1. Summary

The Australian Arthritis and Autoimmune Biobank Collaborative (A3BC) is a national network of patients, clinicians and researchers who share the vision to improve the value of care and health outcomes for the ~8 million men, women and children with musculoskeletal (MSK) and autoimmune conditions in Australia.

The A3BC is focussed on ensuring open, equitable and ethical access to its stored biological samples and related health/clinical data. This Policy respects what our participants have agreed to take part in and encourages appropriate ongoing use of the A3BC resource.

2. Scope

2.1. This Policy covers all research applications to access A3BC samples/data held by one or more A3BC state nodes and funded by A3BC funds (managed by the University of Sydney and/or A3BC nodes). All researchers, including A3BC investigators, will comply with the terms of the Policy.

2.2. The Policy also covers access to data from the Australian Rheumatology Association Database (ARAD), whereby applications are made to the new A3BC-ARAD Access Committee for access to both legacy ARAD data and A3BC data.

2.3. Access A3BC samples/data funded by the NSW Biospecimen Collection Grant will comply with the NSW Health Statewide Biobank (NSWHSB) Access Policy for Supported Strategic Collections.

2.4. Access A3BC samples/data funded by a mix of A3BC and NSW Biospecimen Collection Grant funding will comply with A3BC and NSWHSB access policies based on samples/data requested.

3. Key Principles

3.1. The A3BC is available to all bona fide researchers for research in the public interest relating to musculoskeletal and autoimmune conditions. All approved researchers will undergo the same application and approval processes.

3.2. Access applications will be reviewed (in the Preliminary Application/Expression of Interest, 'Prelim App/EOI') to ensure research proposals are consistent with A3BC policies and the consent provided by participants (prior to Human Research Ethics Committee, HREC, application).

3.3. Access to samples limited in stock or of high value will be reviewed at the Prelim App/EOI and the A3BC may negotiate types/amounts against the potential benefits of the research. Preference will be given to projects of high scientific merit, value-add to samples and A3BC collaborators.

3.4. Ensuring the anonymity and confidentiality of participant data and samples is a priority. Researchers will sign a legal agreement with the A3BC not to make any attempt to identify participants.

3.5. Applications for access by commercial organisations will only be approved if they are partnered with a university, medical research institute or A3BC investigators.

3.6. Researchers may be required to pay for access to the A3BC on a neutral cost-recovery basis including a fixed charge for application review and a variable charge for the samples, tests and/or data required.

3.7. The A3BC will remain the owner of the processed data and samples but will have no claim over any intellectual property (IP) developed by accessing researchers (unless stated otherwise in the MTA).

3.8. For ARAD legacy data (pre July 2020) access, at least one ARAD Principal Investigator must be offered co-authorship in recognition of their long historical effort (and meeting IJMCE criteria).

3.9. For A3BC data (post July 2020), at least one A3BC Principal Investigator must be offered co-authorship in recognition of effort (and meeting IJMCE criteria). To be agreed in the EOI.

3.10. Researchers given access will be required to publish their findings and return their results (and possibly surplus samples) to the A3BC so they are available for other researchers to use in the public interest.

3.11. The A3BC will engage with participants, researchers, clinicians and the community throughout the project's lifetime in regard to approved research access and discoveries made.

4. Objectives of the Policy

4.1. The access procedures herein facilitate A3BC samples and data access to ensure broad and ongoing usage while respecting the undertaking participants have agreed to, the larger public interest, and all relevant laws and regulations that protect participant and researcher rights.

4.2. Decisions whether or not to grant A3BC access comply with a participant's current A3BC consent to:
   a. ensure that any uses of their samples/data are consistent with its stated aims,
   b. to protect participant privacy and confidentiality,
   c. to ensure research projects have scientific and ethical approval, and
   d. to make information publicly available about the uses of the A3BC

4.3. A3BC access procedures are clear, transparent and actioned in a fair and accountable manner. The Policy is a framework and not prescriptive to each and every situation that the A3BC may encounter in access requests over time.

4.4. The Policy and procedures will be reviewed by the A3BC Consortium Committee from time to time, taking into account feedback from participants, researchers, clinicians, funders and other parties.

5. Routine Samples Available

ADULT

Plasma*	Serum*	RNA (in whole blood)*	Buffy Coat*	PBMCs*
Synovial Tissue	Synovial Fluid	Saliva	Stool	Newborn card
Urine				

PAEDIATRIC

Plasma*	Serum*	DNA (in whole blood)*	PBMCs*
Synovial Tissue	Synovial Fluid	Saliva	Newborn card

** Routine collection at 0, 6, 12 and 24 months for incident and prevalent cases.*

6. Routine Data Available

ADULT

Demographics	*Disease History***	*Treatment History ϕ*	*Cancer History*	*Obstetric History*
Quality of Life Δ	Environment	Lifestyle	Sleep Survey	Diet Survey
Physical activity	MBS Claims	PBS Claims	Immunisation	Death

PAEDS

Demographics	*Disease History***	*Treatment History ϕ*	*Cancer History*	*Pregnancy History*
Quality of Life †	Environment	Lifestyle	Sleep Survey	Diet Survey
Physical activity	MBS Claims	PBS Claims	Immunisation	Death

Italics - Captured via both electronic medical records (EMR) and patient-reported outcome (PRO) surveys (routinely at 0, 6, 12 and 24 months for incident and prevalent cases).

