Operating policies of the Immunovirology Research Network (IVRN)

Contents

1. General operating policies for the Immunovirology Research Network (IVRN)

1.1. Background and overview

The Immunovirology Research Network (IVRN) is a network of laboratories across Australia with an appropriate administrative infrastructure (see Appendix 1 for figure) to facilitate strategic clinical immunology and virology research in relation to Australians with blood-borne virus (BBV) infections, including with HIV, HCV, or HBV. The IVRN was established in 2005 under the auspices of the Australian Centre for Hepatitis and HIV Virology Research (ACH4), which is funded by the Commonwealth Department of Health and Ageing.

The IVRN has two infrastructural components: the Tier 1 laboratories (the Network), and a Central Specimen Repository.

- *Tier 1* laboratories are located across the country and have expertise in separation and storage of the samples of interest which include serum, plasma, peripheral blood mononuclear cells (PBMCs).
- The *Central Specimen Repository* laboratories were required to demonstrate expertise in, and capacity for, long term storage of samples of interest. Three laboratories have been appointed. These laboratories are funded on an ongoing basis to complete this service role for the Network.

The IVRN has three activities:

- *Collection of specimens*, either undertaken prospectively or via acquisition of stored specimen sets;
- The *Laboratory QAP* was continued from the QA program for handling and storage of blood samples which was run for several years in relation to HIV research by the Immune-Based Therapies Working Group (IBTWG) of the National Centre in HIV Epidemiology and Clinical Research (now the Kirby Institute). The QAP is now managed directly by IVRN via continuation of the established donor protocols.
- *Redistribution of specimens* to Australian researchers conducting projects relevant to the National Strategies for HIV, HCV, or HBV (https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1)

1.2. Steering Committee

The IVRN is managed by a Steering Committee was appointed to oversee the establishment and conduct of the IVRN (see Appendix 2 for membership).

The **terms of reference** for the Steering Committee of IVRN are to:

1. Establish and maintain an Australia-wide network of laboratories for the collection of research samples from subjects in clinical trials and cohort studies of BBVs.
2. Establish and maintain a central specimen repository for storage of laboratory samples to support research relevant to the Australian BBV strategies (termed ‘strategy research’ - see Appendix 2 for a detailed summary of areas of strategy research).
3. Foster the development of strategy research via project-based support, including provision for high priority, short-term projects at the discretion of the ACH4 Executive and IVRN Steering Committee.
4. Maintain a laboratory quality assurance program for the Network to maintain high standards in separation and storage of serum, plasma, and PBMCs in order to ensure high quality and utility of the specimens in immunological and virological assays in strategy research.
5. Make available to the Australian BBV research community, samples collected via the Network for the conduct of strategy research.
6. Consider, prioritise, and approve applications for sample collection via the Network which entail use of IVRN resources.
7. Consider, prioritise and approve applications for access to samples collected via the Network for use in strategy research.
8. Provide minutes of the Steering Committee meetings to the ACH4 Executive.
9. Report at least annually to the ACH4 Executive about progress in meeting the aims outlined in

these terms of reference.
10. Report at least annually to the Australian BBV research communities about progress in meeting the aims outlined in these terms of reference.

The Steering Committee meets quarterly.

A Project Coordinator supports the conduct of the activities of the Network, including handling all administration and enquiries, coordinating meetings and recording minutes, monitoring budgets, overseeing the logistics of specimen collection and transport, providing project management support via development and implementation of policies and procedures, and supporting strategic planning. A Laboratory QAP manager with skills in separation and storage of serum, plasma, and PBMCs oversees the program by conducting bi-annual quality assurance rounds using common reference samples, as well as by provision of skilled technical support to the Network laboratories.

1.3. Conflicts of interest

As the Australian BBV research community is relatively circumscribed, conflicts of interest inevitably arise in the conduct of the Steering Committee and the associated IVRN activities. A conflict of interest refers to a situation when someone, such as a public official, has competing professional or personal obligations, or personal or financial interests that would make it difficult to fulfill his or her duties fairly.

In relation to the issue of conflict of interest for the IVRN Steering Committee, members are expected to:

- be aware of the full range of potential interests, including direct and indirect benefits such as personal, departmental or institutional financial gain, advancement of the research activities or reputation of the person, department or institution; or the acquisition of materials or facilities, or the provision of travel or accommodation for the person, department or institution.
- disclose at the commencement of Committee meetings, any conflict of interest which has the potential to influence the decisions of the Committee. Such disclosure should cover any situation in which the conflict of interest may, or may be perceived to, affect the decision.
- consider any declarations of conflict of interest and resolve whether the Committee member should be: i) allowed to continue to participate fully in the discussion and decision-making; ii) absent for the decision-making only; or iii) absent for the discussion and decision-making.
- ensure declarations of conflict of interest and Committee decisions regarding their handling are recorded in the Minutes.

1.4. Ethical oversight

The primary ethical review for the IVRN activities is provided by the UNSW Human Research Ethics Committee. This Committee provided the original ethical approval to the IVRN for the processes related to the collection, storage and redistribution of BBV blood samples (HREC 05040) with updated approval incorporating the Laboratory Quality Assurance Program (QAP) (HREC 11391).

The IVRN specimen collection and redistribution systems, and the Laboratory QAP have several different aspects with differing ethical implications:

For clinical trials or cohort studies collecting samples prospectively:
The investigators associated with those studies will provide the UNSW HREC approval and the IVRN proforma Participant Information Sheet and Consent Forms (see Appendix 4.1 attached). Once local HREC approval is obtained for specimens to be collected for IVRN in association with specimens designated for the original study, the local HREC approval will be forwarded to the UNSW HREC.

For studies in which samples have already been collected and stored:
Although all such studies will have been initiated for research into BBVs, it is likely that the scope and details of the research projects facilitated via IVRN will differ (although still in relation to BBVs). Thus, the use of the stored specimens and the ‘limited clinical dataset’ associated with those specimens may fall outside the specific purpose of the original consent (the limited dataset includes

age, gender, BBV risk status, virological status and antiviral treatment status in de-identified format). Accordingly, in circumstances where the original subjects can be contacted, IVRN will recommend that additional consent for use of the samples for IVRN studies be sought.

In circumstances where the original subjects are not accessible (e.g. deceased, lost to follow-up) or the approach may cause undue distress, then IVRN will recommend that de-identification be utilised and that the research exemption in accordance with Section 95 of the Commonwealth Privacy Act and the NSW Health Records and Information Privacy Act 2002 (HRIP) and Statutory Guidelines on Research should apply. This research exemption applies on the basis that: i) the research is of significant public interest, notably for Australian biomedical research; ii) it may be impractical to seek consent from the individual subjects (as above), and significant steps will be taken (as above) to ensure that the data is de-identified; iii) no identifiable information will be published; iv) this research falls within the Statutory Guidelines.

De-identification:
For both specimen transfer processes a strict de-identification protocol will be put in place for collected samples (and the limited clinical dataset associated with those samples) – in brief, all subjects and samples will be de-identified at source with an IVRN code consisting of a study prefix and a six digit study identifier. The link between this code and the original study ID will be retained by the local study investigators.

Laboratory QAP:
A group of healthy subjects who are regular donors to the Red Cross Blood Service have been regular donors for the IVRN QAP. The volunteers provide written informed consent (see Laboratory QAP Participant Information Sheet and Consent Form – Appendix 4.2). The blood collection is transferred to the PC2 laboratory at UNSW by the IVRN QAP manager, Dr Wayne Dyer who aliquots the anticoagulated blood, packages it for shipment, and arranges shipment across Australia to the Network laboratories. The Network laboratories then separate and store the blood products (serum, plasma and peripheral blood mononuclear cells [PBMCs]). At a later date these blood products are returned to the IVRN QAP manager, Dr Wayne Dyer who conducts quality assurance assays assessing the stored samples. All of the blood handling, specimen transfer and shipments, and quality assurance assays are conducted in accordance with standard operating procedures (SOPs) and in accordance with safe work procedures and policies.

