

Terms of Use – SHARIANT AUSTRALIA: Australian Genomics National Variant Sharing Platform

INTRODUCTION

These Terms of Use govern your access to and use of Shariant Australia, a platform to share curated variant classifications and expertise made available by the Australian Genomics Health Alliance (**Australian Genomics**).

Australian Genomics is funded by the National Health and Medical Research Council's (**NHMRC**) Targeted Call for Research into Preparing Australia for the Genomics Revolution in Health Care (2015) and is administered by the Murdoch Children's Research Institute (**MCRI**). As at 1 January 2019, the Australian Genomics network comprises over 80 institutions (and their researchers/investigators). A list of these institutions is available here and updated from time to time:
<https://www.australiangenomics.org.au/partners/>.

Shariant Australia is a controlled-access platform, intended primarily for use by Australian diagnostic laboratories performing germline and somatic sequencing and clinicians involved in the care of patients who have undergone genetic testing.

The Shariant Australia platform is designed to facilitate the sharing of variant information and associated curation evidence, to assist in the resolution of variant classification discordances between laboratories, and to facilitate display of relevant variant classification information in international databases (such as ClinVar). It also aims to allow access to nominated individuals with gene- or disease-specific expertise, and relevant information, to enhance the utility of Shariant Australia for Users. Shariant Australia has been developed to assist diagnostic genetic testing laboratories in meeting the National Pathology Accreditation Advisory Council (NPAAC) recommendations for submission of genotypic data to relevant clinical databases.

For more information, please contact communications@shariant.org.au.

TERMS OF USE

In these Terms of Use:

- 'We', 'Our' and 'Us' means MCRI; and
- 'User' means the party accessing or using Shariant Australia.

THESE TERMS OF USE APPLY TO THE ACCESS AND USE OF THE SHARIANT AUSTRALIA PLATFORM BY ALL USERS.

PLEASE READ THESE TERMS OF USE CAREFULLY. BY SIGNING BELOW OR OTHERWISE BY ACCESSING AND USING SHARIANT AUSTRALIA, THE USER AGREES THAT IT HAS READ AND UNDERSTOOD THESE TERMS OF USE AND AGREES TO BE LEGALLY BOUND BY THEM IN RELATION TO ITS ACCESS AND USE OF SHARIANT AUSTRALIA AT ALL TIMES.

IF THE USER DOES NOT AGREE TO THESE TERMS OF USE, IT MAY NOT ACCESS OR USE SHARIANT AUSTRALIA.

1. Definitions and Interpretation

1.1 Defined terms:

Access Restrictions has the meaning given to that term in clause 3(e);

Authorised Purpose means the use of Shariant Australia by Users to:

- (a) share variants and associated information, including but not limited to, submitting laboratory, variant, condition, variant classification, American College of Medical Genetics and Genomics/Association for Molecular Pathology (ACMG/AMP) criteria and associated evidence within the Shariant Australia platform;
- (b) access and contribute gene- or disease-specific expertise in order to enhance variant classification and the utility of Shariant Australia for Users;
- (c) assist in the resolution of variant classification discordances between laboratories;
- (d) with laboratory approval, facilitate display of relevant variant classification information in international databases (such as ClinVar); and
- (e) assist diagnostic genetic testing laboratories in meeting the National Pathology Accreditation Advisory Council (NPAAC) recommendations for submission of genotypic data to relevant clinical databases.

Data means data in any form that is entered into Shariant Australia;

Data Breach means any loss of Personal Information, or unauthorised access to or disclosure of Personal Information, howsoever caused;

Ethical Obligations means the ethical obligations set out in the *National Statement on Ethical Conduct in Human Research 2007 (updated May 2015)* and the *Australian Code for the Responsible Conduct of Research 2007* published by the NHMRC and the relevant requirements imposed by the Human Research Ethics Committee (HREC) who approved the research project in relation to which the User is accessing and using Shariant Australia;

Intellectual Property Rights includes all rights in relation to inventions (including patent rights), trade marks, designs, all copyright and neighbouring rights and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields including as defined in Article 2 of the Convention Establishing the World Intellectual Property Organisation of July 1967;

Loss means any direct or indirect liability, loss, damage or expense, or any claim, demand or proceeding, suffered, incurred or brought against a party;

NHMRC means the National Health and Medical Research Council;

NHG Policy Framework means the National Health Genomics Policy Framework 2018-2020 developed by the Council of Australian Governments Health Council;

Personal Information means information about an identified individual, or an individual who is reasonably identifiable. Common examples are an individual's name, address, telephone number, date of birth, medical records, bank account details, employment details and commentary or opinion about a person;

Privacy Laws means Health Privacy Principles, the *Privacy Act 1988* (Cth), relevant State and Territory privacy laws, the *Healthcare Identifiers Act 2010* (Cth), the *My Health Records Act 2012* (Cth), as may be amended, replaced or superseded from time to time and any other laws that apply to the User that relates to privacy or to the collection, use, disclosure or handling of information about individuals and any code of practice by which the User is bound.