* EMR capture includes validated diagnostic criteria, physical exam, pathology and medical imaging results.

ϕ PRO capture includes medications, surgeries, complementary/herbal medicines, supplements and analgesia

Δ Includes RAPID-3, RA-FQ, RADAI, PROMIS-29, EQ-5D-5L, BASDAI

† Includes EQ-5D-Y, CHAQ, PROMIS-25

With growing A3BC access and associated return of research results (section 14) to the A3BC, raw data such as gene or protein sequences will also be data available through accessing the A3BC.

7. Application for Non-Routine Samples and Data

Some projects applying for A3BC access may request other sample and/or data specifications and therefore present further consideration regarding contribution and costs. Non-routine sample/data requests may require the A3BC to re-contact participants for permission to participate in a manner additional to the scope of their existing consent. The review of such scenarios is important to ensure that the participant's consent is honoured, the researcher's requirements are considered, and the A3BC's effort is appropriately respected.

7.1. Participant re-contact:

a. Re-contact may be required for several reasons, including additional consent for uses outside existing consent, new biospecimen or data collection, or to ask participants if approved researchers may contact them via the A3BC (e.g. to collect new information). The A3BC will not give names or contact details to any third party, rather we will mediate such contact for the participant.

b. A3BC participants have consented to be re-contacted, however the A3BC will first review the rationale for, and level of, required re-contact to ensure participant burden is not excessive. Initial re-contact for an approved study would always be undertaken by the A3BC.

c. Applicants must make it clear in their Prelim App/EOI if they propose participant re-contact. Decisions on whether re-contact is appropriate will be made by the A3BC Consortium Committee, with advice from the A3BC Ethical Legal and Social Implication (ELSI) Advisory Group.

d. Such participant re-contact must be clearly stated in the applicant's subsequent HREC application and approved thereby. The provision of new information, samples or consent by participants must be stated as entirely voluntary.

7.2. Collection strategy:

a. Where the collection strategy (e.g. participant contact, timepoints, sample/data types, processing requirements) of a research project applying for A3BC access differs from routine A3BC collection strategy, the A3BC would firstly discuss the project design with the applicant research group to understand why they cannot use routine A3BC samples and data.

b. Where possible, the A3BC would negotiate routine collection and processing of the A3BC samples/data in addition to, and/or substitution of, the applicant's requirements.

c. Such negotiation is dependent on the amount/frequency of sample/data requested by the applicant. For example, if the total blood volume requested by the applicant was high, the A3BC may reduce its routine blood volume to manage participant burden and potential risk.

7.3. Costs:

a. Where the collection strategy (sample/data types, timepoints, processing needs) of a researcher applying for A3BC access has markedly different requirements and related costs (i.e. Tempus tubes for RNA, saliva kits, or DNA extraction) to standard A3BC collection, the A3BC would ask the applicant to source and fund such materials themselves.

b. Any such additional cost would be discussed and determined at the point of the Prelim App/EOI. Otherwise, a standard neutral cost recovery schedule would apply, to be invoiced after MTA3 execution and paid prior to sample/data release.

Table 1: Routine Adult Collection-Storage

Biospecimen	Collection Tube/Container	Sample	# -80°C Aliquots	# VPLN Aliquots	Timepoints (months)
Adult Blood	Lavender Cap EDTA 9ml (x1)	Plasma	6*	-	0, 6, 12, 24
		Buffy Coat (DNA)	2*	-	0, 12
	Red/Yellow Cap SST 8ml (x1)	Serum	6*	-	0, 6, 12, 24
	Green Cap Lithium Heparin 9ml (x3)	PBMCs	-	4-6*	0, 6, 12
		Whole blood	2*	-	0, 6, 12
	Tempus Blood RNA Tube 3ml (x1)	RNA	2†	-	0,12

* 0.5ml aliquots. † 3.8ml aliquots.

Table 2: Routine Paediatric Collection-Storage

Biospecimen	Collection Tube/Container	Sample	# -80°C Aliquots	# VPLN Aliquots	Timepoints (months)
Paeds Blood	Lavender Cap EDTA 10ml (x1)	Plasma	6*	-	0, 6, 12, 24
		PBMCs	-	1-2*	0, 6, 12
		Whole blood (DNA)	2*	-	0, 6, 12
	Red Cap SST 5ml (x1)	Serum	2*	-	0, 6, 12, 24
	Green Cap Lithium Heparin 6ml (x1)	PBMCs	-	1-2*	0, 6, 12

* 0.5ml aliquots

8. Ethical Approvals

8.1. The A3BC has full ethical approval from its governing Human Research Ethics Committee (HREC). In accordance with the National Mutual Acceptance (NMA) scheme, this approval is accepted by all public health organisations in all Australian states and territories, except Tasmania. Outside the NMA sites the A3BC manages ethical approval via independent HREC approvals (e.g. private hospitals with defined HRECs) or agreements with private sites (e.g. private clinics with no defined HREC).