1.5. Ownership Issues
Sample ownership/authorship/intellectual property issues associated with both the collection/ acquisition of samples, and the redistribution of samples are addressed on an individual project basis. The IVRN supports the 'Material Transfer Agreement' (MTA) - style contracts between the project investigators and the IVRN Steering Committee. In broad terms, for projects in which the specimens and data are made available to IVRN without significant constraints, MTA-I (Appendix 5.1) will apply; for projects in which the specimens and data are subject to constraints associated with the clinical trial or cohort study, MTA-II (Appendix 5.2) apply. Variations to these proformas may be negotiated.

1.6. Individual policies
The more detailed operating policies for the individual activities conducted by the IVRN follow, including for: i) IVRN support for collection and storage of samples; ii) access to IVRN samples for strategy research; iii) transfer of existing specimen collections to IVRN; iv) appointment of IVRN Tier One laboratories; v) the IVRN Laboratory Performance Quality Assurance Program.

2. Policy for support for collection and storage of samples

Overall aim: To facilitate strategic immunology and virology research in relation to Australians with BBVs.

Structure: The IVRN includes three components: IVRN Network laboratories (the Network), a Central Specimen Repository, and a Laboratory QA program (QAP).

Scope: As outlined in the Operational Strategic Plan for the Australian Centre for HIV and Hepatitis Virology Research (ACH4) (see www.ach4.org.au).

Purpose: To define the criteria for inclusion of prospective clinical trials and cohort studies in BBVs for funded specimen collection for the IVRN.

Applications: For inclusion of clinical trials and cohort studies the proforma for this purpose must be completed.

The Network laboratories participating in separation of samples are listed on the website (www.ach4.org.au/quality-assurance-program).

The criteria for evaluation of an application are five-fold including the:

1. degree to which the proposed sample collection will facilitate Australian BBV Strategy research in accordance with National Blood Borne Viruses and Sexually Transmissible Infections Strategies 2018-2022 (https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1);
2. scientific merit of the clinical trial or cohort study (when necessary external scientific advice may be sought);
3. extent to which samples collected will be made broadly available to other Australian investigators via the Network;
4. degree to which alternative collection and storage systems are available (e.g., pharmaceutical industry sponsored sample collection and storage);
5. competing demands on the resources of the Network.

An in-principle agreement to utilise the Network for Australia-wide specimen collection (without formal application) may be provided upon request to the IVRN Steering Committee to individuals seeking to incorporate this statement into the research plan for applications to public sector funding agencies (e.g. NHMRC or MRFF). If funding is awarded, a formal application to IVRN (as above) should follow.

All applications should be submitted electronically to:

IVRN Project Coordinator
Ms Ruth Waterman
P: 02 9348 0630
E: rwaterman@kirby.unsw.edu.au

There is no closing date for applications. All applications are considered. The Steering Committee decision will be made within one month of receipt.

3. Policy for access to IVRN samples for strategy research

Overall aim: To facilitate strategic immunology and virology research in relation to Australians with BBVs.

Structure: The IVRN includes three components: IVRN Network laboratories (the Network), a Central Specimen Repository, and a Laboratory QA program (QAP).

Scope: As outlined in the Operational Strategic Plan for the Australian Centre for HIV and Hepatitis Virology Research (ACH4) (see www.ach4.org.au).

Purpose: To define the criteria for access to samples collected via the Network.

The criteria for evaluation of specimen requests to the IVRN for sample collection are four-fold:

1. degree to which the project and requested specimens will facilitate Australian research in accordance with National Blood Borne Viruses and Sexually Transmissible Infections Strategies 2018-2022 (https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1);
2. scientific merit of the proposed study (when necessary external scientific advice may be sought);
3. degree to which alternative sources of samples are available;
4. competing demands on the available samples in the IVRN Central Specimen Repository.

All applications should be submitted electronically to:

IVRN Project Coordinator
Ms Ruth Waterman
P: 02 9348 0630
E: rwaterman@kirby.unsw.edu.au

There is no closing date for applications. All applications will be considered. The decision will be made within one month of receipt.

Once the application is approved, the availability of samples from the IVRN will be contingent upon the applicant(s) providing local institutional human research ethics committee approval for the use of IVRN samples in their project and signing a copy of the IVRN Material Transfer Agreement form. Limited clinical and laboratory data about the samples will be made available via read-only access to a custom online database. More detailed clinical data may be available from the investigators of the original study – this may be facilitated by IVRN upon request.

4. Policy for transfer of existing specimen collections to IVRN

Overall aim: To facilitate strategic immunology and virology research in relation to Australians with BBVs.

Structure: The IVRN includes three components: IVRN Network laboratories (the Network), a Central Specimen Repository, and a Laboratory QA program (QAP).

Scope: As outlined in the Operational Strategic Plan for the Australian Centre for HIV and Hepatitis Virology Research (ACH4) (see www.ach4.org.au).

Purpose: To provide guidelines by which the IVRN will assume responsibility for existing sample sets collected from patients with BBVs that are relevant to the areas of strategy research.

The criteria for evaluation of potential specimen set transfer are four-fold:

1. accordance with National Blood Borne Viruses and Sexually Transmissible Infections Strategies 2018-2022 (https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1);
2. quality of the specimens and the associated dataset (clinical and laboratory);
3. extent to which samples collected will be made broadly available to other Australian investigators via the Network;
4. competing demands on the resources of the IVRN Central Specimen Repository.

The transfer of samples may be made under a reimbursement arrangement to cover costs for the original investigators associated with the specimen collection.

Documentation of the original human research ethics approval, Participant Information Statement and Consent Form (PISC), and conditions associated with the use of the samples will be required. Similarly, resolution of an updated human research ethics approval to cover the transfer and re-distribution of specimens via the IVRN will be required.

Correspondence regarding potential specimen collections should be made to:

IVRN Project Coordinator
Ms Ruth Waterman
P: 02 9348 0630
E: rwaterman@kirby.unsw.edu.au

5. Policy for appointment of IVRN Network laboratories

Overall aim: To facilitate strategic immunology and virology research in relation to Australians with BBVs.

Structure: The IVRN includes three components: IVRN Network laboratories (the Network), a Central Specimen Repository, and a Laboratory QA program (QAP).

Scope: As outlined in the Operational Strategic Plan for the Australian Centre for HIV and Hepatitis Virology Research (ACH4) (see www.ach4.org.au).

Purpose: To identify the criteria for review of expression of interest (EOI) applications for appointment as a Network Laboratory:

1. Experience in performance of separation and storage of the samples of interest which include serum, plasma, peripheral blood mononuclear cells (PBMC). This should include supporting documentation such as publications and/or experimental data based on such separated and stored samples.
2. Appropriate level of laboratory accreditation, such as NATA accreditation for laboratories with activities in the diagnostic realm, or other internal QC programs for laboratories with purely research activities.
3. Requisite laboratory facilities including suitable Physical Containment level 2 (PC2) work areas and key equipment such as nitrogen storage vessels for PBMC.
4. Requisite experienced staff and adequate staffing to handle samples in a reliable and timely fashion.
5. Proximity or ready access to major clinical centres conducting treatment trials and cohort studies in BBVs.
6. Staff members experienced and certified in the Transport of Dangerous Goods.

Applications: Will be sought by EOI and considered by the IVRN Steering Committee. The decision will be made within one month of receipt.

Following approval, ongoing participation in the Network is contingent upon maintenance of certification via the IVRN Quality Assurance Program (QAP).

