

CAPTIVATE

Personal Information Collection Notice and Consent: EU-based professionals involved in clinical trials/research projects

The George Institute for Global Health (TGI), together with its subsidiaries and associated companies worldwide (TGI, we and our) is committed to handling personal information (or “personal data”) in accordance with Privacy Laws - including the EU General Data Protection Regulation ((EU) 2016/679) (GDPR), and the Australian *Privacy Act 1988* (Cth), as applicable.

This notice sets out how we handle your personal data:

- Part A: for this Study: The Chronic kidney disease Adaptive Platform Trial Investigating Various Agents for Therapeutic Effect (CAPTIVATE)
- Part B: if you want us to retain your details for future collaboration, please read and **sign and return** the consent form in Part B.

This notice applies to collaborators and research team members. This notice does not create any employment or services contract. We may update this notice at any time.

PART A - PERSONAL DATA COLLECTED

What personal data do we collect?

As you are a member of the research team for the CAPTIVATE Study, we collect, store, and use the following categories of personal data about you:

- your personal details such as your name, address, contact details (including phone/mobile number and email), job title, organisation address, professional qualifications, experience, professional registrations.

We collect this information either directly from you, the TGI Project Lead or via the Institution that you work or contract with.

How we use your personal data and the lawful basis for processing

We collect and hold your personal data for the purpose of administration, management, evaluation and operation of the CAPTIVATE Study. Your consent is not required for this purpose, as we collect and use your personal data to ensure the CAPTIVATE Study is properly conducted. This is in compliance with our legal obligation under GCP and other regulatory requirements to ensure research team members are properly qualified, experienced and registered with appropriate professional regulation bodies, and have not been disbarred or prohibited from working on clinical trials.

How long we keep your personal data

We will keep your personal data for a minimum of 25 years for regulatory purposes. Beyond that period, your personal data will remain with the CAPTIVATE Study file until the Study file is securely destroyed.

Who we share your personal data with

We may disclose your personal data to our staff and CAPTIVATE Study team members including our approved third-parties (e.g. sponsors, collaborators and research partners), but only to such persons who need to know.

We may share your personal data if required under legal or regulatory obligations or for fraud prevention.

We may also share your data with third-party service providers (such as database providers) which host the CAPTIVATE 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.

We may transfer your personal data outside the EU. If we do, you can expect a similar degree of protection in respect of your personal data as required under GDPR.

Processing data outside of the European Economic Area

We will transfer your personal data to where the CAPTIVATE Study databases and our own databases are held (including outside the EU). These databases are located in Australia and in the EU. Some of the countries to which we transfer your data are not deemed to provide an adequate level of protection for your personal data under Privacy Laws.

However, to ensure that your personal data does receive an adequate level of protection we have put in place appropriate measures to ensure that your personal data is treated by those third parties in a way that is consistent with and meets Privacy Law requirements: this may include the confidentiality obligations and standard contractual clauses approved by the European Commission.

Your rights

Rights	What does this mean?
The right to be informed	You have the right to be provided with clear, transparent and easily understandable information about how we use your personal data and your rights.
The right of access	You have the right to obtain access to your personal data that we are processing and certain other information.
The right to rectification	You are entitled to have your personal data corrected if it is inaccurate or incomplete.
The right to erasure	This is also known as ‘the right to be forgotten’ and enables you to request the deletion or removal of your personal data if there is no compelling or legal reason for us to keep using it. This is not a general right to erasure, as there are exceptions.
The right to restriction of processing	This right enables you to ask us to suspend the processing of personal data about you, for example if you want us to establish its accuracy or the reason for processing it.
The right to object to processing	You have the right to object and to ask us to stop processing your data however we may not be able to comply with your request if this conflicts with our regulatory or legal obligations.
The right to lodge a complaint	You have the right to lodge a complaint about the way we handle or process your data with a supervisory authority.

Changes to our privacy notice

We reserve the right to update this privacy notice at any time, and we will provide you with a new privacy notice when we make any substantial updates during the period of our interaction with you. We may also notify you in other ways from time to time about the processing of your personal data (e.g. through the Study institution).

Data security

We have put in place measures to protect the security of your information, and to prevent your personal data from being accidentally lost, used or accessed in an unauthorised way, altered or disclosed. In addition, we limit access (by physical and technical safeguards) to your personal data to those employees, agents, contractors and other third parties who have a business or legal need to know. We have also put in place procedures to deal with any suspected data security breach and will notify you and any applicable regulator of a suspected breach where we are legally required to do so.

Access requests

You will not have to pay a fee to access your personal data (or to exercise any of the other rights). However, we may charge a reasonable fee if your request for access is clearly unfounded or excessive. Alternatively, we may refuse to comply with the request in such circumstances.

We will respond to acknowledge your request and provide the information within one month of receiving your request, depending on the circumstances.

How we contact you

We will communicate with you via email, telephone, post and on occasion SMS. You may also update your contact details at any time by contacting us.