8.2. The A3BC's HREC approval covers access to samples/data for renewable periods of 5 years. As a condition of this approval, the A3BC has made commitments to its governing HREC and requires these commitments to be honoured by accessing researchers, as described in A3BC MTA3.

8.3. The A3BC's HREC approval covers the majority of proposed access uses, whereby researchers typically only need to obtain a low or negligible risk (LNR) HREC approval as part of the A3BC access process (section 10). Applicant HREC approval is particularly relevant in the following circumstances:

a. Any research project involving the re-contact of participants

b. Research uses not covered by the A3BC's approval (e.g. human reproductive technology)

c. The A3BC reasonably considers it appropriate to do so

9. Custodianship

Biobank custodians are trusted intermediaries and caretakers of the biobank's biospecimen and associated data collections. While single-site biobank operations generally have one custodian, for networked biobanks such as the A3BC, each storage site/node functions as the custodian for its local collection, in agreement with the central headquarters (HQ) of the network (A3BC HQ is the Kolling Institute group, NSW).

The A3BC node custodian's responsibilities extend from collection through to research access and align with approved A3BC ethics, governance and policy standards. As responsible custodians, all initial individuals were involved in the design and planning of the A3BC to ensure the ongoing quality of biospecimens and associated data, the privacy and confidentiality of A3BC participants and their data, and the appropriate use of biospecimens and data for research.

9.1. The A3BC uses a primary (Principal Investigator, clinician) and deputy (biobank/lab Manager) custodian per node to ensure clinical, research and operational knowledge in decision-making.

9.2. While both the primary and deputy custodians combine to give oversight of the collection, the local Principal Investigator (primary custodian) is imbued with final decision-making powers.

9.3. Where A3BC collection is managed by a pathology/other entity under service agreement (i.e. NSW StateWide Biobank), the deputy custodian (entity employee) is also responsible as such.

9.4. To safeguard against the impact of custodians having sudden changes in employment status, illness, or other factors making them unavailable to perform their role as custodian, the A3BC has identified a contingency primary and deputy custodian at each node to account for this possibility.

9.5. All custodians are confirmed to their role by members of the A3BC Consortium Committee.

10. Ownership and Intellectual Property Rights

The A3BC Consortium is the cumulative custodian/caretaker of all property in its database(s) and node biobank facilities. As legislative provisions are not clear, the A3BC understands that it nor state/national Health organisations 'own' raw electronic medical record (EMR) or other linked personal data stored in the A3BC database. Instead, all parties are custodians tasked with upholding State and Commonwealth health record privacy/security rights and responsibilities (incl. Privacy Act 1988[1]) for the patient.

The A3BC endorses the National Principles of Intellectual Property (IP) Management for Publicly Funded Research, such that all intellectual property rights (IPRs) arising from a recipient's use of the A3BC's materials and data will be owned by the parties who created or made a significant inventive contribution to those IPRs. Recruitment and sample/data collection alone may not be considered to constitute significant contribution.

10.1. The A3BC's philosophy on IPRs is to encourage use of its samples/data by bona fide researchers. This way, the A3BC resource, including returned results, is available to all other approved researchers, to best enable the accumulation of knowledge and development of healthcare advances from its use.

10.2. The A3BC retains ownership and any intrinsic IPRs in the following:

a. Any property in its database(s), whether captured by A3BC paper or electronic forms, including all recruitment and consent data, all case report form data, all A3BC-ARAD questionnaire data, and other data it has authored or made significant creative contribution to (excludes raw EMR and linked data). Notably, this covers database rights and copyright.

b. Any collected biospecimens (incl. blood, tissue, stool etc) and subsequent processed/stored samples/derivatives (e.g. serum, DNA, PBMCs etc) and associated pre-analytical variable data.

c. Any design or content in paper or electronic documents (stored securely outside the database) created solely/partly by A3BC investigators or node staff (see A3BC MTA1 and MTA2).

d. Any processes/procedures, assays, know-how or internally generated analysis products/data created solely/party by A3BC investigators or node staff (see A3BC MTA1 and MTA2).

10.3. Prior to July 18th 2020 the ARA was the custodian of the ARAD data and oversaw its funding and governance, including the ARAD Management/Steering Committee and ARAD Scientific Advisory Committee. These Committees managed and controlled access to, and release of data within ARAD.

