The George Institute for Global Health

FURTHER TRANSPARENCY NOTICE FOR UK / EU PARTICIPANTS

ADRENAL STUDY: ADjunctive coRticosteroid trEatment iN criticAlly ilL patients with septic shock

This transparency (or privacy) notice is in addition to, and must be read with, the Participant Information Sheet and Consent Form (**PISCF**) given to you by the study site research staff. This notice is part of our ongoing commitment to ensure that your personal data is being processed lawfully and transparently.

Sponsor and Data Controller

The George Institute for Global Health (**we** or **TGI**) is the Sponsor of the study and acts as data controller.

TGI is based in Australia. The study was carried out at study sites (hospitals) in various jurisdictions globally (and in collaboration with the University of Queensland (Australia) for the Genomics (GEPS) sub-study), and local study sites managed your participation in the study with us.

Personal data collected for this study

The study site collected your name and contact details, information about your health, quality of life and medical care and, if you participated in the Genomics (GEPS) sub-study, genetic material in the form of a blood sample (as set out in the study protocol) (collectively, together with the results of the blood sample analyses, **study data**).

The study site is required to keep your name and contact details confidential and not to pass this information to TGI. The site has used and/or may use this information as needed, to contact you about the study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Certain individuals from TGI, or contracted third parties assisting TGI, and regulatory organisations may look at your medical and research records during monitoring visits at the study site to check the accuracy of the research study.

TGI will only receive study data that is coded or pseudonymised – this means, that the people who analyse the study data will not be able to identify you and will not know your name or contact details.

How long your information will be held

The study site will keep identifiable information about you for 15 - 25 years (depending on local regulatory requirements) after the study has finished and/or as otherwise required by law.

We will keep the coded study data (excluding the blood samples) about you for at least 15 years after the study has finished, but potentially indefinitely. After analyses, we may destroy the remainder of the blood sample or keep it indefinitely for related research purposes as set-out in the PISCF.

Purpose and legal basis of processing

Your information is being processed for scientific research purposes.

As an independent, not for profit, medical research institution we have a legitimate interest in using information relating to your health and medical care for research studies, when you agree to take part in a research study. This means that we may use your study data, collected in the course of the research study, in the ways needed to conduct the study and analyse the results.

Who will the data be shared with?

We may disclose your data to our and/or our affiliates' staff and study team members including our approved third parties (e.g. collaborators and research partners) involved with the study, but only to such persons who need to know. Your data will be coded so we cannot identify you or contact you.

We may share your data if we are required to comply with our legal or regulatory obligations or for the purposes of fraud prevention.

Your data may also be shared with third-party service providers (such as database providers) which host the Study database and files. Third parties will be required to respect the security of your data and to treat it in accordance with the law.

Your data may also be used for future research

When you agree to take part in the study, your study data may also be provided to researchers running other research studies in our organisation and in other organisations. These organisations may be our affiliate companies, universities, NHS and other similar organisations, and companies involved in health and medical care in the UK, EU or other jurisdictions.

The study data will not identify you and will not be combined with other information in a way that could identify you. The data will only be used for the purpose of health and medical research and, where required, subject to prior approval by an independent ethics committee.

Processing information outside of the UK or EU

Study data may be transferred outside the UK and EU to where the study database and our own databases and those of approved third party recipients are held. These may be located, without limitation, in Australia, the United States and any other country in which Microsoft (or its sub-processors) operate in. There is not an 'adequacy decision' by the European Commission for some of those countries, meaning those countries are not deemed to provide an adequate level of protection for personal data under UK and EU privacy laws.

However, to ensure that personal data does receive an adequate level of protection, appropriate measures will be in place to ensure that personal data is treated by those third parties in a way that is consistent with and meets UK and EU privacy law requirements. This includes (without limitation): undertaking transfer and privacy impact assessment (where appropriate), anonymising or coding data, and using EU Model Clauses or the UK IDTA (as applicable).

Security and confidentiality

It is important to keep your data safe and secure. In addition to the above measures, there are a number of other ways we have taken steps to protect your privacy, including: limiting access to your data (by physical and technical safeguards) to people who have a clinical, legal, research or project-based need to know, putting in place data breach procedures, and adhering to strict contractual conditions.

Your rights

You have a right to request **access**, **rectification**, **erasure** or **transfer** of your personal information, but these may be limited as we need to manage your information in specific ways in order for the research to be reliable, accurate and to comply with regulations. If you withdraw from the study, we will keep the information about you that we have already obtained but it will not be used in any further analysis. To safeguard your rights, we will use the minimum personally-identifiable information as possible.

If you wish to raise a complaint on how your personal data is handled, you have a right to contact the supervisory authority in your country of residence.

Changes to our privacy notice

This privacy notice may be updated at any time. We will notify you via this website if there are any updates or substantial changes.

Who to contact

If you have any queries or concerns about your data or how it is being handled, please contact:

- **Your local research team**

  Please refer to the contact details provided on the PISCF

- **Sponsor**

  - The George Institute for Global Health, Level 5, 1 King Street, Newtown, NSW 2042, Australia
    Email: privacy@georgeinstitute.org

    Attention: Privacy Officer

  - Sponsor's UK based representative:
    The George Institute for Global Health, UK
    Central Working - Fourth Floor
    Translation and Innovation Hub
    Imperial College London
    84 Wood Lane, London W12 0BZ UNITED KINGDOM

    Email: pcheruvath@georgeinstitute.org.uk
    Tel: +44 1865 617 200

    Attention: Premjith Cheruvath

  - Sponsor's EU based representative:
    European Data Protection Office (EDPO)
    Avenue Huart Hamoir 71, 1030 Brussels, Belgium

    Online request form: https://edpo.com/gdpr-data-request/