Data Access and Sharing Agreement
Australian Genomics Health Alliance

Please note: This is the Australian Genomics standard data access and sharing agreement which cannot be modified or amended given that Australian Genomics requires all Recipients to comply with the same terms and conditions regarding data access and use.

1. Parties

Murdoch Children’s Research Institute (ABN 21 006 566 972) of the Royal Children’s Hospital, 50 Flemington Road, Parkville Victoria 3052, being the administering institution for Australian Genomics (Administering Institution)

and

The party named on the signature page (Recipient)

2. Background

(A) The Australian Genomics Health Alliance (Australian Genomics) is a research collaboration launched in 2016 to build the evidence and inform policy directed to the integration of genomics into mainstream healthcare. Australian Genomics comprises over 80 organisations including hospitals, research institutes, universities, sequencing laboratories and community groups across Australia. Australian Genomics is funded by the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF) and is administered by the Administering Institution.

(B) Through the Australian Genomics flagships, genomic sequencing and phenotypic data is collected from research participants and then aggregated in whole or in part in various Australian Genomics data repositories (Australian Genomics Data Repositories), namely:
   (i) the Genomic Data Repository (GDR);
   (ii) the REDCap study database;
   (iii) the standardised clinical phenotypes FHIR server; and
   (iv) the Variant Atlas genotype-phenotype database.

(C) The Administering Institution shares data from the Australian Genomics Data Repositories (directly or through secure third party repositories), strictly in accordance with the consent given by the participants or their legal guardians and in accordance with the Australian Genomics Policy on Data Access and Sharing for Secondary Use.

(D) The Administering Institution proposes to provide the Recipient with the Data (as defined below) for the Purpose (as defined below).
3. Definitions

**Agreement** means this Data Access and Sharing Agreement, as may be amended from time to time in accordance with its terms;

**Application Form** means the Australian Genomics Data Access Application Form which is attached to this Agreement as Annexure A, together with any other Australian Genomics Data Access Application Form which is submitted by the Recipient and approved by the Data Access Committee for access to and/or use of Data under the terms of this Agreement;

**Australian Genomics** has the meaning given to that term in Recital A;

**Australian Genomics Data Repositories** has the meaning given to that term in Recital B;

**Australian Genomics Policies** means any Australian Genomics policies, procedures, terms or other guidelines, as updated from time to time, which are published on the Australian Genomics website or otherwise made available to Recipient, including:

(a) Data Access and Sharing for Secondary Use Policy; and

(b) Data Breach Policy; and

(c) Statement on Secondary Data Use Research Findings.

**Authorised Collaborator** means the third parties named in the relevant Application Form who are collaborating with the Recipient and also require access to the Data for the Purpose;

**Authorised User** has the meaning given to that term in clause 6.3;

**Commencement Date** means the date that this Agreement is executed by the last party to execute;

**Data** means the data in Australian Genomics Data Repositories as described in the relevant Application Form, to which the Administering Institution has agreed to grant access to Recipient under this Agreement;

**Data Access Committee** means the Australian Genomics Data Access Committee.

**Data Breach** means the unauthorised access, disclosure or loss of Personal Information;

**Ethics Committee** means the Human Research Ethics Committee/Institutional Review Board (or equivalent body) reviewing research proposals involving human participants to ensure that they meet ethical standards and guidelines;

**Ethical Obligations** means the relevant requirements imposed by the Ethics Committee who approved the research project in relation to which the Data will be used;

**Intellectual Property Rights** means all intellectual property rights subsisting anywhere in the world, including the following rights:

(a) patents, copyright (including future copyright and software), rights in circuit layouts, designs, trade and service marks (including goodwill in those marks), domain names and trade names, confidential information and any right to have confidential information kept confidential whether or not such rights are registered or capable of being registered; and
4. Interpretation

In this agreement, the following rules apply:

(a) headings are for convenience only and do not affect interpretation;
(b) another grammatical form of a defined word or expression has a corresponding meaning;
(c) a reference time is to time in Melbourne, Australia;
(d) a reference to legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced, and includes any subordinate legislation issued under it;
(e) a reference to a person includes a natural person, partnership, body corporate, association, governmental or local authority or agency or other entity; and
(f) the meaning of general words is not limited by specific examples introduced by including, for example or similar expressions.