[1] Australian Government. Privacy Act 1988. Compilation No 78 – July 1 2018. https://www.legislation.gov.au/Details/C2018C00292

10.4. From July 18th 2020, a Memorandum of Understanding (MOU) between the ARA, ARAD and A3BC was adopted, to enable members of the ARAD Management/Steering Committee to combine with the A3BC Consortium Committee (CC) as the ongoing custodians of the combined ARAD legacy data, and the new A3BC data and biospecimens (excludes raw EMR and linked data). The ARA's role was changed to that of a Partner Organisation, with ongoing representation on the CC.

10.5. Approved applicant researchers are granted limited non-transferable, revocable, non-exclusive licences (without any ownership or the right to grant sub-licences) to use the A3BC sample and data resources to conduct approved research for a defined period of time (stated in A3BC MTA3).

10.6. If a research group creates separate datasets from their use of A3BC resources, any IPRs in these datasets will be owned by the researchers and/or their institutions, but subject to a non-exclusive licence back to the A3BC for its use on an irrevocable, perpetual, worldwide, no-fee, royalty-free, sub-licensable basis. These datasets would then be available to other A3BC researchers.

10.7. The A3BC will have no claim over IPRs developed by researchers through their use of the A3BC resource, unless these IPRs are used to limit research and/or healthcare access. For example, the A3BC would look unfavourably on one entity seeking to limit the use of naturally-occurring sequences, biomarkers or biochemical processes. If such limiting occurs, the A3BC would require the licence granted back to them on an irrevocable, perpetual, worldwide, no-fee, sub-license basis.

11. Acknowledgements and Co-Authorship

11.1. When a reasonable volume of samples, data and/or project consultation resourcing has been contributed by the A3BC (or partner source, like ARAD or ANZ CLARITY) to the applicant researcher for the results described in a publication, it is preferential that the A3BC (or partner) be included in the title of that publication.

11.2. It is mandatory for investigators provided with A3BC samples and/or data to clearly acknowledge the A3BC in any publication, presentation or other public work that results from using its samples, data, services (a condition of MTA3). All publications must include the following acknowledgement:

> "This research [A3BC Access ID] has only been possible through use of the Australian Arthritis and Autoimmune Biobank Collaborative (A3BC) resource (samples and/or data). The A3BC team are sincerely grateful for the generosity of the patient participants, carers, clinicians and researchers in continuing to give their time and effort to allow research discovery such as that herein. The A3BC is generously supported by the CLEARbridge Foundation and competitive grant funding from the NHMRC (APP2006579), the Australian Government's Medical Research Future Fund (MRFF; MRF2007502, MRF2016105) and the NSW Ministry of Health."

If only ARAD legacy data is provided, the following acknowledgement may be used instead:

> "This research [A3BC Access ID] has only been possible through use of the Australian Rheumatology Association Database (ARAD) data. The ARAD team are sincerely grateful for the generosity the patient participants, carers, clinicians and researchers in continuing to give their time and effort to allow research discovery such as that herein".

11.3. ARAD legacy data *(before to 18.7.2020):*

ARAD Investigators continue to make a substantial long-term contribution to develop and maintain this data. As such, at least one of the ARAD Principal Investigators (now included in the A3BC) of this data must be offered the option of co-authorship by the accessing researchers in recognition of the intellectual development, funding and governance over the past 20 years (2000 to 2020). Authorship would still address IJMCE author criteria, including review and endorsement of any final publication.

11.4. A3BC samples and/or data *(after 18.7.2020):*

Researchers applying for A3BC access must include a co-authorship proposal as part of the Prelim App/EOI, to be discussed on a case-by-case basis. At least one A3BC Principal Investigator must be offered the option of co-authorship by the accessing researchers in recognition of the intellectual development, funding and governance required to establish the national resource. Authorship would still address IJMCE author criteria, including review and endorsement of any final publication. International authorship guidelines for biobank studies are under review, hence the A3BC will review its authorship criteria periodically. A list of A3BC Principal Investigators can be found in the A3BC protocol.

11.5. It is recommended, where appropriate, that the role of our REDCap database is cited in the methods:

"Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at the University of Sydney."

11.6. For publications using Services Australia data (MBS, PBS, AIR):
Services Australia must be acknowledged as the information source within the methods section. Services Australia require a copy of any impending publications (preferably 2 months prior to publication) for comments and/or reasonable amendments to the publication in relation to Services Australia and/or its data, provided they are given to the researcher in writing 20 working days from the submission to Services Australia.

12. Application Process

The A3BC access application process will be entirely online, with all communications relating to each application retained in a comprehensive file. The process is summarised by the following 4 steps:

12.1. Registration of Researchers (~1 week):

a. The identity of applicants, publications and track history is verified via an online form in the A3BC's REDCap system and A3BC staff register them as an approved researcher with ID (letter provided).

b. Each applying researcher only needs to be registered once and then simply confirms their ID and updates details for future application(s).