All applications should be submitted electronically to:

IVRN Project Coordinator
Ms Ruth Waterman
P: 02 9348 0630
E: rwaterman@kirby.unsw.edu.au

6. Policy for the Laboratory Performance Quality Assurance Program of IVRN Tier One Laboratories

Overall aim: To provide certification to laboratories participating in cryopreservation of serum, plasma and peripheral blood mononuclear cells (PBMC), and to facilitate quality assurance for involvement of IVRN Tier One laboratories in handling of specimens from clinical trials or cohort studies.

Structure: Under direction of the IVRN Steering Committee, a Quality Assurance Program (QAP) for separation and cryopreservation of PBMC is conducted twice-yearly. The QAP is coordinated by Dr Wayne Dyer at UNSW in Sydney, and involves: shipment of QA specimens to the participating laboratories, as well as local collection of healthy donor comparison samples; shipment of cryopreserved PBMC specimens to UNSW for assessment of viability, recovery and functional activity; preparation of de-identified performance reports; and follow-up with Tier One laboratory staff when performance is below standard. In addition, the QAP Coordinator may visit laboratories to provide remedial training when discussions fail to resolve a technical issue identified during a QA round. Blood collection from HIV+ and healthy donors for the QAP is coordinated by the IVRN. The regularly updated Laboratory Manual for the PBMC processing protocol is available to all laboratories (www.ach4.org.au/quality-assurance-program).

Scope: Reliable separation and cryopreservation of PBMC requires both specialised laboratory equipment and significant technical skills. PBMC cryopreserved from subjects participating in clinical trials and cohort studies must be of the highest quality to ensure the feasibility of subsequent studies of immune function and virological parameters. These premises underpin the activities of the IVRN Tier One laboratory network. Accordingly, participation in the IVRN QAP and ongoing accreditation based upon agreed performance standards is essential.

Overview of the assessment process: A standard blood donation (~600ml) is drawn from one HIV+ and one healthy donor, into CPDA1 anticoagulant blood collection packs, and 2 x 15ml aliquots from each donor are shipped at ambient temperature by overnight courier to each of the participating Tier One laboratories. The ambient temperature is monitored and recorded during shipment by a Tiny Tag™ device. The blood samples are protected from extreme ambient temperature fluctuations during air freight by packing between gel packs pre-warmed to approximately 25°C. The blood is then processed simultaneously the following morning by each of the Tier One laboratories, according to the IVRN protocol, along with a freshly collected blood sample from a locally sourced HIV- donor. Total available PBMC in the whole blood samples is determined using a Coulter Act Diff cell differential counter, as the sum of lymphocytes and monocytes. Frozen PBMC from all three donors are shipped back from each Tier One laboratory to the IVRN testing laboratory in Sydney. All specimens are thawed and tested on the same day by the same scientist. Viability is determined by manual counting of Trypan Blue-stained cells, and absolute counts for yield determined on the Coulter Act Diff cell differential counter. PBMC function is determined by interferon (IFN)-γ ELISPOT, in response to a pool of 23 HLA class I-restricted T cell epitopes from human cytomegalovirus, Epstein-Barr virus and influenza virus (CEF) to assess CD8+ T cell function, and PMA/ionomycin to determine total IFN-γ release.

Assessment performance standards: Fractionation and cryopreservation of PBMC from one of the single donor blood specimens is deemed satisfactory if:

- Fractionation yield of a minimum 30% of the total PBMC, as determined by automated counts of the whole blood specimen;
- Post thaw PBMC viability is >80%;
- Post thaw recovery of viable PBMC is between 75% and 125% of the stated vial contents;
- ELISPOT response to CEF antigen and background, mean – SD and mean + SD, respectively (applicable to the IVRN supplied specimens only), and total response to PMA + ionomycin >5000 spots/10^6 PBMC (all PBMC specimens).

Performance required for ongoing certification as a Tier 1 Laboratory: The performance standards

(above) must be attained from at least one PBMC specimen (IVRN donor or local donor), from at least 2 out of the past 3 QAP rounds. Non-participation in a QAP round is designated as a failed result. A certificate of satisfactory performance will be issued to each successful laboratory after each QAP round.

All results for performance within the QA are fully confidential and are not discussed with other participating laboratories or sponsors that may fund IVRN for specimen collection. However, only certified laboratories will be recommended to participate in clinical trial sample collection. Only the QAP project director and IVRN Steering Committee will be aware of individual laboratory results. If there is a change in performance status, it is the responsibility of the participating laboratory to communicate their performance level, certified or otherwise, with any relevant sponsor.

Remedial action if a laboratory fails to maintain certification:

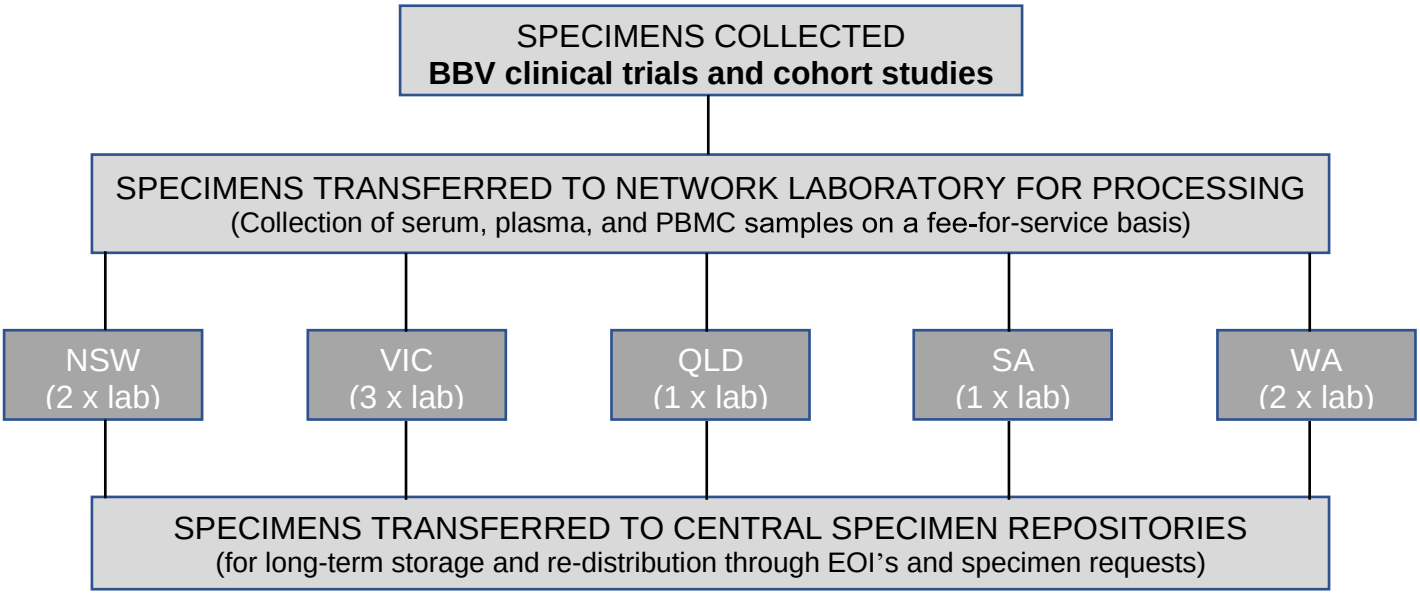
- Upon losing fully "Certified" status, a laboratory will be issued with an "Certified - Under Review" report, which recommends that the laboratory continue participation in current clinical trials and cohort studies, but involvement in new studies be deferred. Laboratory staff will be contacted by the QAP coordinator with the aim of identifying potential causes for the below standard performance, and interventions put in place to achieve the quality standard.
- After two consecutive failed attempts at satisfactory performance, the laboratory will be classified as "Unsatisfactory". In due regard for confidentiality of the status of each laboratory, it is the responsibility of the laboratory that is downgraded to "Unsatisfactory" status to notify the relevant clinical trial sponsor of this change of status. The IVRN will not distribute any details of laboratory performance to a third party. The consequence of this change in status is for negotiation between the laboratory and the clinical trial coordinator/sponsor.
- The IVRN Steering Committee will negotiate a remedial plan with the head of a laboratory that becomes "Unsatisfactory" to assist in improving performance. If the response is deemed acceptable, "Certified Under Review" status will be reinstated upon attainment of a satisfactory result in the subsequent QAP round. If the negotiation is unsuccessful, termination of Tier One laboratory status will be recommended to the IVRN Steering Committee.

