Clinical Trial Participant Privacy Notice

1. Introduction – Why This Notice Applies to You

This privacy notice explains how Avacta Therapeutics collects, uses, stores, shares and protects your personal data when you take part (or consider taking part) in one of our clinical trials.

Avacta Therapeutics is a company based in the United Kingdom. We are the Sponsor of the clinical trial in which you are participating. As a UK based organisation, we are subject to UK data protection law, specifically the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018 (DPA 2018). These laws apply to our processing of your personal data because the processing takes place in the context of our UK operations, regardless of where you are located or where the trial is being conducted.

Under data protection law, we are a "controller" of your personal data, which means we are responsible for deciding why and how your personal data is processed in connection with the trial.

This notice should be read alongside the Informed Consent Form (ICF) you received from the clinical trial site and (if applicable) any HIPAA Authorisation or other local privacy documentation provided at the site. This notice governs how we, as the Sponsor, handle the information we receive about you.

2. Who We Are

Avacta Therapeutics is a company registered in England and Wales, with its registered office at Scale Space, White City, Imperial College Campus, 58 Wood Lane, London, W12 7RZ, UK.

If you have questions about how your data is processed or wish to exercise your rights, you can contact:

- **Data Protection Officer:** DPO@avacta.com
- Postal address: Scale Space, White City, Imperial College Campus, 58 Wood Lane, London, W12 7RZ, UK

3. What Personal Data We Collect

When you participate in a clinical trial, the clinical trial site collects information about you as part of the trial procedures. Some of this information is shared with us, usually in coded form (see Section 3.1 below). The categories of information we may receive include:

Category	Examples
Identifiers	Participant ID number, screening number, date of birth or year of birth, initials (where permitted)
Demographic data	Age, sex, race/ethnicity (where relevant to the trial)
Health and medical data	Medical history, diagnosis, test results, vital signs, imaging data, adverse events, concomitant medications, laboratory results, biomarker data

Biological sample data	Data derived from blood, tissue, or other biological samples collected during the trial
Trial participation data	Consent records, visit dates, protocol deviations, study completion or withdrawal information
Genetic data (where applicable)	Pharmacogenomic data or other genetic analysis if included in the trial protocol

3.1. How Your Data Is Coded (Pseudonymised)

We do not receive your name, address, or other directly identifying information. Instead, the clinical trial site assigns you a unique participant ID number and the data we receive is linked to that number rather than to your name. This is called “pseudonymisation.”

The clinical trial site holds the key that links your ID number to your identity. We do not hold this key and cannot identify you from the coded data we receive. However, because the data could in principle be re-linked to you (by the site), it is still treated as personal data under data protection law and we protect it accordingly.

4. Why We Process Your Data and Our Legal Basis

We process your personal data for the purposes of conducting, managing and overseeing the clinical trial. Specifically:

- Conducting the trial in accordance with the protocol, applicable regulations and Good Clinical Practice (GCP)
- Monitoring the safety of the investigational medicinal product, including adverse event reporting and pharmacovigilance
- Ensuring the quality and integrity of trial data through monitoring, audit and quality assurance
- Meeting our regulatory obligations to the applicable authorities (which may include the MHRA, FDA, EMA and national competent authorities)
- Supporting future regulatory submissions, including marketing authorisation or new drug applications
- Archiving trial data in line with regulatory retention requirements
- Publishing or presenting trial results (in anonymised or aggregated form only)

4.1. Legal Basis Under UK Data Protection Law

Our legal bases for processing your personal data are as follows:

For your general personal data: the processing is necessary for the performance of a task carried out in the public interest. Clinical trials serve the public interest because they are essential to developing safe and effective medicines.

For your health, genetic and biometric data: these are classified as “special category data” under data protection law and receive additional protection. The processing is necessary for scientific research purposes, subject to appropriate safeguards including pseudonymisation and data minimisation. Under the DPA 2018, we satisfy the additional condition for research purposes and maintain an Appropriate Policy Document as required.

