

Management and Storage of blood serum samples collected as part of the Study of Health Outcomes in Aircraft Maintenance Personnel (SHOAMP)

The following advice is provided from the Secretariat of the SHOAMP Serum Management Committee, in respect to the management of the long term storage of, and access to, the blood samples collected as part of the SHOAMP. The advice is dated 14 December 2010.

Background

In 2004, the study (SHOAMP) collected blood serum samples from F-111 aircraft maintenance personnel and control groups who were study participants. Many, but not all, participants gave consent* for their blood serum samples to be stored, beyond the period of the study and used for research (as detailed to study participants at the time).

** It is important to note that any future proposed research that was not part of the initial research will require further consent from each participant.*

In 2005, a Serum Management Committee (SMC) was established to manage the long term storage of, and access to, the blood samples collected. This Committee advises and makes recommendations to the Repatriation Commission on the merit of any future research applications seeking access to the serum samples. The Terms of Reference (ToR), Governance Rules and Committee membership for the SMC are attached). The SMC is chaired by the Repatriation Commissioner.

Recent Activity – Overview

Over the past year (2010), the SMC has been active in ensuring that the management and oversight of the blood serum samples has been placed on a sound footing. The ToR, Governance rules and contractual arrangements have been reviewed, and periodic reporting to key stakeholders has been introduced. Specific activities are discussed below.

Storage of Serum Samples

Approximately 1000 SHOAMP participants donated blood. Their blood is stored at QML Pathology, Brisbane, in the following forms:

- Blood serum samples,
- B cell Lymphoblast (BCL) specimens (cell lines),
- Peripheral Blood Mononuclear Cells (PBMC) specimens (cell lines), and
- Guthrie cards – a drop of blood on a piece of card.

There are 6000 samples, and just under 1000 Guthrie cards, stored at QML Pathology. The 6000 samples include one duplicate sample for each participant. The number of stored samples has not changed since the SHOAMP. A key is used to link the samples to the donors – that is the samples are not labelled with the participant's name for privacy reasons.

Inspection of Samples

The last inspection of the samples found that the storage arrangements met all contractual requirements and relevant “industrial” standards to ensure safe and secure storage of the serum samples and Guthrie cards.

Purchase of Freezers

Notwithstanding the above, as a further added safeguard, the SHOAMP Serum Management Committee has determined that the duplicate samples and cell lines should be stored in separate containers. To this end, DVA has purchased two freezers with the following specifications:

- minus 80 degree Celsius chest freezers;
- capacity to hold 2,000 blood serum samples i.e. effective internal capacity of between 80-100 litres;
- keyed locks on doors;
- Visual and audible alarms which indicates high/low temperature conditions, power failure and fault conditions;
- Battery back-up for alarms and temperature displays; and
- Voltage - Standard 240V.

QML Pathology is in the process of some minor modifications prior to completing the transfer of samples to the new freezers.

Destruction of Samples

There has been no destruction of SHOAMP serum samples and no requests from study participants to have their samples destroyed.

Access to Samples

There have been no research or other requests to access the SHOAMP blood serum samples.

Attachments

Terms of Reference for the SHOAMP Serum Management Committee (reprinted 14/12/2010)

The Committee is responsible to the Repatriation Commission in terms of its operational activities.

The Committee will provide annual reporting to the Commission, Chief of Air Force and nominated representatives of the veteran community (including the Returned Services League (RSL), RAAF Association, Defence Force Welfare Association (DFWA) and SHOAMP participants) on the continued storage of the samples.

The Committee or a representative nominated by the Committee will undertake an annual on-site inspection of the samples.

The Committee will evaluate the merits of continued retention of the samples and make recommendations to the Repatriation Commission on the advisability of continued storage. If it is decided not to retain the samples, the samples will be destroyed according to the Standard Operating Procedures for destruction of blood samples, as approved by the Serum Management Committee.

The Committee will ensure that all research proposals have in principle approval from the DVA HREC and other relevant Ethics Committees.

The Management Committee if required, will seek expert opinion on the merit of any research proposals seeking access to the samples.

The Committee will advise and make recommendations to the Repatriation Commission on the merit of future research applications seeking access to individual or pooled samples.

The Committee will meet at least every two years and as necessary to consider research applications and/or other issues, either face to face or by electronic means.

The Secretariat will report via e-mail to Committee members at least every six months.

Governance Rules for the SHOAMP Serum Management Committee

The Committee members will be representative of the Department of Veterans' Affairs, Australian Defence Force, and the veteran community. The Committee will also comprise an Ethicist.

The contractors who conducted the Study for which the samples were collected and the contractor responsible for the storage and safe keeping of the samples, will act as "observers" on the Committee.

Observers will participate in all Committee meetings but will have no input into any recommendation made by the Committee related to future research proposals.

The Committee will abide by the NHMRC *National Statement on Ethical Conduct in Human Research (2007)* and comply with the *Information Privacy Principles*.

The Committee will monitor the management of the long-term storage of the samples to ensure that the storage contractor meets its contractual obligations.

The Committee will consult with the DVA Human Research Ethics Committee prior to the destruction of any samples belonging to deceased donors .

The Management Committee is responsible for ensuring that research proposal applicants are advised of any decision related to the proposal.

The Committee will maintain detailed records pertaining to the request for use of the samples.

The Committee will ensure that an appropriate mechanism is established to handle complaints related to storage, Committee operation or any new research proposals.

Membership of SHOAMP Serum Management Committee

Major General Mark Kelly AO (Chair)	Repatriation Commissioner
Wing Commander Ron Usher (Retd)	RAAF Association
Wing Commander Lance Halvorson (Retd)	RAAF Association
Mr Geoff Curl	SHOAMP Deseal/Reseal Support Group
Dr Malcolm Parker	University of Queensland
Dr Victoria Ross	Department of Defence
Dr Graeme Killer	DVA
Dr Warren Harrex	DVA
Ms Peta Stevenson	DVA
Professor Cate D'Este	University of Newcastle, Observer
Professor John Attia	University of Newcastle, Observer
Mr John McKechnie	QML Pathology, Observer