Contact details for enquiries on the QAP process:

QAP Coordinator
Dr Wayne Dyer
P: 0408 039 329
E: ivnrqap@sharkdentist.com.au

IVRN Steering Committee
Professor Andrew Lloyd
P: 02 9385 2534
E: a.lloyd@unsw.edu.au

Appendix 1(a): IVRN structure and roles



Appendix 1(b): Certificates for Tier One Laboratory Satisfactory Performance

Immunovirology Research Network (IVRN)
A network of laboratories across Australia to facilitate strategic clinical immunology and virology research in relation to Australians with HIV or HCV.

IVRN Tier One Laboratories Certificate of Satisfactory Performance (ongoing)

The [insert name] Laboratory under the direction of [insert name] has participated in the Quality Assurance Program (QAP) for cryopreservation of peripheral blood mononuclear cells coordinated by the Immunovirology Research Network (IVRN) of the Australian Centre for HIV and Hepatitis Virology Research (ACH4).

The Performance Standards for the QAP as outlined in the Operating Policies of the IVRN have been met.

The Laboratory is therefore **CERTIFIED** as of [INSERT DATE].

Dr Wayne Dyer
Coordinator
IVRN QAP on behalf of the IVRN Steering Committee

IVRN Tier One Laboratories Certificate of Satisfactory Performance (under review)

The [insert name] Laboratory under the direction of [insert name] has participated in the Quality Assurance Program (QAP) for cryopreservation of peripheral blood mononuclear cells coordinated by the Immunovirology Research Network (IVRN) of the Australian Centre for HIV and Hepatitis Virology Research (ACH4).

The Performance Standards for the QAP as outlined in the Operating Policies of the IVRN have been partially met.

The Laboratory is therefore **CERTIFIED UNDER REVIEW**† as of [INSERT DATE].

Dr Wayne Dyer
Coordinator
IVRN QAP on behalf of the IVRN Steering Committee

† The IVRN recommends that laboratories with 'Certified Under Review' status, continue participation in current clinical trials and cohort studies, but involvement in new studies be deferred pending interventions put in place in association with the QAP Coordinator to achieve the quality standard.

Appendix 2: Areas of Strategy Research for ACH4

ACH4 will potentially support prioritised projects, aimed at:

a) developing vaccine candidates for HIV, HBV subtypes, HCV;
b) developing preventatives such as HIV microbicides and pre-exposure prophylaxis (PrEP);
c) cure and treatment interventions for HIV, HBV, including immunotherapy;
d) novel diagnostics and prognostics for HIV, HBV, HCV, or hepatitis B/C/HIV co-infection;
e) molecular tools for tracking epidemics caused by these viruses; and
f) development of new tests for supporting vaccine and antiviral trials.

ACH4 will not support projects:

a) conducting basic (rather than translational) BBV research;
b) development of new direct-acting antivirals against HCV;
c) not dealing primarily with HIV, HBV, HCV itself such as those focussed primarily on complications of the infections, such as hepatocellular carcinoma or glomerulonephritis associated with HBV or HCV infection; or such as lymphoma, cardiovascular disease, or opportunistic infections associated with HIV infection.

The specific areas of research of highest priority for support are listed below. Collaboration with other National Centres for HIV and hepatitis research are strongly encouraged.

In relation to HIV:

- Development of *vaccine candidates* up to the stage of clinical trials or commercial development;
- *Development of assay systems* to measure immunological and virological outcomes in vaccine trials;
- Development of *preventatives* such as microbicides, and pre-exposure prophylaxis (PreP) and post-exposure prophylaxis (PEP) regimes;
- *Development of assay systems* to monitor effectiveness of microbicides, and pre-exposure prophylaxis (PreP) and post-exposure prophylaxis (PEP) regimes;
- Development of *cure interventions* up to the stage of clinical trials or commercial development;
- *Development of antiviral targets and drug strategies*, including immunotherapy;
- *Development of tests* for antiviral drug resistance and toxicity;
- *Development of assay systems* to measure appropriate immunological and virological
- outcomes in clinical trials of cure interventions;
- Development of *diagnostics and prognostics* for the HAART era, such as point-of-care tests;
- Development of *molecular virology* tools for tracking the HIV epidemic.

In relation to HCV:

- Development of *vaccine candidates* up to the stage of clinical trials or commercial development;
- *Development of assay systems* to measure immunological and virological outcomes in vaccine trials;
- Development of *preventatives* such as disinfectants for cleansing of injecting apparatus;

- *Development of assay systems* to monitor effectiveness of disinfectants for cleansing of
- injecting apparatus;
- Development of *diagnostics and prognostics* for the direct-acting antiviral (DAA) era, such as
- point-of-care tests and drug resistance tests;
- Development of *molecular virology* tools for tracking the HCV epidemic.

In relation to HBV:

- Development of *novel vaccine candidates* for therapeutic use, or for non-responders to the existing vaccine, up to the stage of clinical trials or commercial development;
- *Development of assay systems* to measure immunological and virological outcomes in vaccine trials;
- Development of *cure interventions* up to the stage of clinical trials or commercial development,
- *Development of antiviral targets* and drug strategies, including immunotherapy;
- *Development of tests* for antiviral drug resistance and toxicity;
- *Development of assay systems* to measure appropriate immunological and virological
- outcomes in clinical trials of cure interventions;
- Development of *diagnostics and prognostics* for the modern era, such as point-of-care tests;
- Development of *molecular virology* tools for tracking the HBV epidemic.

Appendix 3: Steering Committee for IVRN

The IVRN Steering Committee currently comprises of 7 members. These include clinician-researchers, scientists and a community representative.

Membership of the 2022 Committee includes:

Prof Andrew Lloyd AM (IVRN Chair)
Viral Immunology Systems Program (VISP), The Kirby Institute

Prof Anthony Cunningham AO (ACH4 Director)
Westmead Institute for Medical Research

Dr Wayne Dyer (IVRN QAP Coordinator)
Australian Red Cross Blood Service

Prof Anthony Kelleher (IVRN Deputy Chair)
Immunovirology and Pathogenesis Program (IVPP), The Kirby Institute

Mr Aaron Cogle (Steering Committee Member)
National Association of People Living with HIV/AIDS, Australia (NAPWHA)

Dr Katherine Woods (Steering Committee Member)
National Serology Reference Laboratory (NRL),

Prof Kumar Visvanathan (Steering Committee Member)
Medicine, Dentistry & Health Sciences, University of Melbourne

Institutional logo
from where the sample will be collected

Approval No UNSW HREC xxxx

AUSTRALIAN CENTRE FOR HEPATITIS AND HIV VIROLOGY RESEARCH (ACH4), UNSW SYDNEY, *(AND THE OTHER PARTICIPATING ORGANISATION[S]*

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

The Immunovirology Research Network (IVRN)

You are invited to participate in providing additional clinical samples for research studies of HIV, hepatitis B (HBV) or hepatitis C (HCV). These samples would be made available to the IVRN, which is an Australia-wide research program funded by the Commonwealth Department of Health and Aging, which aims to assist investigations considered to be high priority for the prevention and control of the epidemics of these infections in this country. You were selected as a possible participant in this study because you are at risk or have been infected with one of these viruses and are participating in a clinical trial or cohort study related to this infection.