5. Use of Australian Genomics Data

5.1 The Recipient may only use the Data for the Purpose. If the Recipient wishes to use the Data for a purpose other than as described in the Application Form, the Recipient must re-submit the Application Form or otherwise obtain the Administering Institution’s prior written consent.

5.2 The Recipient must not use the Data, or any products containing any part of the Data, or resulting from the use of the Data, for any commercial purposes without the prior written consent of the Administering Institution.

5.3 In relation to the use of the Data, the Recipient must comply with:

(a) all applicable laws (including, without limitation, any applicable Privacy Laws);
(b) all Ethical Obligations;
(c) all Australian Genomics Policies;
(d) any applicable data standards developed by the Commonwealth Department of Health under or pursuant to the National Health Genomics Policy Framework;
5.4 The Recipient must not, and must not attempt to, use the Data:
(a) for any improper or unlawful purpose;
(b) in a manner that breaches any Privacy Laws;
(c) in a manner that infringes the Intellectual Property Rights of the Administering Institution or any third party; or
(d) in a manner that is likely to cause offence or otherwise have a negative impact on any third party, including any member of Australian Genomics.

5.5 The Recipient must not use any Data to attempt to re-identify a study participant and if the Recipient becomes aware of any attempt to do so (including by any of the Recipient’s Authorised Users or any Authorised Collaborator), the Recipient must immediately notify Australian Genomics immediately by sending an email to: security@australiangenomics.org.au.

6. **Data Security and Protection**

6.1 The Recipient must use best practice methods to keep all Data which is in the power, possession or control of the Recipient secure and protected from unauthorised access, misuse, damage, destruction, unauthorised disclosure or modification, or theft.

6.2 Subject to clause 6.3 below, the Recipient must not distribute or release the Data to any third party, and must make sure that no one is allowed to take or send the Data to any location other than a location under the control of the Recipient without the Administering Institution’s prior written permission.

6.3 The Recipient may disclose the Data to:

(a) those of its employees, officers, students and contractors who:
   (i) have a need to access the Data for the Purpose;
   (ii) are named on the Application Form; and
   (iii) who have agreed to use the Data in accordance with the terms of this Agreement (Authorised Users); and

(b) Authorised Collaborators, on condition that the Administering Institution has confirmed in writing to the Recipient that the Authorised Collaborator has executed an Australian Genomics Data Access and Sharing Agreement with Administering Institution which governs the Authorised Collaborator’s use of the Data for the Purpose.

6.4 The Recipient is responsible for monitoring and ensuring that all Authorised Users comply with the terms of this Agreement and will be liable for any breaches by Authorised Users.

6.5 The Recipient must immediately notify the Administering Institution if any Authorised User ceases to have a legitimate reason to continue to access the Data under the terms of this Agreement (whether due to cessation or transfer of employment, change of duties or project or any other reason).
6.6 If the Recipient wishes to disclose the Data to a person or third party who is not named on the Application Form as an Authorised User or Authorised Collaborator, the Recipient must re-submit the Application Form or otherwise obtain the Administering Institution’s prior written consent to such disclosure of the Data.

6.7 In the event that Recipient becomes aware of a Data Breach (or suspected Data Breach) or any other use or disclosure of the Data that is inconsistent with this Agreement, the Recipient must:

(a) notify Australian Genomics immediately by email to: security@australiangenomics.org.au; and

(b) comply with the procedures set out in the Data Breach Policy, as applicable.

6.8 Without limiting the Recipient’s obligation to comply with the procedures set out in the Data Breach Policy, the Recipient must cooperate with the Administering Institution, and provide all reasonable assistance which the Administering Institution may request in order to remedy and otherwise manage any Data Breach, whether or not caused by or contributed to by the Recipient (or any Authorised User).

7. Publications and Outputs

7.1 The Recipient has the right to publish its findings and results from the research with the Data, provided that in relation to any such publications:

(a) Australian Genomics is acknowledged as the source of the data as follows:

   “[Genomic and/or standardised clinical phenotypic] data for this study were accessed through Australian Genomics. Australian Genomics is funded by the National Health and Medical Research Council (Grants 1113531, 2000001) and the Medical Research Future Fund, administered by the Murdoch Children’s Research Institute.”