12.2. Preliminary (Pre-HREC) Application/Expression of Interest ('Prelim App/EOI'; ~4 weeks):

a. The researcher completes an online form including lay study summary (400 words max), number/ type of samples/data sought, re-contact, funding, contentious issues and co-authorship proposal.

b. The A3BC Consortium Committee (CC) considers the Prelim App/EOI, based largely on feasibility, scientific merit, resource sustainability, logistics, funding and any conflicts of interest (COI).

c. The CC will communicate one of the following to the applicant:

- An invitation to complete the Post-HREC Application and an indication of access costs. The applicant will be asked to obtain HREC approval before submitting the Post-HREC Application, or
- A letter declining the Prelim App/EOI with a brief summary of reasons. The applicant may elect to amend the application or withdraw the application.

12.3. Main (Post-HREC) Application (~4 weeks):

a. The Post-HREC Application is submitted online to the Access Committee (AC), including a brief Application Form, full HREC application and approval letter, and SSA approval letters (where required).

b. The A3BC requires that the HREC-approved application content be submitted 'as is' for review by the AC (see note below). The combined HREC-approved application and A3BC Post-HREC Application information should include:

i. Lay summary
ii. Details of funding (or applications for funding)
iii. Names of all collaborators (need to be Approved Researchers) and approved sites
iv. Scientific rationale of project (background, pilot data, aims/objectives, experimental design and methods, power calculations, expected results, contentious issues, relevant references)
v. Required quantity and type of samples/data,
vi. Need for re-contact with process and brief justification,
vii. Any non-standard protocols for collection, processing, storage of data and/or samples
viii. Proposed timetable (start; duration; submission of publication, return of results)
ix. Any outstanding feasibility issues (incl. other required approvals, researcher training)

c. The focus of this step is to confirm compliance with the Prelim App/EOI request, review scientific merit and refine any project parameters in the context of A3BC policies.

d. If data alone is applied for, independent scientific review is generally not required, although the A3BC may undertake review in certain circumstances (e.g. contentious issues).

e. The AC will communicate one of the following to the applicant:

i. Access approval subject to execution of an MTA3 form and full payment of access fees.
ii. Conditional access approval based on outstanding items (e.g. award of funding) being met.
iii. A letter declining the Post-HREC Application with a brief summary of reasons. The applicant may elect to clarify/ amend the application, withdraw the application, or appeal the decision.

12.4. MTA and Access Fees (~4 weeks):

a. The approved applicant works with the A3BC to execute Material Transfer Agreement #3 (MTA3) and pay access fees before the release of samples/data.
b. Apart from the inclusion of specific details of the approved research (e.g. researchers; data/samples required, timelines etc), the MTA terms and conditions are non-negotiable.