For this research we will take an extra (*insert the acceptable amount of blood (mls)*) of blood at the times you are already having samples collected for the study.

The samples collected for this research will be made available to researchers in Australia and overseas to conduct laboratory projects seeking to understanding of characteristics of the viral infection and the body's defense against the virus (the immune response) with the goal of improving treatment and prevention approaches. To analyse the results from these studies a limited amount of information about your illness will be made available to the IVRN. This information will only be provided in a coded (de-identified) format and will include items such as: your age, sex, the means of transmission, the duration of infection, the viral genotype (or strain) and the viral load, blood cell counts, and treatments you have received.

One aspect of the research supported by the IVRN is to study aspects of an individual's genetic make-up, which may influence the disease. For this research, only genes that are believed to be relevant to the onset or outcomes of the individual viral infection (HIV, HBV or HCV) and its treatment will be studied.

As the studies, which will be conducted on your samples, are for research purposes and do not have clear or direct relevance to the disease in your case or its management, no results of the testing of your samples will be provided to you. This includes the results of genetic tests.

The additional risks associated with this research are only those related to providing

additional tubes of blood at the time of the sampling for the clinical trial or cohort study. There is a very small likelihood that the extra amount of blood may increase the risk of bruising and discomfort.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission, except as required by law. The research that will use your samples may publish or present results in scientific journals or scientific meetings. In any publication, information will be provided in such a way that you cannot be identified.

Complaints may be directed to the Ethics Secretariat, UNSW SYDNEY 2052 AUSTRALIA (P: 02 9385 4234, F: 02 9385 6648, E: ethics.sec@unsw.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

Your decision whether to participate will not prejudice your future relations with ACH4, UNSW SYDNEY, or *(the other participating organisation[s], or other professional[s]).* If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice.

If you have any questions, please feel free to ask us. If you have any additional questions later about the IVRN contact the Chair of the IVRN Steering Committee, Professor Andrew Lloyd, or the IVRN Project Coordinator on 02 93480630.

You will be given a copy of this form to keep.

AUSTRALIAN CENTRE FOR HEPATITIS AND HIV VIROLOGY RESEARCH (ACH4), UNSW SYDNEY, *(AND THE OTHER PARTICIPATING ORGANISATION[S]*

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

The Immunovirology Research Network (IVRN)

You are deciding whether to participate.

Your signature indicates that, having read the Participant Information Statement, you have decided to take part in the study.

Research Participant (signature)

Full name (Please PRINT)

Witness (signature)

Full Name (Please PRINT)

Date

Nature of Witness

Investigator(s) (signature(s))

Full Name(s) (Please PRINT)

AUSTRALIAN CENTRE FOR HEPATITIS AND HIV VIROLOGY RESEARCH (ACH4), UNSW SYDNEY, *(AND THE OTHER PARTICIPATING ORGANISATION[S]*

REVOCATION OF CONSENT FORM

The Immunovirology Research Network (IVRN)

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with ACH4, UNSW SYDNEY, or *(other participating organisation[s] or other professional[s])*.

Research Participant (signature)

Full name (Please PRINT)

The completed Revocation of Consent should be forwarded to:

Professor Andrew Lloyd
Chair, IVRN Steering Committee
Viral Immunology Systems Program (VISP), The Kirby Institute
Level 5, Wallace Wurth Building
UNSW SYDNEY NSW 2052

Appendix 4.2: IVRN Laboratory QAP Participant Information Statement and Consent Form

Immunovirology Research Network (IVRN)
A network of laboratories across Australia to facilitate strategic clinical immunology and virology research in relation to Australians with HIV or HCV.

ACH²

Approval No. UNSW HREC xxxx

IVRN Laboratory Quality Assurance Program

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

You are invited to donate blood to support a program that evaluates the quality of work from several immunology and virology research laboratories around Australia studying HIV, hepatitis B (HBV), or hepatitis C (HCV) infection – the Laboratory Quality Assurance Program (QAP) of the Immunovirology Research Network (IVRN). You are being asked to participate either because you are HIV antibody positive or HCV antibody positive, or alternatively because you are a healthy blood donor.

The purpose of the QAP is to ensure that specialised tests of the immune system and tests for detection of HIV and HCV are accurately performed in laboratories around Australia. There is no scientific "question" that will be answered in this study.

If you decide to participate, a blood sample will be collected from your arm into a plastic bag. The amount of blood will be equivalent to approximately two thirds of a normal blood donation which is approximately 600mls (one standard blood donation). You will only be able to participate if your haemoglobin (blood level) is above 130g/L for men or above 115g/L for women. These haemoglobin levels were chosen as this is the normal level above which the Red Cross Blood Bank would allow you to donate blood, as it is considered to be safe. If for any other reason your doctor does not feel it is safe for you to donate blood, it will not be taken.

Collection of the blood will take approximately 20 minutes, although you will be asked to remain in the blood collection centre for approximately one hour.

The risks associated with drawing blood from your arm may include pain, bruising, and light-headedness. These risks are very small. Fainting may occur when people lose blood, but the amount of blood that is being taken from you for this project is very unlikely to cause this. Your body will replace the amount of blood taken within a week. Although it is unlikely, you may feel more fatigued than usual in the week after your blood donation.

We cannot and do not guarantee or promise that you will receive any benefits from this study. However, you will be contributing to the development of improved research outcomes in studies of HIV and HCV in Australia.

Your donation will be utilised after labelling in a coded, de-identified format. Any information that is obtained in connection with this study and that can be identified with you will remain confidential, and will be disclosed only with your permission or except as required by law. If

you give us your permission by signing this document, we will share the blood sample and the results of the QAP with the participating laboratories. In any publication arising from the QAP, information will be utilised in such a way that you cannot be identified.

Your blood will be used for specialised laboratory studies at no expense to you. You will not incur any costs associated with this study. You will be given AUS$50 for reimbursement of time and inconvenience.

Complaints may be directed to the Ethics Secretariat, The University of New South Wales, Sydney, 2052, Australia (Phone 9385 4234, Fax 9385 6648, email ethics.sec@unsw.edu.au). Any complaint you make will be investigated promptly and you will be informed out the outcome.

Your decision whether or not to participate will not prejudice your future relations with The University of New South Wales and the Immunovirology Research Network. If you do decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice.

If you have any questions, please feel free to ask us. If you have any additional questions later, please contact Professor Andrew Lloyd on 9385 2534, who will be happy to answer them.

You will be given a copy of this form to keep.

PARTICIPANT CONSENT
IVRN Laboratory Quality Assurance Program

You are making a decision whether or not to participate. Your signature indicates that, having read the information provided above, you have decided to participate.

Signature of Research Participant	Signature of Witness
(Please PRINT name)	(Please PRINT name)
Date	Nature of Witness
Signature(s) of Investigator(s)	
Please PRINT Name	

REVOCATION OF CONSENT
IVRN Laboratory Quality Assurance Program

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with The University of New South Wales and the Immunovirology Research Network

Signature of Research Participant	Date
(Please PRINT name)	

The section for Revocation of Consent should be forwarded to Professor Andrew Lloyd, Kirby Institute, University of New South Wales, SYDNEY, NSW, 2502

IVRN Material Transfer Agreement - I

Effective ___/ / 20__, between

The **PROVIDER:**
The Immunovirology Research Network (IVRN),
Australian Centre for Hepatitis and HIV Virology Research (ACH4),

and

The **RECIPIENT:**

_____

_____

Agree as follows:

The **RECIPIENT** will conduct the **RESEARCH PROJECT:** *"RESEARCH PROJECT TITLE"* (Attachment 1) using the

SAMPLES: *SAMPLES BEING USED* and agrees to the following conditions of use:

1. Sample Use

The **IVRN Steering Committee (IVRN SC)** has given approval (date) for the **RECIPIENT** to use the **SAMPLES** for the sole purpose as outlined in the **RESEARCH PROJECT**.