(b) When the Recipient received data from any of the following flagships they are to be acknowledged as follows:

   Cardiovascular Flagship, “The Cardiovascular Disorders Flagship is funded by the Medical Research Future Fund (Grant EPCD000028).”

   Massimo’s Mission/Leukodystrophy Flagship, “The Leukodystrophy Flagship is funded by the Medical Research Future Fund (Grant EPDC000034).”

   Acute Care Genomics, “The Acute Care Genomics program is funded by Medical Research Future Fund Genomics Health Futures Mission (Grant 76747).”
7.2 The Recipient is to provide any final proposed manuscript intended for publication to the Administering Institution at least 14 days in advance of submission for publication. The Administering Institution (or another member of Australian Genomics nominated in writing by the Administering Institution) may provide comments and/or reasonable amendments to the manuscript to protect their confidential information and/or Intellectual Property.

8. Intellectual Property

8.1 The ownership of Intellectual Property Rights in the Data is not transferred to the Recipient under this Agreement.

8.2 The Administering Institution grants to the Recipient a non-exclusive, royalty-free licence to use, adapt, reproduce and exploit the Data for the Purpose and on the terms of this Agreement.

8.3 In consideration of the Administering Institution supplying the Data to the Recipient, the Recipient will, as soon as practicable, inform the Administering Institution in writing of any findings or other information it has derived from the Data (Results) that generate new Intellectual Property Rights developed from its use of the Data. The Recipient and the Administering Institution will enter into negotiations to discuss their respective ownership rights in relation to any new Intellectual Property Rights in the Results.

9. Term and Limitation, Suspension and Termination

9.1 This agreement will remain in effect from the Commencement Date until such time as the Agreement is terminated in accordance with this clause 9.

9.2 The Administering Institution may by written notice limit or suspend the Recipient’s right to access the Data (or to access a particular Australian Genomics Data Repository), or terminate this Agreement with immediate effect, in any of the following circumstances:
   (a) where the Recipient is in breach of this Agreement;
   (b) if the Administering Institution becomes aware that the security of the Data or any Australian Genomics database has been compromised;
   (c) to comply with any legal requirement or any request or direction by a law enforcement agency; or
   (d) where the Administering Institution, acting reasonably, determines that access or use of the Data should be limited, suspended or terminated for any other reason.

9.3 The Recipient may terminate this Agreement with immediate effect on written notice to the Administering Institution.

9.4 In the event of termination of this Agreement, the Administering Institution will immediately terminate the Recipient’s access to Australian Genomics Data Repositories and the Recipient must follow the Administering Institution’s instructions in relation to the destruction or
return of any local copies of the Data in the power, possession or control of the Recipient, provided however that Recipient may retain such local copies as are required solely for accreditation or audit trail purposes, to enable the Recipient to comply with its record keeping obligations or to determine the scope of its legal obligations under this Agreement.

9.5 Termination of this Agreement does not affect any accrued rights or remedies which a party may have.

10. Liability and Indemnity

10.1 To the extent permitted by law:

(a) the Administering Institution gives no guarantee, warranty or representation in relation to the Data, including in relation to its availability, quality, fitness of purpose or security or in relation to the non-infringement of any third party Intellectual Property Rights. Any warranties or guarantees that may be implied or conferred by statute, custom or the general law are expressly excluded;

(b) the Recipient assumes all liability for damages which may arise from its use, storage or disposal of the Data (including any decision made, or action taken, in relation to or in reliance upon the Data);

(c) the Administering Institution 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 Data by the Recipient, except when caused by the gross negligence or wilful misconduct of the Administering Institution.

10.2 The Recipient agrees to indemnify the Administering Institution against any direct loss, claim or demand that the Administering Institution may sustain or incur in connection with:

(a) a breach by the Recipient of this Agreement;
(b) any Data Breach which is caused or contributed to by the Recipient;
(c) any unlawful or negligent act or omission of the Recipient under this Agreement;
(d) any breach by the Recipient of any third party Intellectual Property Rights, except to the extent that the Administering Institution caused or contributed to such loss, claim or demand.

