**Needs Analysis for Laboratory Inventory Management Software**

**Background**

Cancer Council is conducting a number of epidemiological studies with a biobanking component.

In each case, participants are asked to complete a questionnaire and give a blood sample.

Personal information about the participants (name and address, consent, cancer diagnosis) is kept in the Study database at Cancer Council (separate for each study, but within one SQL framework). Responses to questionnaires are in separate files as they are data entered by external businesses. All these records can be linked by a single identifier, the Study ID.

Consent has been obtained to link to other information about the participant’s health (clinical records, dental records, pharmaceutical records, cancer registry, death registry) and to obtain tissue samples.

Questionnaire data and blood samples from CLEAR Study will be made available for external analysis from about 2011. LIMS will need to record movements of samples in and out of the collection, and associated processes. Results of these analyses will be returned and recorded against the participant information.

Current studies are CLEAR Study and Skin Health Study. The Biobank also houses samples from the Johannesburg case control study, the cervical health study and some Prostate Cancer Care Outcomes Study sub-studies.

In 2009 the Biobank conducted the blood processing for the pilot phase of blood collection for 45 and Up Study. It is likely that 45 and Up will seek to collect bloods for up to 100,000 participants in the near future. The LIMS system will need to be able to deal with the associated numbers of records.

It will be necessary to be able to access the LIMS system from Cancer Council and from the lab. It could rest on a server at Woolloomooloo or be hosted on a remote server. Security of the data and regular back ups are of the utmost importance.

Multiple users will need to have access at any one time.

**Study Management Information**

**CLEAR Study**.

CLEAR Study consent forms and questionnaires are returned to Cancer Council by study participants. Personal information about the participants (name and address, consent, cancer diagnosis) is kept in the Study database at Cancer Council (separate for each study, but within one SQL framework for Skin and CLEAR).

If the person has agreed to provide a blood sample they are sent a pathology request form. They go to the pathology service at their convenience.

*This could be tightened up eg ask them to present within 7 days, but there is currently no link between the study team and the lab for this process*.

Blood samples are received from patients with cancer or pre-cancer (cases) and cancer free (controls). Each blood sample is divided into a number of 0.5ml aliquots of plasma, serum or buffy coat (DNA). Each aliquot can be analysed for different markers. Comparisons will be made between participants. The most common comparisons will be between cases with controls, most often with matches for sex and age but possibly multiple other questionnaire defined variables. Bloods from the controls become most valuable as they can be matched with any cancer type, and thus might be depleted sooner. Management of control samples needs to be more rigorous than that for cases.

Lab notifies CLEAR Study team every week of pathology samples received using entries in the spec log. Recorded in Study data base as yes.

Pathology request forms received with samples are date stamped and filed away. They are used during the day of processing to manually record # aliquots made and freezer box location prior to entry in the database.

Some samples for CLEAR Study are retained in a separate place for back up.

Database entry is required before labels can be printed.

Questionnaires are data entered externally.

Researchers will request access to samples (plasma, serum, DNA) for participants who will be selected according to their responses to questionnaire data. Eligible study participants will be identified in questionnaire response data and a list of study IDs generated by the study team and submitted to the biobank.

The request will have an associated Project Application Number and Data Request Number, Requestor Information and date required.. The samples requested will be identified at the lab by study ID.

**Skin Health Study**

Skin Health Study consent forms are returned to Sax Institute by study participants. Then sent to Cancer Council lab. Skin cancer records are verified by general practitioners.

Personal information about the participants (name and address, consent, cancer diagnosis) is kept in the Study database at Cancer Council (separate for each study, but within one SQL framework for Skin and CLEAR).

Participants are sent questionnaire and a pathology request form. They go to the pathology service at their convenience.

*This could be tightened up eg ask them to present within 7 days, but there is currently no link between the study team and the lab for this process*.

Specimen arrival is recorded daily in spec log. Counted daily for audit purposes against records in database and pathology request forms.

Lab notifies study team if any specimens are outside protocol. Recorded by project coordinator.

Lab notifies Skin Study team every week of pathology samples received using entries in the spec log. Recorded in Study data base as yes.

Pathology request forms received with samples are date stamped and filed away. They are used during the day of processing to manually record # aliquots made and freezer box location prior to entry in the database.