If additional **SAMPLES** are required to complete the **RESEARCH PROJECT**, the **RECIPIENT** will seek additional approval from the **IVRN SC**.

In the event that the **RECIPIENT** wishes to extend the scope of the **RESEARCH PROJECT**, additional approval will be sought from the **IVRN SC**.

The **SAMPLES** will only be used by the **RECIPIENT**, or others under the direct supervision of the **RECIPIENT**.

The **RECIPIENT** will not transfer the **SAMPLES** to others without advance written approval of the **IVRN SC**. Distribution of the **SAMPLES** to any other investigator may only be performed under the terms of a separate Material Transfer Agreement.

These **SAMPLES** or **MODIFICATIONS** thereof may not be used for **COMMERCIAL PURPOSES**, without advance written approval from the **IVRN SC**.

2. Publication Review

All publications (abstracts and manuscripts) resulting from the use of the **SAMPLES** must be forwarded to the **IVRN SC** within one week of submission.

3. Acknowledgements

All publications arising from the use of the **SAMPLES** should acknowledge the **IVRN**. For example, “The samples for this project were provided by the Immunovirology Research Network (IVRN) of the Australian Centre for Hepatitis and HIV Virology Research (ACH4).

All publications arising from funding for the **RESEARCH PROJECT** should acknowledge the ACH4 as a sponsor. For example, “The samples for this project were provided by the Immunovirology Research Network (IVRN) of the Australian Centre for Hepatitis and HIV Virology Research (ACH4).

4. Ethical Considerations

The **RESEARCH PROJECT** must conform to strict ethical standards. Evidence of local institutional human research ethics approval for the **RESEARCH PROJECT** will be provided to the **IVRN SC** to accompany that provided for the **IVRN** by the Human Research Ethics Committee of the UNSW SYDNEY.

5. Ownership

The **SAMPLES** remain the property of the **IVRN** and should be returned if research described in the **RESEARCH PROJECT** is not carried out. All remaining **SAMPLES** following the completion of the **RESEARCH PROJECT** (or after two years has elapsed since receiving the **SAMPLES**) must be returned to the **IVRN** Central Specimen Repository.

6. Financial Responsibility

The **IVRN** will not be responsible for any additional expenses incurred as a result of the use the **SAMPLES** in the **RESEARCH PROJECT** beyond the allocated funding (if any). The **IVRN** will be responsible for the costs associated with shipment of **SAMPLES** to the **RECIPIENT**, and the costs of shipping residual **SAMPLES** back to the **IVRN** Central Specimen Repository.

7. Patents

The **RECIPIENT** is free to file patent application(s) claiming inventions made by the **RECIPIENT** through the use of the **SAMPLES** but will notify the **IVRN SC** upon filing a patent application claiming **MODIFICATIONS** or methods of manufacture or uses of the **SAMPLES**.

8. Hazards

All **SAMPLES** are understood to be experimental in nature and may have hazardous properties. The **IVRN** makes no representations and extends no warranties of any kind, either expressed or implies warranties of merchantability or fitness for a particular purpose, or that the use of the **SAMPLES** will not infringe and patent, copyright, trademark or other proprietary rights.

9. Damages

Except to the extent prohibited by law, the **RECIPIENT** assumes all liability for damages, which may arise from its use, storage, or disposal of the **SAMPLES**.

The **IVRN** will not be liable to the **RECIPIENT** for any loss, claim or demand made by the **RECIPIENT**, or made against the **RECIPIENT** by any other party, due to or arising from the use of the **SAMPLES** by the **RECIPIENT**, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the **IVRN**.

10. Reporting

The **RECIPIENT** will be required to provide an annual report to the **IVRN SC** on the progress of the **RESEARCH PROJECT**.

IN WITNESS thereof, the parties have caused this Agreement to be executed as of the respective dates written below:

Signed on behalf of the Immunovirology Research Network (IVRN):

_____

Prof Andrew Lloyd IVRN SC, Chair (signature)

_____

Date

_____

RECIPIENT (signature)

_____

RECIPIENT (full name)

_____

Date

DEFINITIONS

PROVIDER: Organisation providing the **SAMPLES**, which is the Immunovirology Research Network (IVRN), Australian Centre for Hepatitis and HIV Virology Research (ACH4)

RECIPIENT: Scientist receiving the **SAMPLES**.

SAMPLES: The description of the material being transferred as specified above.

MODIFICATIONS: Substances created by the **RECIPIENT** which contain or incorporate the **SAMPLES**.

IVRN: The Immunovirology Research Network (IVRN) of the Australian Centre for Hepatitis and HIV Virology Research (ACH4)

IVRN SC: The Steering Committee of the Immunovirology Research Network (IVRN) and is used interchangeably with the **IVRN;** and represents the committee responsible for the organisation and running of the **IVRN**.

COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the **SAMPLES** or **MODIFICATIONS** to a for-profit organization. **COMMERCIAL PURPOSES** shall also include uses of the **SAMPLES** or **MODIFICATIONS** by any organisation, including **RECIPIENT**, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the **SAMPLES** or **MODIFICATIONS** to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the **SAMPLES** or **MODIFICATIONS** for **COMMERCIAL PURPOSES** per se, unless any of the above conditions of this definition are met.

IVRN Material Transfer Agreement - II

Effective ___/ / 20__, between

The **PROVIDER:**
The Immunovirology Research Network (IVRN),
Australian Centre for Hepatitis and HIV Virology Research (ACH4),

and

The **RECIPIENT:**

_____

_____

Agree as follows:

The **RECIPIENT** will conduct the **RESEARCH PROJECT:** *"RESEARCH PROJECT TITLE"* (Attachment 1) using the

SAMPLES: *SAMPLES BEING USED* and agrees to the following conditions of use:

1. Sample Use

The **IVRN Steering Committee (IVRN SC)** and the **Protocol Steering Committee (PSC)** have given approval (date) for the **RECIPIENT** to use the **SAMPLES** for the sole purpose as outlined in the **RESEARCH PROJECT**.

If additional **SAMPLES** are required to complete the **RESEARCH PROJECT**, the **RECIPIENT** will seek additional approval from the **IVRN SC** and from **the PSC**.

If the **RECIPIENT** wishes to extend the scope of the **RESEARCH PROJECT**, additional approval will be sought from the **IVRN SC** and from the **PSC**.

The **SAMPLES** will only be used by the **RECIPIENT**, or others under the direct supervision of the **RECIPIENT**.

The **RECIPIENT** will not transfer the **SAMPLES** to others without advance written approval of the **IVRN SC** and from the **PSC**. Distribution of the **SAMPLES** to any other investigator may only be performed under the terms of a separate Material Transfer Agreement.

These **SAMPLES** or **MODIFICATIONS** thereof may not be used for **COMMERCIAL PURPOSES**, without advance written approval from the **IVRN SC** and from the **PSC**.

2. Publication Review

All publications (abstracts and manuscripts) resulting from the use of the **SAMPLES** must be forwarded to the **PSC** prior to submission to assess whether clinical data within the abstract or manuscript from clinical trial samples may be made publicly available prior to the completion of the clinical trial. All publications (abstracts and manuscripts) must be forwarded to the **IVRN SC** within one week of submission.

3. Acknowledgements

All publications arising from the use of the **SAMPLES** should acknowledge the **IVRN**. For example, “The samples for this project were provided by the Immunovirology Research Network (IVRN) of the Australian Centre for Hepatitis and HIV Virology Research (ACH4).

All publications arising from funding for the **RESEARCH PROJECT** should acknowledge the ACH4 as a sponsor. For example, “The samples for this project were provided by the Immunovirology Research Network (IVRN) of the Australian Centre for Hepatitis and HIV Virology Research (ACH4).