1.2 Interpretation

In these terms, 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 to time is to Melbourne, Australia time;
- (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 party or 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”, “such as” or similar expressions.

2. Use of Shariant Australia

- (a) Subject to these Terms of Use, We agree to grant the User access to Shariant Australia.
- (b) The User acknowledges and agrees that We may amend these Terms of Use from time to time. We will notify the User of minor amendments by way of an electronic notification on the Shariant Australia log-in page. For significant amendments, the amended Terms of Use will have to be signed on behalf of the User, in order for the User (and its employees) to continue using and accessing Shariant Australia.
- (c) The User may access and use Shariant Australia solely for the Authorised Purposes, and not for any other purpose (including any commercial purpose), except with Our prior written permission.
- (d) The User will limit access and use of Shariant Australia to those of its employees who reasonably require such access and use for the Authorised Purposes and who have agreed to comply with these Terms and Use (and the User will be liable for any breach of these Terms of Use by its employees). The User is responsible for controlling access to Shariant Australia in accordance with these Terms of Use using appropriate identification and password requirements.
- (e) In relation to the User’s access to and use of Shariant Australia (including Data), the User must:
 - (i) comply with all applicable laws and Ethical Obligations;
 - (ii) comply with any applicable data standards developed under or pursuant to the National Healthcare Group (NHG) Policy Framework; and
 - (iii) comply with all Australian Genomics Policies as published on the Australian Genomics website, including the Australian Genomics Data Access Policy 2018 (as may be updated from time to time).
- (f) The User must not, and must not attempt to, use Shariant Australia (or any Data):
 - (i) for any improper or unlawful purpose;
 - (ii) in a manner that breaches any Privacy Laws;
 - (iii) in a manner that infringes the Intellectual Property Rights of Us, any other User or any third party; or
 - (iv) in a manner that is likely to cause offense or otherwise have a negative impact on other Users or any third parties.
- (g) The User must not, and must not attempt to, bypass Shariant Australia’s user authentication, internal access permissions or privacy controls in order to access Data which the User would not otherwise have access to, nor will the User perform any unauthorised or malicious actions leading to destruction or corruption of Data.

- (h) The User must follow any directions or guidelines given by Us in relation to the use of Shariant Australia and the sharing of Data or other information and expertise with other Users.
- (i) The User may elect to withdraw from the Shariant Australia network at any time by notifying the Shariant Australia management team in writing by sending an email to: communications@shariant.org.au.

3. **Data made available by the User on Shariant Australia**

- (a) The User must not use Shariant Australia to share, store, collect, use or otherwise process any Personal Information.
- (b) In relation to all Data which the User makes available on Shariant Australia, the User:
 - (i) warrants that it has all necessary and appropriate consents and approvals which authorise the User to make the Data available on Shariant Australia in accordance with these Terms of Use; and
 - (ii) grants to all other Users, a non-exclusive, worldwide, royalty-free licence to access and use the Data on Shariant Australia in accordance with these Terms of Use.
- (c) The User will retain all Intellectual Property rights and interests in the Data which the User makes available on Shariant Australia.
- (d) All Users are expected to:
 - (i) share gene- and/or disease-specific expertise as requested by other Users and/or members of Australian Genomics;
 - (ii) collaborate with other Shariant Australia Users to facilitate discordance resolution and variant re-classification; and
 - (iii) provide support to the Shariant Australia implementation team to assist in deployment and on-going development of Shariant Australia.
- (e) The User acknowledges and agrees that:
 - (i) at the time the User uploads Data to Shariant Australia, the User may select an option to restrict access to its Data (such as to restrict access to personnel in the submitting laboratory) (the “**Access Restrictions**”);
 - (ii) any Access Restrictions set by the User will remain in place for sixty (60) days; and
 - (iii) once sixty (60) days have elapsed following the uploading of the Data to Shariant Australia by the User, We will remove such Access Restrictions such that the Data will be accessible by all Users.
- (f) Provided that the User has given its approval in writing to the Shariant Australia management team by sending an email to communications@shariant.org.au, We may facilitate the publication of the User’s Data relevant to variant classification (namely variant-level information and associated evidence) in publicly accessible and/or controlled access databases (including ClinVar). For guidance as to the type of User’s Data that may be displayed publicly through such databases, please see https://shariant.org.au/variantclassification/evidence_keys (which Australian Genomics may update from time to time).
- (g) The User grants a non-exclusive, royalty-free, perpetual licence to Us (with an unrestricted right to sub-licence to other members of Australian Genomics) to use all Data which the User has made available on Shariant Australia for the purposes of operating Shariant Australia, assessing the performance of Shariant Australia,

