Research Path Privacy Policy — Study Participants

This privacy policy explains how Research Path Pty Ltd (ABN 62 124 637 163, “Research Path”, “we”, “us”, or “our”) uses the personal data we collect from you when you participate in a clinical study that utilises our software. Research Path acts as a data processor on behalf of the study sponsor (the “Data Controller”) in accordance with applicable data protection laws, including the EU General Data Protection Regulation (GDPR), the Australian Privacy Act 1988, and relevant clinical trial regulations.

This privacy policy supplements, but does not replace, the study-specific Informed Consent Form (ICF) provided to you at your enrolling hospital or clinic. Please refer to your ICF for detailed information about the specific data collected in your study and the identity of the Data Controller (study sponsor). If there is any inconsistency between this policy and your ICF, the ICF shall prevail in respect of study-specific matters.

Topics

What data do we collect and why?

Research Path collects the following data as instructed and on behalf of the Data Controller (study sponsor). All personal data collected is pseudonymised: your full name is not stored in Research Path systems, and identification is limited to coded identifiers that cannot be used to directly identify you without additional information held separately by your clinical site.

- Personal identification information (limited to date of birth, sex, initials, and a unique study participant code)
    - On occasion, studies may request consent to collect data linkage information such as your Medicare number (Australia only) or an ID for another study or registry to support data sharing amongst projects or organisations that participants have consented to sharing information with. In this case, additional informed consent will be obtained.
- Health information and clinical data as required by the study you have consented to (special category data under GDPR Article 9), which may include:
    - hospital or clinic name where you were enrolled
    - hospital admission and other clinical event dates and times
    - surgical or other medical intervention monitoring data
    - blood and other laboratory test results
    - quality of life surveys and/or other validated questionnaires
    - adverse event data during admission
    - follow-up status after hospital discharge such as mortality, hospital readmissions, and quality of life questionnaires

How do we collect your data?

The hospital clinical research nurse or staff member at the hospital or clinic where you consented to the study will directly provide Research Path with all of the data we collect. These data are only entered into our system once you have provided informed consent to study participation in accordance with applicable clinical trial regulations (including ICH Good Clinical Practice guidelines and, where applicable, EU Clinical Trial Regulation No 536/2014). Research Path does not collect data directly from you.

How will we use your data?

Research Path collects your data so that we can:

- Provide the clean and validated datasets to the researchers that manage the trial
- Provide your hospital or clinic where you enrolled with aggregate statistics to monitor the progress of their study participation and management

Research Path has no rights to share, analyse, or retain your data for any purpose other than to provide the study researchers with the monitoring information and the interim and final datasets. Your data will not be used for automated decision-making or profiling. Your data will not be used for any secondary purpose without your additional informed consent.

Legal basis for processing

Research Path processes your personal data on the following legal bases under the General Data Protection Regulation (GDPR):

General personal data (Article 6): Processing is necessary for the performance of a task carried out in the public interest (Article 6(1)(e)), specifically the conduct of clinical research to advance medical knowledge and patient care. Where consent is relied upon as the primary basis, this is the freely given, specific, informed consent obtained through the study-specific ICF process.

Special category health data (Article 9): Processing is necessary for reasons of substantial public interest in the area of public health (Article 9(2)(i)), and/or for scientific research purposes in accordance with Article 9(2)(j), subject to appropriate safeguards including pseudonymisation, data minimisation, and ethics committee approval. The specific legal basis applicable to your study will be identified in the study-specific ICF and Data Processing Agreement.

Under Australian law, the processing of health information in research is governed by the Privacy Act 1988 and the Guidelines approved under Section 95A of that Act.

How do we store your data?

Research Path securely stores your data at the Google Cloud Platform (GCP) Sydney Data Centres, protected by secure encryption (AES-256) at all times during collection, transmission, storage, and backup. All access to the data is performed under strict controls requiring multi-factor authentication and role-based authorisation limited to designated Research Path staff. All access to physical infrastructure used to store your data is under strict controls managed by the Google Cloud Platform team.

For further information on Google Cloud Platform's security and compliance certifications, see: https://cloud.google.com/security/gdpr

All access is audit logged at the application and infrastructure level. These audit trails are maintained in compliance with ICH Good Clinical Practice guidelines and applicable regulatory requirements, and are available for review by authorised parties including sponsors, ethics committees, and regulatory authorities during monitoring visits, audits, and inspections.