4. Ethical Considerations

The **RESEARCH PROJECT** must conform to strict ethical standards. Evidence of local institutional human research ethics approval for the **RESEARCH PROJECT** will be provided to the **IVRN SC** and the **PSC** to accompany that provided for the **IVRN** by the Human Research Ethics Committee of the University of New South Wales.

5. Ownership

The **SAMPLES** remain the property of the **IVRN** and should be returned if research described in the **RESEARCH PROJECT** is not carried out. All remaining **SAMPLES** following the completion of the **RESEARCH PROJECT** (or after two years has elapsed since receiving the **SAMPLES**) must be returned to the **IVRN** Central Specimen Repository.

6. Financial Responsibility

The **IVRN** will not be responsible for any additional expenses incurred as a result of the use the **SAMPLES** in the **RESEARCH PROJECT** beyond the allocated funding (if any). The **IVRN** will be responsible for the costs associated with shipment of **SAMPLES** to the **RECIPIENT**, and the costs of shipping residual **SAMPLES** back to the **IVRN** Central Specimen Repository.

7. Patents

The **RECIPIENT** is free to file patent application(s) claiming inventions made by the **RECIPIENT** through the use of the **SAMPLES** but will notify the **IVRN SC** and the **PSC** upon filing a patent application claiming **MODIFICATIONS** or methods of manufacture or uses of the **SAMPLES**.

8. Hazards

All **SAMPLES** are understood to be experimental in nature and may have hazardous properties. The **IVRN** makes no representations and extends no warranties of any kind,

either expressed or implies warranties of merchantability or fitness for a particular purpose, or that the use of the **SAMPLES** will not infringe and patent, copyright, trademark or other proprietary rights.

9. Damages

Except to the extent prohibited by law, the **RECIPIENT** assumes all liability for damages, which may arise from its use, storage, or disposal of the **SAMPLES**. The **IVRN** will not be liable to the **RECIPIENT** for any loss, claim or demand made by the **RECIPIENT**, or made against the **RECIPIENT** by any other party, due to or arising from the use of the **SAMPLES** by the **RECIPIENT**, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the **IVRN**.

10. Reporting

The **RECIPIENT** will be required to provide an annual report to the **IVRN SC** and **PSC** on the progress of the **RESEARCH PROJECT**.

IN WITNESS thereof, the parties have caused this Agreement to be executed as of the respective dates written below:

Signed on behalf of the Immunovirology Research Network (IVRN):

_____

Prof Andrew Lloyd IVRN SC, Chair (signature)

_____

Date

_____

RECIPIENT (signature)

_____

RECIPIENT (full name)

_____

Date

DEFINITIONS

PROVIDER: Organisation providing the **SAMPLES**, which is the Immunovirology Research Network (IVRN), of the Australian Centre for Hepatitis and HIV Virology Research (ACH4)

RECIPIENT: Scientist receiving the **SAMPLES**.

SAMPLES: The description of the material being transferred as specified above.

MODIFICATIONS: Substances created by the **RECIPIENT** which contain or incorporate the **SAMPLES**.

IVRN: The Immunovirology Research Network (IVRN) of the Australian Centre for Hepatitis and HIV Virology Research (ACH4)

IVRN SC: The Steering Committee of the Immunovirology Research Network, and is used interchangeably with the **IVRN;** and represents the committee responsible for the organisation and running of the **IVRN**.

PSC: The Protocol Steering Committee represents the committee responsible for the provision of samples to the IVRN that are obtained from current clinical trials.

COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the **SAMPLES** or **MODIFICATIONS** to a for-profit organization. **COMMERCIAL PURPOSES** shall also include uses of the **SAMPLES** or **MODIFICATIONS** by any organisation, including **RECIPIENT**, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the **SAMPLES** or **MODIFICATIONS** to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the **SAMPLES** or **MODIFICATIONS** for **COMMERCIAL PURPOSES** per se, unless any of the above conditions of this definition are met.

Appendix 6: Template for applications for collection and storage of samples from a new study by IVRN

Study title: A descriptive title of the study.

Investigator(s) and institution(s): Name, address, telephone and fax numbers, as well as e-mail address of the proposing investigator(s)

Study or sub-study rationale: A concise outline of the rationale for the application, including enough background information (e.g., data, references, etc.) to support both the scientific merits and the strategic importance of the proposed sample collection.

Study objective(s): A statement of the specific aims of the proposed sample collection.

Study design: A description of the overall design of the clinical trial or cohort study.

Study site(s): Specify the recruitment site(s) for the study and indicate the proximity to Tier 1 laboratory venue(s) (see www.ach4.org.au).

Subjects: A description of the number of planned subjects and their disease characteristics.

Samples: A detailed description of the proposed sampling timepoints in relation to the study timeline (baseline, one month, etc) and to study interventions (pre-drug, on-drug, 12 month follow-up), and a detailed description of the sample characteristics, including sample type (serum, plasma, PBMC), proposed labelling (study ID, etc) and sample quantity.

Collection and transport: A detailed description of where and when (i.e. time of day) the samples will be collected and how they will be transported to the Network collection laboratory (Appendix 6.1(a) for proforma)

Planned assays: A description of assays by the investigators utilising the IVRN samples (if any). Note that an application to the Network for access to the samples is required.

Ethics: Indicate whether institutional ethics committee approval for the study and sample collection has been obtained (see Appendix 6.1(b) for the ethics approval process)

Funding: Indicate funding source(s) for the study and the available contribution to costs for this specimen collection (if any).

Timelines: Indicate the likely start date and completion date for the study.

Sample sharing arrangements: Clarify the extent to which samples and clinical data will be shared or made available to the IVRN. Potential options are below:

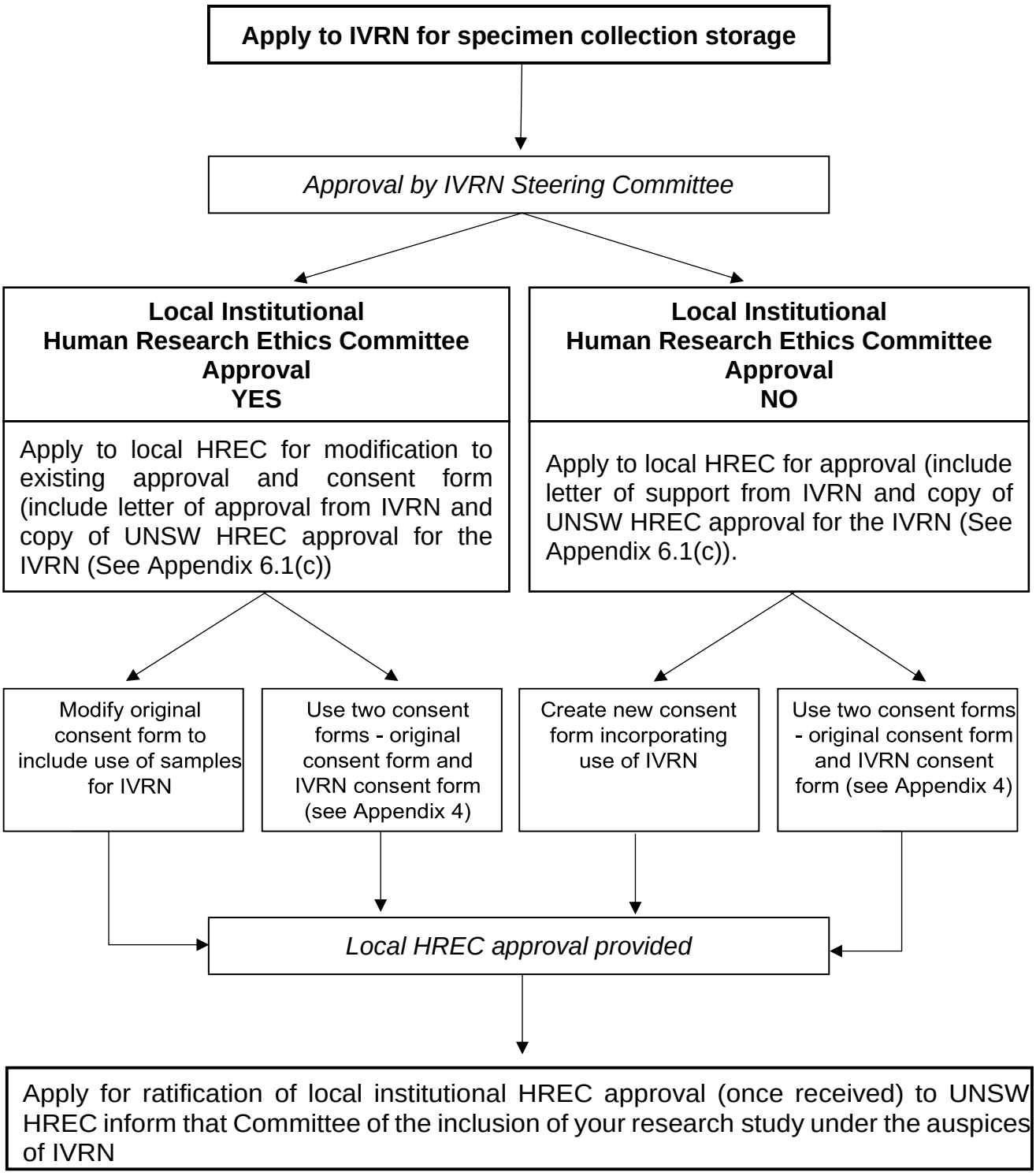
a) Making selected PBMC/serum samples from the whole subject group fully available to the IVRN (e.g. one aliquot available from each timepoint, or all samples from a timepoint, such as week 12 and late follow up)
b) Make all samples from selected subjects fully available to the IVRN (e.g. from subjects not of interest to the primary project)
c) Other alternatives, you may wish to propose (e.g. all samples retained by the investigators of the study before being made fully available to the IVRN after 12 months)

