC monitor (desktop)

5.6 Double click on “Bond”.

5.3 Initial checks and loading reagents

- a. Check the bulk reagents and top up if needed.
- b. Check the bulk waste.
- c. Check the mixing station.
- d. Place the reagent containers into reagent trays.
- e. Place the reagent tray in the reagent platform of the Processing Module.
- f. Make sure all reagents have been read by reviewing the reagent area in the System status screen.

5.4 Set up slides

- a. Create a case (or patient) on the “Slide setup” screen of the BOND software.
- b. Enter details of the slides for each case;
- c. Click on “Add case”, fill in the required fields and click on “OK”.
- d. Click on “Add slide”, fill in the required fields and click on “Add slide”.
- e. Print slide labels and apply them to the slides.
- f. Place the slides on slide trays and place a Covertile on each slide.
- g. Insert the trays into the Processing Module.

5.5 Run protocols (CHW – System status screen)

- a. Press the Load/Unload button.
- b. When the slide labels have been imaged, check that the correct details are displayed in the slides section on the System status screen.

- c. Click Start (→) to run protocols on the loaded slides.

5.6 Unload the slides and reagents when run has finished

- a. Press the Load/Unload button.
- b. Remove the slide tray.
- c. Remove the Covertiles from the slides and place in a small bucket containing 0.5% bleach for 30 minutes.
- d. Remove the slides and place in a container containing tap water and slide rack.
- e. Remove the reagent tray(s) and store the reagents.

5.7 Do end of run clean

- a. Wipe clean the slide and reagent trays.
- b. Clean Covertiles (0.5% bleach for 30 mins, several rinses in tap water, air dry).
- c. If necessary, clean around the slide staining assemblies with 70% alcohol.
- d. Check the Covertile clamp springs.
- e. Check bulk containers, top up if needed.

5.8 Dehydrate, clear and mount stained slides

5.9 Interpretation is based on nuclear, cytoplasmic or membranous staining (or any combination thereof) of the individual cells.

6. SAFETY

- Users must be aware of local regulations and correct procedures at site when handling and disposing of hazardous material.
- Some of the reagents used in IHC and ISH are hazardous, for example, some chromogen reagents are potential carcinogens. When working with the Processing Module or components, including reagents or reagent containers, use precautions appropriate for handling of potential biohazards including the wearing of protective gloves, gown and eye wear.

7. REFERENCES

- BOND System User Manual

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