Database entry is required before labels can be printed.

Questionnaires are data entered externally.

Skin Health Study collects samples for both Skin Study and 45 and Up Study. Their samples are managed as for separate studies. Skin Study bloods will ultimately go to Germany for analysis.

Skin study swabs go to Germany monthly for analysis.

Some samples for Skin Study and 45 and Up Study are retained in a separate place for back up.

**Cervical Health Study**

CHS Study consent forms and questionnaires are returned to Cancer Council by study participants.

Personal information about the participants (name and address, consent, cancer diagnosis) is kept in the Study Access database at Cancer Council. If the person has agreed to provide a blood sample they are sent a pathology request form. They go to the pathology service at their convenience.

Pathology is handled by pathology companies. Samples are processed and frozen, and stored at pathology company. Samples are delivered to Biobank approximately quarterly.

There are three aliquots for each participant (A,B, C). A sample is sent to Queensland for analysis from time to time. That sample will not return. B sample remains at Biobank. C sample (if there is one) is stored in a back up location.

Sometimes there is a liquid based cytology sample as well. These come at irregular intervals from pathology companies. They need to be aliquotted, labelled and stored at -80.

Arrival of specimens is recorded in a specimen log.

Questionnaires are data entered externally.

**Johannesburg Case Control Study**

Approximately 10,000 aliquots are stored at -80. Some may be sent to Germany for analysis from time to time. They will not return.

Personal information about the participants (name and address, consent, cancer diagnosis) is kept in the Study database in Johannesburg. Some information is also stored at Cancer Council.

**Prostate Cancer Care Outcomes Study**

Two sub-studies of this study (PSAD and PCOSun)have sent bloods to the Biobank for processing and storage.

Personal information about the participants (name and address, consent, cancer diagnosis) is kept in the Study database in Woolloomooloo or Brisbane.

PCOSun samples are being stored while we await further instruction.

All Queensland samples will eventually go to Brisbane for analysis.

**Essential Requirements**

* Sample handling/Workflows
  + Record date and time of arrival of specimen
  + Detail of specimen (this must be possible at tube level, not just participant)
    - Study participant number
    - Date of birth
    - Sex
    - Pathology provider
    - Bar code number of collection
    - Date of Collection
    - Time of Collection
    - Processing date
    - Number of buffy coats
    - Number of plasmas
    - Number of serums
    - Number of whole bloods
    - Haemolysis
  + Calculate anything out of protocol (this must be possible at tube level, not just participant)
    - tubes missing
    - , delayed delivery
    - Wrong temperature
    - Haemolysis
    - Short collection
    - Wrong tube type
    - DOB missing
    - Sex missing
  + Create alert appropriate to problem
    - sample to be re-collected
    - path company to be advised of missing tube
    - project coordinator to be advised outside protocol
  + Allocation of protocol
  + Provide all steps within protocol
  + Recording number of sub-specimens - daughter aliquots
  + Labelling of samples
    - Words and numverals
    - 2 D barcode
* Inventory Management of Specimens
  + Define freezer locations and characteristics
    - Name
    - Place
    - Temperature
    - Capacity of each shelf
    - Number of shelves
  + Define characteristics of specimens, for each daughter aliquot
    - Type
      * EDTA Plasma
      * ACD Plasma
      * Serum
      * EDTA Buffy coat
      * ACD Buffy Coat
      * LiHep plasma
      * LiHep
      * Buffy coat
      * LBC
      * Whole blood
      * Other (space for new)
    - Volume
    - Known problems
      * Haemolyzed
      * Outside temp protocol
      * Outside time protocol
  + Freezer space allocation
    - allocate next available space
    - allow for holding space
    - Allow for “de-fragmentation
  + Location of samples
    - freezer box spot (eg a9)
    - freezer box number
    - shelf
    - freezer number
    - freezer location
  + Record of sample handling at an individual sample level
  + Record of transfer out of the location including reason and destination
    - Permanent departure eg to Germany, made available to external research
    - Temporary departure, eg for re-aliquotting
    - Destruction of specimen
* Protocol Management
  + Record protocol for each study – and thus each aliquot within that study
* Equipment Management records
  + Location of each piece of major equipment (freezers, centrifuges, hoods)
  + Maintenance records for each piece of equipment
  + Alarm list (type and date, time)
* Staff record management
  + Names and employment record
  + Appropriate levels of access to information/ IT management
  + Training records
  + Time sheet
  + OH&S issues
* Contact record management
  + Contact Details
    - Name of customer
    - Organisation
    - Telephone
    - Address
    - Town
    - Email address
    - Type of customer
  + Date of request
  + Purchase history
  + Invoicing
  + Despatch requirements
  + Type of customer (customer, service provider)
* Sample request management – Study database end
  + Develop list of eligible study participants from study questionnaire data
  + Check to see if those participants have given a blood sample
  + Generate list of eligible participants who have given bloods
* Sample Request Management – lab end
  + Company and contact details of requestor
  + Project allocation number
  + Despatch address
  + Delivery method
  + Program specimens relate to
  + Biospecimen types required
  + Number of samples and types required
  + Date required
* Allocation of samples to request
  + Search for samples which are appropriate for request
  + Identify samples which are appropriate for request
  + Select samples
  + Identify location of samples
  + Generate pick list
* Despatch management
  + Generate consignment notes
  + Generate invoices
  + Record arrival information
* Return Management
  + Generate consignment notes
  + Record arrival information
  + Record processes which have happened to sample
  + Adjust volume
* Participant management
  + Identify number and type of aliquots available
  + Alert when levels are low
  + Alert when samples are of particularly high value
* Audit trail