Signature of investigator(s) and date.

Appendix 6.1(a): Logistical information required for inclusion in IVRN specimen collection

Date:			
Study title:			
Study Contact Name:			
Phone:		**Email:**	
Sample collection sites (i.e. blood collection site)			
Site 1 (Institution)**:**		Site 1 Contact:	
Phone:		Email:	
Estimated number of samples per year for site 1:			
Tier One Laboratory for site 1:			
Mechanism for transporting sample from collection site to Tier One Laboratory: *(Include transport/courier details and how advance warning will be given to Tier One Lab)*			
Site 2 (Institution)**:**		Site 2 Contact:	
Phone:		Email:	
Estimated number of samples per year for site 2:			
Tier One Laboratory for site 2:			
Mechanism for transporting sample from collection site to Tier One Laboratory: *(Include transport/courier details and how advance warning will be given to Tier One Lab)*			
Blood tubes being collected for processing by the Tier One Lab for IVRN (e.g.9ml LiHep, 5ml SST)			
SITE 1		**SITE 2**	
# of tubes	**Type of blood tube**	**# of tubes**	**Type of blood tube**

Appendix 6.1(b): Ethical approval process for application for inclusion of a new study in IVRN specimen collection



Appendix 6.1(c): UNSW HREC Ethics Approval for the IVRN

03-May-2021

Dear Professor Andrew Lloyd,

Project Title	Immunovirology Research Network (IVRN)
HC No	HC200777
Re	HC200777 Notification of Ethics Approval
Approval Period	03-May-2021 - 02-May-2026

Thank you for submitting the above research project to the **HREC Executive** for ethical review. This project was considered by the **HREC Executive** at its meeting on **29-Apr-2021**.

I am pleased to advise you that the **HREC Executive** has granted ethical approval of this research project. The following condition(s) must be met before data collection commences:

Conditions of Approval:
N/A

Conditions of Approval - All Projects:

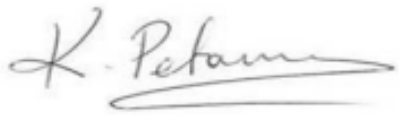
- The Chief Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Chief Investigator will seek approval from the **HREC Executive** for any modifications to the protocol or other project documents.
- The Chief Investigator will notify the **HREC Executive** immediately of any protocol deviation or adverse events or safety events related to the project.
- The Chief Investigator will report to the **HREC Executive** annually in the specified format and notify the **HREC Executive** when the project is completed at all sites.
- The Chief Investigator will notify the **HREC Executive** if the project is discontinued before the expected completion date, with reasons provided.
- The Chief Investigator will notify the **HREC Executive** of his or her inability to continue as Coordinating Chief Investigator including the name of and contact information for a replacement.

The **HREC Executive** Terms of Reference, Standard Operating Procedures, membership and

standard forms are available from https://research.unsw.edu.au/research-ethics-and-compliance-support-recs.

If you would like any assistance, or further information, please contact the ethics office on:
P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007
E: humanethics@unsw.edu.au

Kind Regards,



Associate Professor Kathy Petoumenos
Human Research Ethics Presiding Member

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

Appendix 7: Proforma for application for access to samples in the IVRN specimen collection

Study title: A descriptive title of the study.

Investigator(s) and institution(s): Name, address, telephone and fax numbers, as well as e-mail address of the proposing investigator(s)

Study rationale: A concise outline of the rationale for the application, including sufficient background information (e.g., data, references, etc.) to support both the scientific merits and the importance of the proposed research in relation to the designated strategic research priorities of ACH4.

Study objective(s): A statement of the specific aims of the proposed research.

Proposed methods: A description of the proposed assays for the project. Indicate for each assay whether it has been established in the laboratory (provide supporting references if available).

Samples: A detailed description of the requested sample types (serum, plasma, PBMC), sample quantities (e.g. volume of serum) and sample numbers.

Ethics: Indicate whether institutional ethics committee approval for the study has been obtained.

Funding: Indicate funding source(s) for the study and the available contribution to the costs of the specimen collection and storage (if any).

Timelines: Indicate the likely start date and completion date for the study.

Signature of investigator(s) and date.

Appendix 8: Process for accessing samples from the IVRN

Prepare an application using the appropriate template and submit to IVRN (this may either be using the proforma in Appendix 7 for applications without IVRN funding, or via an ACH4/IVRN Expression of Interest (EOI) application for funding based on IVRN samples)

↓

Await approval of application for samples from the IVRN Steering Committee (or award of funding for the EOI).

↓

The IVRN requires all projects using IVRN samples to have approval from the local Human Research Ethics Committee (HREC) in the institution in which the project will be carried out.

↓

If the intended project does not have such approval, then an application to the institutional HREC should be submitted.

If the project had institutional HREC ethics approval prior to submitting the IVRN application, a modification to the existing approval from the institutional HREC specifically to use IVRN samples in the project should be sought.

↓

Forward a copy of the institutional HREC ethics approval to use IVRN samples to the IVRN Project Coordinator at UNSW.

Note: The applicant(s) should ensure that the title of the project in the IVRN application matches the title of the project approved by the institutional HREC. If this is not the case, the applicant(s) should submit a covering letter to the IVRN with the HREC ethics approval confirming that the ethics approval includes the project using IVRN samples.

↓

A Material Transfer Agreement (MTA) will be sent to applicant(s) once the project is approved by the IVRN Steering Committee. Sign and return the MTA to the IVRN Project Coordinator at UNSW.

↓

The IVRN Project Coordinator at UNSW will liaise with the IVRN Central Specimen Laboratories at UNSW and NRL to organise shipment of samples to the applicant(s). Read-only access to the Blood and Tissue Samples Inventory System (BATSIS) database will be arranged for the applicant(s) in advance if the applicant(s) needs to select samples by viewing the associated clinical and laboratory data.