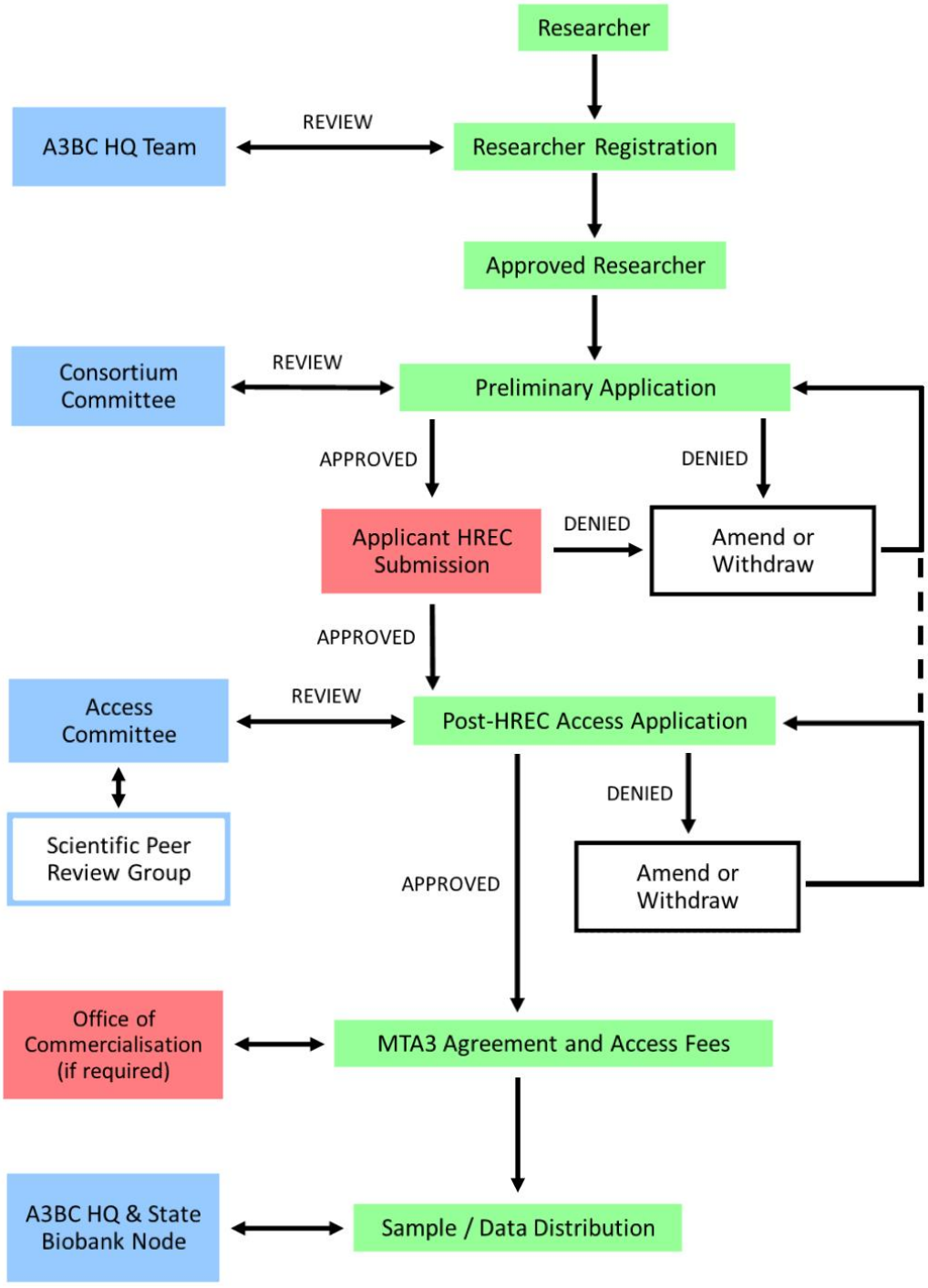

Figure 1: National A3BC Access Process

NOTE: In the first instance, the Post-HREC Application will be reviewed by the Scientific Peer Review Group (allocated by the Access Committee), comprised of senior scientists/clinicians with expertise relevant to the application. The SPRG will assess the application's scientific and clinical relevance, appropriateness of study design and potential for commercialisation. Applications approved by the SPRG will be referred to the Access Committee who will review the application based on all information and advice provided.

13. The Access Committee

The Access Committee oversees all access applications to A3BC collections by assessing the input-output implications to the biobank, coordinating scientific assessment through the SPRG, liaising with the appropriate research offices for ethical, MTA and invoicing, and seeking ELSI advice regarding disputes.

Access Committee membership includes:

- A3BC Coordinating PI/Director
- Sponsor Representative (University of Sydney)
- A3BC Node Custodian Representatives
- Consumer Group Representative
- Patient research partner(s)
- Workstream representative(s) (rotating membership for specific consideration of workstream-related access requests e.g. ARAD, CRE, PROSPECT, A3BC for Kids, AJAR, ANZ CLARITY)

Includes a Chair to be agreed to by all. Composition may vary with complexity of the application.

Committee quorum is majority (>50%) attendance. A majority vote by the AC members will decide whether the application is approved or denied.

Of note, node collection custodians related to the requested samples will participate in the Prelim App/EOI phase but would be omitted from Post-HREC Application review if any conflict of interest is evident.

14. Appeals Process

If any dispute arises between parties regarding any element in this document, either party may in writing to the other, specify the nature of the dispute. If a mutually acceptable resolution is not reached between the parties, either party can call for its application to be reviewed by the independent A3BC ELSI Advisory Group.

The process for having an application reconsidered is:

14.1. Within 8 weeks of the relevant decision, the applicant PI should submit a written request to the ELSI Advisory Group, detailing their reasons why they consider the decision should be revised.

14.2. Within 4 weeks of receipt, the ELSI Advisory Group will consider the request and Main Application (and other information considered appropriate) then respond to the applicant via the A3BC Coordinating PI/Director.

14.3. If necessary, the ELSI Advisory Group may seek additional advice (e.g. from scientific or other experts), in which case the applicant PI will be advised of any revision to the review timeline.

15. Access Terms

15.1. The data/ analysis will be used by the recipient solely for the research purpose described in their Main Application and not for any research that is not disclosed therein and approved by the A3BC.

15.2. When an applicant's Prelim App/EOI is approved by the A3BC, they are given priority for the samples they intend to access over other applicants, however if they cannot achieve HREC approval for their Post-HREC Application within 3 months from their Prelim App/EOI approval, the samples become listed as available to the next interested applicant.

15.3. If the final Post-HREC Application does not contain all the required items in the form, the A3BC reserves the right to deny access on this basis.

15.4. Applications for access by commercial organisations are unlikely to be approved unless they are partnered with a university, medical research institute or A3BC investigators. The A3BC may provide aggregate data to commercial organisations.

15.5. Applicants agree that the data/ information/ samples provided by the A3BC will not be used, either alone or in combination with other data/ information/ samples, in any effort whatsoever to establish the individual or group identities of any of the participants from whom the data/ information/ samples or subsequent analysis was obtained.