Our contact details

If you have any queries, questions or concerns about your data or how we are handling it, please contact any of the following:

the Project Lead: Sradha Kotwal, The George Institute, Level 18, International Tower 3, 300 Barangaroo Avenue, Sydney, NSW 2000, Australia. Tel no: + 61 2 8052 4300, email: captive@georgeinstitute.org.au; or

the Privacy Officer: email: privacy@georgeinstitute.org; or
our EU based representative (Privacy): European Data Protection Office (EDPO), 1030 Brussels, Avenue Huart Hamoir 71, Belgium, email: info@edpo.com

Thank you for your participation in the CAPTIVATE Study.

If you wish your details to be held by us for consideration and potential participation for other studies or projects, please read, complete and return **Part B** below. If you are not interested in this, you do not need to read any further.

PART B - PERSONAL DATA COLLECTED FOR FUTURE PROJECTS

If you consent to TGI, together with its subsidiaries and associated companies worldwide (**TGI, we and our**) collecting and holding your **personal data** (as described under **Part A** above) for possible participation for future studies and projects, please read the information below and *sign and return the consent form* below.

Personal data collected and purpose

Your personal details collected under the CAPTIVATE Study will be retained for potential consideration and collaboration on future research projects. These details are:

- your name, address, contact details, job title, organisation address professional qualifications, experience, professional registrations.

This information has been collected either directly from you, or via the regional coordinator or the Institution that you worked or contracted with on the CAPTIVATE Study.

We may use your personal data to:

- contact you for potential work or collaboration on other studies or research activities;
- send you newsletters, updates, information, activities and services that we or our collaborators provide;
- send you information about our trials;
- contact you to ensure that the information we hold is kept accurate and up to date;
- refer/recommend you and your professional expertise to other research institutions, collaborators, sponsors and CROs; and
- share your details within our group of companies for potential collaboration and/or recommendations to third parties for your involvement in research projects or clinical trials.

The lawful basis for processing your data

We rely on your consent to process your data for the above purposes.

Your rights

In addition to your rights outlined in Part A, you also have the following rights:

The right to data portability	You may obtain your personal data from us and direct us to send your data to a third party. We will do our best to provide the information in an easy-to-read format.
The right to withdraw consent	If you have given your consent to anything we do with your personal data, you have the right to withdraw your consent at any time (although if you do so, it does not mean that anything we have done with your personal data under Part A or with your consent up to that point is unlawful).

If you would like us to stop processing or using your data, please contact us. Our contact details are further below.

How long we keep your personal data

We will keep your personal data indefinitely unless you notify us that you withdraw your consent for processing under this Part B.

Who we share your personal data with

We may disclose your personal data to our staff (within TGI and our group of companies) and third parties involved in potential collaborations, research projects, clinical trials and associated activities (our **Collaborators**). Disclosure may also be required to comply with legal, regulatory, ethical committee or insurance obligations or applications for funding or initiating projects or studies.

We may also share your data with third-party service providers (such as database providers) which host our databases and the databases of our Collaborators.

Third parties will be required to respect the security of your data and to treat it in accordance with the law.

We may transfer your personal data outside the EU. If we do, you can expect a similar degree of protection in respect of your personal data, as required under GDPR.

Processing data outside of the European Economic Area (EU)

We will transfer your personal data to where our own databases and those of our Collaborators are held (including outside the EU). These databases are located in Australia, United States and elsewhere in the world. There is not an 'adequacy decision' by the European Commission for some of these countries, meaning some of these countries are not deemed to provide an adequate level of protection for your personal data under Privacy Laws.

We have put in place appropriate measures to ensure that your personal data is treated in a way that is consistent with and meets privacy law requirements, as set out in Part A. We will endeavour to ensure our Collaborators provide details to us of the security measures that they have in place to protect your data.

Information relating to data security measures, access requests and changes to our privacy notice are explained in Part A.

How we contact you

We will communicate with you via email, telephone, post and on occasion SMS. You may also update your contact details at any time by contacting us.

Our contact details

If you have any queries, questions or concerns about your data or how we are handling it under this Part B, please contact either of the following:

the Project Lead: Sradha Kotwal, The George Institute, Level 18, International Tower 3, 300 Barangaroo Avenue, Sydney, NSW 2000, Australia. Tel no: + 61 2 8052 4300, email: captive@georgeinstitute.org.au; or

the Privacy Officer: email: privacy@georgeinstitute.org; or

our EU based representative: European Data Protection Office (EDPO), 1030 Brussels, Avenue Huart Hamoir 71, Belgium, email: info@edpo.com

Acknowledgement and Consent

I acknowledge that I have read the information above and understand the reasons why my personal data is being collected under Part B, and how it may be used and distributed.

I voluntarily consent to TGI (and its subsidiaries and associated companies) collecting, storing, using, disclosing and transferring my personal data for the purposes set out in this Part B.

Print Name _____

Institution _____

Signature _____

Date _____

Please return this signed consent form to: captivate@georgeinstitute.org.au