Research Path maintains validated computerised systems in accordance with ICH GCP, FDA 21 CFR Part 11, and applicable regulatory requirements for electronic records and electronic signatures. System qualification documentation is maintained separately and is available to sponsors and regulatory authorities upon request.

International data transfers

Your data is stored in Australia at the Google Cloud Platform Sydney Data Centres. Australia does not currently hold a data adequacy decision from the European Commission. Where your data originates from a clinical trial conducted within the European Economic Area (EEA) or the United Kingdom, the following safeguards are in place to ensure your data is protected to an equivalent standard:

- Standard Contractual Clauses (SCCs) approved by the European Commission are incorporated into our Data Processing Agreements with study sponsors and with Google Cloud Platform as our infrastructure sub-processor
- A Transfer Impact Assessment (TIA) has been conducted to evaluate the legal framework in Australia and confirm that adequate protections are in place for personal data transferred from the EEA
- Technical measures including AES-256 encryption in transit and at rest, and strict access controls, provide supplementary safeguards as recommended by the European Data Protection Board

Research Path staff who access data are located in Australia. Data is not routinely transferred to any other country. In the event that access from an additional jurisdiction is required (for example, to provide technical support), the same contractual and technical safeguards will be applied, and the study sponsor will be notified.

Data retention

Research Path will keep your data for the life of the clinical study, which begins at your enrolment until the final data lock is issued by the study managers, or the mandatory archival period has been reached, whichever is longer. The applicable retention period depends on the regulatory requirements governing your study and may include:

- At least 15 years from the date of publication of the final study report, as required by the Australian Code for the Responsible Conduct of Research (NHMRC, 2018)
- At least 25 years for studies involving clinical trials of medicinal products, in accordance with ICH E6 Good Clinical Practice guidelines and Annex I of the EU Clinical Trial Regulation
- At least 2 years after the last marketing approval or formal discontinuation of the investigational product, as required by ICH E6
- Any longer period required by the study sponsor, applicable national legislation, or the relevant ethics committee

The longest applicable period will be followed. Once this time period has expired, we will delete your data by securely removing all databases and backups which contain the data, in accordance with our data destruction procedures.

What are your data protection rights?

Research Path would like to make sure you are fully aware of all of your data protection rights. Every study participant is entitled to the following:

The right to access — You have the right to request Research Path for copies of your personal data.

The right to rectification — You have the right to request that Research Path correct any information you believe is inaccurate. You also have the right to request Research Path to complete information you believe is incomplete.

The right to erasure — You have the right to request that Research Path erase your personal data, under certain conditions. Please note that in clinical trials, erasure may be limited by regulatory obligations requiring data retention for patient safety and scientific integrity.

The right to restrict processing — You have the right to request that Research Path restrict the processing of your personal data, under certain conditions.

The right to object to processing — You have the right to object to Research Path's processing of your personal data, under certain conditions.

The right to data portability — You have the right to request that Research Path transfer the data that we have collected to another organisation, or directly to you, in a structured, commonly used, and machine-readable format, under certain conditions.

The right to withdraw consent — Where processing is based on your consent, you have the right to withdraw that consent at any time. Withdrawal of consent does not affect the lawfulness of processing carried out before the withdrawal. Please note that in the context of clinical trials, withdrawal from the study may not require deletion of data already collected if retention is required by law or regulatory obligation.

Rights related to automated decision-making — Research Path does not use your personal data for automated decision-making or profiling.

If you make a request, we have one month to respond to that request via the Data Controller (study sponsor). In complex cases, this period may be extended by a further two months, in which case we will notify you within the first month. If you would like to exercise any of these rights, please contact us at our email: compliance@researchpath.com.au or contact our Data Protection Officer (see below).