10.3 Under no circumstances will a party be liable to the other party under or in respect of this Agreement (whether in contract, tort, statute or any other cause of action) for any special, indirect or consequential damages, or loss of anticipated profits, reputation or revenue.

11. General

11.1 Clauses 3, 4, 7, 8, 9.4, 10 and 11 will survive termination of this Agreement.

11.2 This agreement may be executed in any number of counterparts. All counterparts will constitute one instrument. The parties agree that facsimile or email signatures will be accepted as originals.
11.3 This Agreement may not be amended or varied other than with the written agreement of the Recipient and the Administering Institution.

11.4 A party must not assign or otherwise transfer any or all of its rights arising out of this agreement without the written consent of the other party.

11.5 This agreement constitutes the entire agreement between the parties with respect to the Recipient’s access to and use of the Data. This agreement may be amended only by written agreement of both parties.

11.6 These terms are governed by the law of the State of Victoria, Australia. The parties submit to the exclusive jurisdiction of its courts.
Executed as an agreement

Signed for Murdoch Children’s Research Institute
by its authorised representative:

Signed for Recipient
by its authorised representative:

______________________________________________________
Signature

______________________________________________________
Legal entity name of Recipient

______________________________________________________
Print Name

______________________________________________________
ABN of Recipient (Australian Recipients only)

______________________________________________________
Position

______________________________________________________
Signature

______________________________________________________
Print Name

______________________________________________________
Position

______________________________________________________
Date

Read and understood by the Recipient Principal Authorised User:

______________________________________________________ [Signature]

______________________________________________________ [Print name]

______________________________________________________ [Position]

______________________________________________________ [Date]
ANNEXURE A

Data Access Application Form
Data Access Request Form

Australian Genomics is an independent research collaboration launched in 2016 to build the evidence and inform policy for the integration of genomics into mainstream healthcare. Through its research program, Australian Genomics has administered many clinical ‘flagship’ projects, and participants are provided genomic testing as part of their care. As a result, detailed clinical (phenotypic), psychosocial/economic and genomic data will be collected on over 25,000 participants enrolled in the Australian Genomics flagships: in rare diseases, cancers and reproductive carrier screening.

This application form must be completed to request access to and/or use of Australian Genomics data for research and other permitted purposes.

Applications will be assessed by a Data Access Committee in accordance with the Australian Genomics Policy on Data Access and Sharing for Secondary Use and subject to the terms of the Australian Genomics Data Access and Sharing Agreement.

Before approving your application, the Data Access Committee needs to be satisfied that:

The aim of the proposed data access is keeping with the scientific interests of Australian Genomics and that the scientific experimental or analytic background and design of the proposed project is appropriate; The project has appropriate institutional HREC approval, if required; Australian Genomics is storing the requested data, and there are no technical limitations nor limitations with data permissions that would prevent Australian Genomics from sharing the requested data for the proposed purpose. In order to address the above requirements, please complete this application form and provide all relevant supporting documentation.

PLEASE NOTE: This Data Access Request form has been designed to capture the details of research projects that are covered under one (1) ethics protocol only. If you wish to request Australian Genomics data for multiple projects under different ethics protocols, you must submit multiple request forms.

Once your Data Access Application is approved, your organisation will be required to execute a Data Access and Sharing Agreement with Murdoch Children's Research Institute (the "Administering Institution") before Australian Genomics is able to grant you access to the data.

Please note that access to data stored by Australian Genomics will only be granted strictly in accordance with the study participants' consents and preferences at the time the access is granted.

By submitting this application you acknowledge that you have read, understood and will comply with the Data Access and Sharing for Secondary Use Policy and the Data Breach Policy in relation to your organisation's access and use of Australian Genomics data.

If you have any queries do not hesitate to contact the Australian Genomics data request team:
AG-datarequest@mcri.edu.au

Application date: __________________________________

Has this project received ethical approval?

☐ Yes  ☐ Not yet

Please note: Data will only be released upon the receipt of a valid ethics approval letter.

If you are using this data access application as part of your ethics application, and subsequently receive ethical approval, please notify the Data Request team via email at ag-datarequest@mcri.edu.au and the team will instruct you to update your application with your ethics approval letter and research protocol.