15.6. Applicants agree to maintain secure control over the data/ information/ samples provided by the A3BC and not to transfer the data/ information/ samples, with or without alteration, to any other entity or individual not approved by the A3BC.

15.7. Applicants agree to keep data/ information/ samples provided by the A3BC secure so that it/they is/are not accessible by anyone not approved by the A3BC. Data will be the responsibility of the project leader (typically the Applicant) and must be stored and disposed of in accordance with HREC, NHMRC and other appropriate guidelines/ regulations.

15.8. If the applicant unreasonably refuses to agree with the terms and conditions of this Policy or MTA3, in particular the privacy and confidentiality terms, the A3BC reserves the right to deny access on this basis.

15.9. If a researcher who receives A3BC samples and/or data breaches the terms and conditions in this Policy or MTA3, the A3BC may immediately revoke the applicant's licence to use samples/data, and depending on breach severity, inform the researcher's institution/ funders, regulatory bodies and ban the researcher's institution from future A3BC access.

16. Provision of Data

Deidentified A3BC data may be provided to approved researchers through mechanisms approved by the University of Sydney:

16.1. Secure File Transfer
In order to transfer files in accordance with the Health Records Act (2010) and Privacy Act (1988), the A3BC uses an Australian SFTP (CloudStor FileSender) or a Highly Protected (encrypted) SharePoint Enterprise folder. SFTP is a secure method of file transfer with password-protected end-to-end encryption using the industry standard AES-256 encryption. All data uploaded to CloudStor is located in Australia at four geographically dispersed locations. These sites are directly connected to the AARNet backbone network. Files will only exist in the folder for a limited time before being permanently deleted.

16.2. Access via virtual laboratory (e.g. ERICA[2], SURE[3])
Safe haven environments like SURE (Secure Unified Research Environment) are remote-access data research laboratories for analysing collected data, allowing researchers to securely analyse data from sources such as hospitals and registries using a suite of statistical tools.

Industry (e.g. pharmaceutical companies partnered with academic research organisations) will only be given access to A3BC data through SURE. Or the A3BC may conduct analysis for these approved researchers.

Once an application is approved, the A3BC will notify the applicant Principal Investigator when and how the data will be accessible, the total cost for access, and any third-party costs (e.g. SURE use).

17. Provision of Samples

Samples will be provided to approved researchers by the following process:

17.1. The A3BC will notify the applicant when samples will be retrieved from storage and ready for delivery, the total cost for access, and the cost of delivery by an approved third-party.

17.2. The applicant will then notify the A3BC of convenient dates and location for delivery of the samples.

[2] ERICA - E-Research Institutional Cloud Architecture (managed by the University of NSW)

[3] SURE - Secure Unified Research Environment (managed by the Sax Institute, NSW)

17.3. The A3BC will arrange for delivery to be made through an approved third-party (paid by the applicant). If samples are being retrieved and sent from the NSW Health Statewide Biobank, the A3BC will liaise with staff there, not the applicant.

17.4. Within one working day of receipt, the applicant must confirm to the A3BC (in writing) that the samples have been successfully received.

18. Surplus Samples

18.1. To prevent the wastage of samples that become surplus to the researcher's project use, sample integrity should be maintained in appropriate storage unless imminent use is guaranteed.

18.2. If it becomes known that 50% or more of a sample will be surplus after use, the surplus should be immediately returned to cold storage in its A3BC cryotube and an accurate record kept of the excursion.

18.3. Upon completion of the project, the researcher will provide the A3BC with a record of all surplus sample excursions (including time out of freezer, lab temp, was defrosting of contents visible, contamination).

18.4. The A3BC reserves the right to have the researcher securely ship surplus samples back to the A3BC Node from which they came. Returned samples will only be used for internal research, after quality checks.

18.5. Shipping and quality check costs are taken from the deferred fee paid on project completion (section 23).

18.6. Researchers may apply (in Post-HREC Application) to keep surplus samples. Approval will only be granted if rationalised by a reasonable pre-defined use related to the project (e.g. additional tests/assays of value).

19. Results Publication

19.1. Researchers agree to provide a copy of the manuscript (or other media release) to the A3BC (info@a3bc.org.au) at least 4 weeks prior to submission for publication or release, in order for the A3BC to ensure compliance with this policy and the terms and conditions of MTA3.

19.2. Researchers are required to, using their best efforts, publish the findings of any research derived from use of the A3BC resource in an academic journal (preferred) or open-source publication site within 12 months of the agreed date that the research would be completed.

19.3. Approval of publication is not required from the A3BC, but the researcher should notify the A3BC at least 2 weeks before their expected date of first public presentation or publication.

19.4. Researchers must advise the A3BC at least 2 weeks in advance if any publication or presentation is likely to incite controversy or significant public attention.

19.5. Researchers must attempt to publish any negative results and, where this is not possible, negative results must be submitted back to the A3BC to ensure that work is not unnecessarily repeated.