Data breach notification

In the event of a personal data breach that affects your data, Research Path will:

- Notify the Data Controller (study sponsor) without undue delay and in any event within 72 hours of becoming aware of the breach, in accordance with our Data Processing Agreement and GDPR Article 33

- Cooperate with the Data Controller to notify the relevant supervisory authority where the breach is likely to result in a risk to your rights and freedoms
- Cooperate with the Data Controller to notify you directly where the breach is likely to result in a high risk to your rights and freedoms, in accordance with GDPR Article 34
- Document all breaches, including the facts, effects, and remedial actions taken, regardless of whether notification to the supervisory authority is required
- Notify the Australian Information Commissioner in accordance with the Notifiable Data Breaches scheme under the Privacy Act 1988, where applicable

Regulatory authority access

As part of your participation in a clinical study, your pseudonymised data may be accessed by authorised representatives of the following parties for the purposes of monitoring, auditing, and inspection in accordance with ICH Good Clinical Practice guidelines and applicable clinical trial regulations:

- The study sponsor and their authorised delegates (including monitors and auditors)
- Independent ethics committees or institutional review boards overseeing the study
- Regulatory authorities including, but not limited to, the Australian Therapeutic Goods Administration (TGA), the European Medicines Agency (EMA), national competent authorities in EU/EEA member states, and the United States Food and Drug Administration (FDA)

These parties are bound by confidentiality obligations and may only access your data to the extent necessary to verify the integrity of the clinical trial and protect your safety. Your consent to this access is obtained as part of the study-specific ICF.

Sub-processors

Research Path engages the following sub-processor in the delivery of its services:

- **Google Cloud Platform (Google LLC)** — Provides the cloud infrastructure (compute, storage, networking, and managed database services) on which Research Path is hosted. Data is stored in the Sydney, Australia region (australia-southeast1). Google's data processing terms, security certifications, and GDPR compliance documentation are available at cloud.google.com/terms/data-processing-addendum

A Data Processing Agreement incorporating Standard Contractual Clauses is in place with Google Cloud Platform. Research Path will not engage additional sub-processors without prior written authorisation from the Data Controller (study sponsor). An up-to-date list of sub-processors is available upon request by contacting compliance@researchpath.com.au.

What are cookies?

Cookies are text files placed on a user's computer to collect standard Internet log information and visitor behaviour information. For further information, visit allaboutcookies.org.

How do we use cookies?

Research Path uses cookies for a single purpose: to keep the clinical research staff securely signed into our system. No personal data is stored in cookies. We do not use cookies for analytics, advertising, or tracking purposes. Only strictly necessary session cookies are used, and no consent is required for these under the EU ePrivacy Directive.

Privacy policies of other websites

At times Research Path software websites contain links to other websites. Our privacy policy applies only to our software, so if you click on a link to another website, you should read their privacy policy.

Changes to our privacy policy

Research Path keeps its privacy policy under regular review and places any updates on this web page. Where changes are material, we will notify the Data Controller (study sponsor) who may in turn inform participants. This privacy policy was last updated in February 2026.

Data Protection Officer

Research Path has appointed a Data Protection Officer (DPO) who is responsible for overseeing our data protection strategy and ensuring compliance with applicable data protection laws. You may contact our DPO directly with any questions or concerns regarding the processing of your personal data:

Data Protection Officer
Research Path Pty Ltd
Email: dpo@researchpath.com.au

How to contact us

If you have any questions about Research Path's privacy policy, the data we hold on you, or you would like to exercise one of your data protection rights, please do not hesitate to contact us.

Email us at: compliance@researchpath.com.au

Research Path Pty Ltd

Room 5, 233 Barker St, Castlemaine Victoria 3450, Australia
ABN: 62 124 637 163

How to contact the appropriate authority

Should you wish to report a complaint or if you feel that Research Path has not addressed your concern in a satisfactory manner, you may contact the relevant supervisory authority:

- Australia: Office of the Australian Information Commissioner (OAIC) — www.oaic.gov.au — Phone: 1300 363 992
- European Union: The Data Protection Authority in the EU/EEA member state where you are located or where the alleged infringement occurred. A list of EU Data Protection Authorities is available at edpb.europa.eu
- United Kingdom: Information Commissioner's Office (ICO) — ico.org.uk

References:

Australian Code for the Responsible Conduct of Research, 2018 | NHMRC (www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018)

Regulation (EU) 2016/679 (General Data Protection Regulation)

Regulation (EU) No 536/2014 (Clinical Trial Regulation)

ICH E6(R2) Guideline for Good Clinical Practice