Please upload the ethics approval letter for this project

Please provide your ethics application number for this project
Date of ethics approval: ____________

Please upload the ethics protocol for this project (optional)

**Project Information**

In the text boxes below, please provide detailed information about your project that is relevant for the current Data Access Request. This should include details about:
- What you specifically aim to do with Australian Genomics data;
- The methods used to analyse the data;
- How the data will be managed, stored, and destroyed in a secure manner.

**Project Title:** ____________________________________________

**Project Background**

**Project Aim(s)**

**Project Method**

**Data Management Plan**

**Public Project Summary.** Please provide a short description (max. 150 words) of the research project in lay terms. **NOTE:** This project summary will be displayed publicly on the Australian Genomics website (australiangenomics.org.au) once your project has been approved. This ensures transparency for other data requestors, research participants, and the general public, regarding who is accessing participant data.

**Project public summary**
Data Access Requested

In this section, please describe the type of research you will be undertaking, and the type of data you are requesting for this research project. In the “Types of research” question below, the relevant Data Use Ontology codes have been attached for reference of intended usage. For more information on the Data Use Ontology, please access their GitHub page.

Type of research (please select all that apply):

- Research re-analyses
- Clinical re-analyses
- Methods development and validation studies (DUO:0000031)
- Controls for case control studies (DUO:0000036)
- Population structure studies (DUO:0000032)
- Health / Medical / Biomedical research (DUO:0000006)
- Population origins or ancestry research (DUO:0000033)
- Disease related studies (DUO:0000007)
- Other

You have indicated that you aim to undertake research or clinical re-analysis of participant data. Please provide an ethically defensible plan for the return of results to participants below.

Return of results plan

The table below briefly describes the data available for each flagship cohort for your reference. For easier reading, you may click the image to enlarge it. The image will open in a new tab.

<table>
<thead>
<tr>
<th>Flagships of interest</th>
<th>Cancer Flagship(s)</th>
<th>Rare Diseases Flagship(s)</th>
<th>General Population Cohort(s)</th>
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<td>(Tick all that apply)</td>
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<th>Acute Care Genomics</th>
<th>Brain Malformations</th>
<th>Cardiovascular Disorders</th>
<th>Epileptic Encephalopathy</th>
<th>HIDDEN Renal Genetics</th>
<th>Genetic Immunology</th>
<th>Intellectual Disabilities</th>
<th>Interstitial or Diffuse Lung Disease</th>
<th>KidGen Renal Genetics</th>
<th>Leukodystrophies</th>
<th>Mitochondrial Diseases</th>
<th>Neuromuscular Disorders</th>
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<th>Somatic Cancer (iPREDICT)</th>
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<th>General Population flagships</th>
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**Data types requested**

- FASTQs
- BAMs
- VCFs
- Phenotypic/Clinical Data
- Participant Survey Data
- Participant Contact Details
- Other

(Tick all that apply)

---

To assist with your Data Access Request, the Australian Genomics Data Access Committee recommends reviewing our Clinical Data Catalogue and specifying the categories of clinical data you are requesting in the fields below.

**Phenotypic/Clinical data categories requested**

- Demographics (e.g. age, sex, etc.)
- Ethnicity
- Family History
- Clinical investigations
- Variant information

(Tick all that apply)

---

**Additional clinical data request details (optional)**

---

**Flagship set requested**

- Full flagship cohort
- Subset of flagship cohort

---

Describe the subset of participants you are requesting

Note: Do NOT input any identifying information into this field

(e.g. participants with variants in a particular gene of interest, inclusion/exclusion criteria, etc.)

---

**Applicant Details**

**Title**

(e.g., Ms, Mr, Prof, Dr, etc.)