19.6. Researchers must include their assigned A3BC Access ID in their publication/ presentation acknowledgement to enable the A3BC to match findings to approved researchers.

20. Results Return

20.1. Within 6 months of publication or 12 months of completion of the research project, the applicant must provide the results of the research and the supporting raw data (includes verified gene or protein sequences) from which the results are derived, for inclusion back into the A3BC data resource.

20.2. Returned data should be provided at a level of detail and format as reasonably required by the A3BC for the purpose of a data offering to other researchers to enable further research.

20.3. The A3BC will consider written requests for a time limit extension to return results and raw data, if accompanied by an appropriate explanation.

21. Return of Incidental Findings

21.1. Applicants agree to notify the A3BC of the discovery of incidental findings (but not what the finding is) and the participant's ID within 24 hours of preliminary verification. An incidental finding is a research finding that has a health implication for the participant or their genetic relatives.

21.2. Depending on whether the participant's sample collection is funded by (a) the NSW Health Biospecimen Collection Grant or (b) other A3BC funding, the A3BC will either:

a. Forward the researcher to the NSW Health Statewide Biobank (NSWHSB) to progress the discovery in compliance with *Policy NSWHSB_P_0001 - Return of Incidental Findings*, or
b. Follow the A3BC's own ethically defensible plan for returning significant incidental research findings (SIRFs) as described in the A3BC Operational Protocol, or
c. A combination of a. and b. above.

21.3. Applicants agree to return all related incidental findings data for the participant to the A3BC within 7.

22. Public Communications

22.1. The A3BC is committed to open lines of communication with its key stakeholders groups and the community and will seek to update them on the progress of the A3BC and research carried out using the A3BC samples and/or data.

22.2. After the applicant has received the A3BC samples and/or data for their research project, the A3BC will publish a summary of the research project (with the exception of any content agreed by the parties to be kept confidential) and an indication of status (e.g. project approved, research in progress, research completed, research published) on its website or other material.

22.3. Following publication by the researchers, a summary of the project's research findings (derived from use of A3BC samples and/or data) will be posted to the A3BC website or other material.

22.4. The A3BC reserves the right to post contentious and/or ethically challenging issues related to proposed access uses of the A3BC website for comment by participants and the wider public. Such posts would not contain any researcher information (related to the proposed access).

22.5. Researchers must not use the A3BC name (or logo) or name of its personnel in any publicity, advertising or news release without prior written approval by an A3BC Principal Investigator or the National Operations Management Team.

23. Access Costs

23.1. Researcher registration and approval processing is free-of-charge.

23.2. An administrative fee may be charged to researchers for their application review (Prelim and Post-HREC Access Application review).

23.3. An indication of access costs for sample/data collection/processing/storage, provision of expertise, and administration effort will be provided to researchers as part of the Prelim App/EOI review feedback.

23.4. There is no charge to contributing A3BC investigators for basic sample/data applications and their access costs may vary dependent on funding circumstances and project requirements.

23.5. Material Transfer Agreement (MTA) drafting and negotiation is free, however the A3BC reserves the right to negotiate an hourly charge with the applicant if significantly more time is required.

23.6. Successful applicants will need to pay for access (within 30 days of invoicing) to the A3BC samples and/or data, extraction, processing, packaging and shipping on a neutral cost-recovery basis.

23.7. If applicants have surplus samples but are not approved for pre-defined use, the cost for shipping them back to the A3BC and quality check will be taken from the 10% sample cost deferred to project completion.

23.8. All not-for-profit researchers will be subject to a cost-recovery schedule, although the A3BC will apply a levy to access fees where for-profit research is involved.

23.9. Data subscription options may also be offered (TBC), once the requisite A3BC database and related connectivity provisions have been implemented.

23.10. Costs paid by researchers may vary and need to be negotiated on an individual basis, depending on operational requirements, material cost and the value of the Australian Dollar.

Table 3: Indicative Sample Types / Quantities

Sample Type	Quantity/Size
Buffy coat	~500µl
DNA	3-5µg
RNA	~1µg
PBMCs	~5x10^6 cells
Plasma	250-500µl
Serum	250-500µl

Table 4: Indicative Data Related Charges

Data Type	Charges
Fixed review charge	$250
Project consultation	$60/hr TBA
A3BC analytics services	$60-100/hr TBA
Data extraction / linkage	TBA by custodian
Third party fees	TBA by vendor

THIS ACCESS POLICY WAS LAST UPDATED 03 April 2023.

The Access Policy will be updated as required and the latest version made available on the A3BC website.

Note: It is the responsibility of applicants to be aware of and comply with any policy changes.

Date of Change	Changes
26-Sep-2022	Added A3BC funders to acknowledgement text in Acknowledgements and Co-Authorship (11.2)
03-Apr-2023	Added acknowledgements and review process for publications related to Services Australia (11.6). Minor updates throughout for consistency with latest study protocol and terms of reference.