developing improvements, and in order to publish or present evaluations of Shariant Australia, provided that any such publication or presentation will include or refer to only anonymised aggregate data.

4. Data obtained by the User from Shariant Australia

- (a) The User agrees that it is solely responsible for its handling, storage, interpretation and use of any Data that the User obtains through Shariant Australia. The User is responsible for independently verifying the accuracy, currency and completeness of such Data.
- (b) In relation to Data which the User obtains through Shariant Australia, the User may share such Data with other Users within the Shariant Australia platform, and will not otherwise disclose any Data to any third parties without permission from Us and the submitting laboratory.
- (c) The User must not use or attempt to use any Data obtained from Shariant Australia in order to re-identify any person or to assist any other person to do so.
- (d) If the User has used Data obtained from Shariant Australia for the purposes of variant re-classification, the User agrees to take reasonable steps to return results to the relevant clinician.
- (e) The User acknowledges that Data obtained from Shariant Australia is not intended for direct diagnostic use or medical decision-making without review by a genetic professional, and the User agrees not to make any such use of the Data.
- (f) The User will not use any Data obtained from Shariant Australia for benchmarking (comparison of performance between laboratories) or for the User's research activities and/or publication purposes without prior written permission from both the User which owns the Data and from Us.
- (g) The User agrees not to use any Data obtained from Shariant Australia in any manner which infringes the Intellectual Property rights of any other User.
- (h) Subject to the written permission granted in Clause 4(f) in any publications which use or refer to any Data or other information or expertise which the User obtained through use of Shariant Australia, the User agrees to acknowledge Australian Genomics (NHMRC GNT1113531) and Shariant Australia by including the form of acknowledgement that is published on the Shariant Australia website (<https://shariant.org.au>) in their publication.

5. Privacy and Security

- (a) The User must comply with all Privacy Laws in connection with the User's access to and use of Shariant Australia.
- (b) The User must have in place and maintain appropriate security measures for the storage and handling of Data that is obtained from Shariant Australia. The User acknowledges and agrees that We are under no obligation to implement any back up procedures or to maintain the Data that is made available on Shariant Australia.
- (c) The User acknowledges that Shariant Australia is not designed or suitable for the storage of any Personal Information.
- (d) If the User becomes aware:
 - (i) of any Personal Information or potentially identifying Data or information:
 - A. being stored or processed using Shariant Australia; or
 - B. becoming unintentionally available to the User or a third party by virtue of Data from Shariant Australia being linked with other data; or

- (ii) of any actual or potential Data Breach in connection with use of Shariant Australia;
- (iii) of any complaint in relation to any of the Data stored in Shariant Australia; or
- (iv) of any legal requirement for the disclosure of any such Data,

the User must immediately notify Australian Genomics in writing by sending an email to security@australiangenomics.org.au with a copy to communications@shariant.org.au and the User agrees not to notify any third party of any of the matters described in this clause 5(d) until at least 30 days after giving Australian Genomics written notice of the relevant matter.

- (e) The User must cooperate with Us, and provide all reasonable assistance which We may request in connection with any Data Breach which relates to Shariant Australia (whether or not caused by or contributed to by the User).