A requirement will be the tracking of all changes to data, providing a viewable trail on entered and modified results

Reporting

Regular reports will be required for

* + - Number of aliquots in collection (by study, by month and total)
    - Number of people’s bloods in collection
    - Aliquots or boxes per freezer
    - Freezer temperature
    - Aliquot movements
    - Financial/Cost recovery
    - Audit
    - Printing out protocols
    - Specimens outside protocol
    - Sample movements
    - Specimen inventory (daily receipt of samples, path co of origin, state of sample
    - Pick list
    - Staffing hours per time period wrt sample numbers

Forms

* Pathology request forms will be scanned and stored as a database file against the specimen record:
* Sample request form will be scanned and stored as a database file against the specimen request record:
* Participant consent form will be scanned and stored as a database file against the participant record

**Release of Samples for Research**

**Receive Requests**

* Customer request
  + Name of customer
  + Organisation
  + Telephone
  + Address
  + Town
  + Email address
  + Type of customer
  + Date of request
  + Sample type(s) requested
  + Number of samples requested
  + Collection details

**Search for appropriate samples in Research data base**

Search availability of sample types on single or multiple variables (eg ultimate aim # aliquots serum for males aged under 50 with prostate cancer; # aliquots serum for males aged under 50 with no cancer. Identify number of samples available and which/where they are).

* First step: search by every variable in Study Data to identify eligible participants, but examples are:
  + Case
  + Control
  + Sex
  + DOB
  + Cancer type
  + Pre- or post intervention
  + Location
  + Ethnicity
* Second step: for every individual identified
  + Determine number of samples left for each participant
  + Number of each aliquot type
  + Set a minimum level beyond which no more to be made available

**Cost recovery**

* Raise an invoice for
  + Number of samples
  + Variable cost for sample type
  + Variable cost for purchaser type
  + Date of sample movement
* Payments received
  + Record payment received amount
  + Record payment received date
* Provide reports on
  + Movements of samples in a time period
  + Value of samples invoiced in a time period

Payments received

Under consideration

Ark (Wager) [www.uwa.edu.au](http://www.uwa.edu.au) Paul White

About to be released as an open platform software

* Disadvantage
  + Support is (currently) from WA.
  + System is new
* Advantage
  + In the cloud. Supported by Aust Government
  + No purchase cost
  + Infinitely modifiable

has been adapted

CaTissue (used by Lowy Cancer Centre). Share ware from USA.

* Disadvantage
  + Support is from USA.
  + System is not quite configurable
* Advantage
  + has been adapted for Lowy. Needs are similar

Caisis (used by Westmead Breast Cancer Network) Share ware from USA

* Disadvantage
  + Support is from USA
  + has been adapted for tissue collection
* Advantage

LabWare (used by Cancer Council Victoria). Retail product

* Disadvantage
  + Cost
* Advantage
  + CCVic will give us IP for their current configuration