**Full Name**

---

**Institution**

---

**Institution Address**

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(Institutional email address only)

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<th>Is the applicant the Principal Investigator for this project?</th>
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(Institutional email address only)

**Collaborating Sites** Please list all collaborating institutions who are involved in the project. If collaborating institutions will be additionally housing the data, they will be required to sign a Data Access and Sharing Agreement.
Number of collaborating sites/institutions

- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20

Collaborating Site 1

1. Site name
   __________________________

1. Site address
   __________________________

1. Contact person
   __________________________

1. Contact person role at site
   __________________________

1. Contact person email
   __________________________

1. Will this site be housing requested data?  ○ Yes  ○ No

Collaborating Site 2

2. Site name
   __________________________

2. Site address
   __________________________

2. Contact person
   __________________________

2. Contact person role at site
   __________________________

2. Contact person email
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<th>Site address</th>
<th>Contact person</th>
<th>Contact person role at site</th>
<th>Contact person email</th>
<th>Will this site be housing requested data?</th>
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<td>Yes/No</td>
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5. Contact person email
__________________________________

5. Will this site be housing requested data?  ○ Yes  ○ No

Collaborating Site 6

6. Site name
__________________________________

6. Site address
__________________________________

6. Contact person
__________________________________

6. Contact person role at site
__________________________________

6. Contact person email
__________________________________

6. Will this site be housing requested data?  ○ Yes  ○ No

Collaborating Site 7

7. Site name
__________________________________

7. Site address
__________________________________

7. Contact person
__________________________________

7. Contact person role at site
__________________________________

7. Contact person email
__________________________________

7. Will this site be housing requested data?  ○ Yes  ○ No

Collaborating Site 8

8. Site name
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8. Site address
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8. Contact person
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<th>10. Contact person</th>
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<th>11. Site address</th>
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</table>
11. Contact person

11. Contact person role at site

11. Contact person email

11. Will this site be housing requested data?  ○ Yes  ○ No

Collaborating Site 12

12. Site name

12. Site address

12. Contact person

12. Contact person role at site

12. Contact person email

12. Will this site be housing requested data?  ○ Yes  ○ No

Collaborating Site 13

13. Site name

13. Site address

13. Contact person

13. Contact person role at site

13. Contact person email

13. Will this site be housing requested data?  ○ Yes  ○ No

Collaborating Site 14

14. Site name
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<th>Contact person email</th>
<th>Will this site be housing requested data?</th>
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<td>Site name</td>
<td>Site address</td>
<td>Contact person</td>
<td>Contact person role at site</td>
<td>Contact person email</td>
<td>Will this site be housing requested data?</td>
</tr>
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</tbody>
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Collaborating Site 20

20. Site name ____________________________________

20. Site address ____________________________________

20. Contact person ____________________________________

20. Contact person role at site ____________________________________

20. Contact person email ____________________________________

20. Will this site be housing requested data? ☐ Yes ☐ No

Expected Project Outputs
Please select the expected outputs arising from this data analysis. Note the conditions of publications are outlined in the Data Access and Sharing Agreement to be signed by your institution and the proposed project principal applicant.

Expected project outputs
☐ Journal Publication(s)
☐ Conference Proceedings
☐ Other ______

Have you read and understood our policies and agreements regarding requesting access to our data?

☐ Yes ☐ No

I/We will only use the data from Australian Genomics (the Data) for the ethically-approved research project outlined in this proposal;

☐ I agree

I/We will not mine for ethnicity details unless specified in the Data Access Request

☐ I agree

I/We understand that Australian Genomics retains all ownership rights in the Data;

☐ I agree

I/We will not on-share the Data with a third party (other than approved collaborators on my project) without prior written approval from Australian Genomics;

☐ I agree

I/We will not use any Data to attempt to re-identify a study participant and if made aware of any attempt to do so will immediately notify Australian Genomics by emailing security@australiangenomics.org.au;

☐ I agree
I/We will keep the Data secure, and will notify Australian Genomics of any unauthorised access, disclosure or loss;

☐ I agree

I/We will comply with all Australian Genomics Policies;

☐ I agree

I/We have read and understood the Statement on Secondary Data Use Research Findings, and will comply with the terms laid out in this statement;

☐ I agree

I/We will inform Australian Genomics of the findings and results derived from my use of the Data;

☐ I agree

I/We will submit any proposed publications from research using the Data to Australian Genomics for review;

☐ I agree

I/We will acknowledge Australian Genomics in any publications or presentations related to the Data in the form required by Australian Genomics;

☐ I agree

I/We will supply the relevant information when required for data usage and publication audits.

☐ I agree