6. Limitation, Suspension and Termination

- (a) At any time, without prior notice, We may:
 - (i) limit, suspend or terminate the User's use of Shariant Australia; or
 - (ii) remove any Data that the User has uploaded to Shariant Australia,
 in any of the following circumstances:
 - (A) where the User is in breach of these Terms of Use;
 - (B) in the event that We become aware that the security of Shariant Australia has been compromised;
 - (C) to comply with any legal requirement or any request or direction by a law enforcement agency; or
 - (D) where We reasonably determine that access should be limited, suspended or terminated, or Data should be removed, for any other reason.
- (b) The User agrees that, in the event that the User's access to Shariant Australia is terminated under clause 6(a), or it elects to withdraw from Shariant Australia in accordance with clause 2(i):
 - (i) the User will cease all use of Shariant Australia, and will not use any local copies of the Data which it has obtained from Shariant Australia other than as required for audit and other purposes in connection with variant interpretations performed by the User prior to termination;
 - (ii) all Data which the User uploaded to Shariant Australia and which has been used to inform a consensus variant interpretation and/or assist in variant discordance resolution will remain on Shariant Australia and the licences granted under clause 3(b)(ii) and clause 3(g) will remain in effect in relation to such Data;
 - (iii) other than the Data referred to in clause 6(b)(ii) the User may either:
 - (A) agree that such Data will remain in Shariant Australia (and the licences granted under clause 3(b)(ii) and 3(g) will remain in effect), in which case the User will also add a note that the particular variant will no longer be updated; or
 - (B) submit a written request to Us that the Data be deleted from Shariant Australia, in which case We will action such request within 28 days of receipt.

7. Limitation of Liability and Indemnity

- (a) To the maximum extent permitted by law, We:
 - (i) give no guarantee, warranty or representation in relation to Shariant Australia or any Data, including in relation to availability, quality, fitness of purpose, or maintenance and security. Any warranties or guarantees that may be implied or conferred under applicable law are expressly excluded;
 - (ii) give no guarantee or warranty and accept no responsibility for the integrity, value, reliability, accuracy and completeness of any Data, or the actions of any Users or other third parties who may gain access to any Data;
 - (iii) accept no liability to the User arising directly or indirectly under or in connection with Shariant Australia, the Data or these Terms of Use, whether arising under any indemnity, statute, in tort (for negligence or otherwise), or on any other basis in law or equity.
- (b) We make no warranty that access to and use of Shariant Australia by any User will be continuous or uninterrupted.
- (c) The User agrees that We will not be liable to the User or to any other party for any Loss which is caused by or in connection with the User's use of Shariant Australia or any Data, including any decision made, or action taken, in relation to or in reliance upon any Data obtained through Shariant Australia, or for any loss or corruption of any Data uploaded to Shariant Australia.
- (d) The User agrees to indemnify Us against any Loss that We may sustain or incur, whether directly or indirectly, arising out of or in connection with:
 - (i) a breach by the User of these Terms of Use;
 - (ii) the User's access to or use of Shariant Australia or the uploading or use of any Data;
 - (iii) any Data Breach which is caused or contributed to by the User;
 - (iv) any Loss suffered by a third party as a result of any infringement of any third party rights, including without limitation Intellectual Property Rights, by the User.

8. General

- (a) Clause 1, 3(b), 3(c), 3(e), 3(f), 3(g), 4, 5(d), 5(e), 6(b) and 7 shall remain in effect following the withdrawal or termination of the User's right to access and use Shariant Australia under these Terms of Use.
- (b) The User may not assign or otherwise transfer any or all of its rights arising out of these Terms of Use without Our prior written consent.
- (c) The failure of any party to enforce at any time any provision under these Terms of Use or any rights in respect thereto is not a waiver of such provision or right and shall not in any way affect the validity and enforceability of these Terms of Use.
- (d) Any provision of this Agreement which is unenforceable or partly unenforceable is, where possible, to be severed to the extent necessary to make this Agreement enforceable, unless this would materially change the intended effect of this Agreement.
- (e) These terms are governed by the law of the State of Victoria, Australia. The parties submit to the non-exclusive jurisdiction of the courts of the State of Victoria, Australia.

AGREEMENT

By signing below, the User agrees to be bound by and comply with these Terms of Use:

Signed for and on behalf of the following User:

_____ *[Insert legal entity name of User]*

_____ *[Insert ABN]*

_____ *[Insert registered address]*

By its authorised representative:

_____ *[Signature]*

_____ *[Print name]*

_____ *[Position]*

_____ *[Date]*

The signatory above represents and warrants that he or she is authorised to sign and thereby bind the User to these Terms of Use.

Read, understood and accepted by:

_____ *[Signature (Laboratory Supervisor or delegate)]*

_____ *[Print name]*

_____ *[Position]*

_____ *[Date]*