For ancillary processing (such as safety monitoring, quality assurance and regulatory reporting): we may also rely on legitimate interests, including ensuring participant safety, maintaining trial data integrity and meeting our obligations as trial Sponsor.

4.2. EU GDPR (For Trials Conducted in the EU/EEA)

Where we conduct clinical trials at sites within the European Union or European Economic Area, the EU General Data Protection Regulation (EU GDPR) may also apply to the processing of participants' personal data. The legal bases we rely on under the EU GDPR are equivalent to those described above. Where the laws of the EU member state in which your trial site is located provide additional requirements or protections (for example, specific conditions for processing health data for research purposes), we will comply with those requirements.

4.3. How This Relates to Your Informed Consent

At the clinical trial site, you will have signed an Informed Consent Form (ICF) and at US sites, a separate HIPAA Authorisation. It is important to understand the relationship between these documents and this privacy notice:

- **Your ICF consent** is a regulatory and ethical requirement under Good Clinical Practice (ICH-GCP) and applicable clinical trial regulations. It confirms that you understand the trial and agree to participate. It is not the legal basis on which we process your data under UK or EU data protection law.
- **Your HIPAA Authorisation (US sites only)** governs how the clinical trial site (as a HIPAA-covered entity) uses and discloses your Protected Health Information. It does not directly apply to us as a UK organisation, but we respect the commitments made within it.
- **This privacy notice** explains the separate legal basis on which we, as a UK controller, process your personal data under data protection law.

This means that if you withdraw from the trial, or (at US sites) revoke your HIPAA Authorisation, we may still retain and process data already collected about you up to the point of withdrawal. This is explained further in Section 9.

5. Who We Share Your Data With

To conduct the trial, your personal data may be shared with the following categories of organisations. Each processes your data only for the purposes described in this notice and is subject to appropriate contractual and legal safeguards:

Recipient	Role / Purpose
Contract Research Organisation (CRO)	Managing and monitoring the trial on behalf of the Sponsor.
Clinical trial sites and investigators	Conducting the trial, treating and assessing participants.
Electronic data capture (EDC) and technology vendors	Hosting and managing clinical trial data systems.
Central and local laboratories	Analysing biological samples and providing test results.
Bioanalytical laboratories	Pharmacokinetic and pharmacodynamic sample analysis.

Safety and pharmacovigilance service providers	Adverse event reporting and safety monitoring.
Regulatory authorities	Including the MHRA, FDA, EMA and other national competent authorities for regulatory oversight, inspection and approval of medicines.
Ethics committees / Institutional Review Boards (IRBs)	Ethical oversight and approval of the trial.
Auditors and inspectors	Quality assurance, regulatory compliance and GCP audits.
Avacta group companies	Including US subsidiary for internal administration and trial related management activities.

Where any of these organisations acts as our processor (processing data on our instructions), we have data processing agreements in place that comply with applicable data protection law.

6. How Your Data Moves Between Countries

Clinical trials frequently involve the transfer of personal data between countries. Your data may flow between the country where your trial site is located, the United Kingdom (where we are based) and other countries where trial service providers operate. The safeguards that apply depend on the direction of transfer:

6.1. Transfers To and From the UK

From the UK to countries without a UK adequacy decision (e.g. the United States): we use approved transfer mechanisms, specifically the UK International Data Transfer Agreement (UK IDTA) or the UK Addendum to the EU Standard Contractual Clauses, as approved by the UK Information Commissioner's Office. These instruments bind the recipient to protect your data to a standard essentially equivalent to UK data protection law.

From the UK to countries with a UK adequacy decision (e.g. EU/EEA member states): no additional transfer mechanism is required, as the UK Government has recognised these countries as providing adequate protection.

From EU/EEA countries to the UK: the European Commission has adopted an adequacy decision for the United Kingdom, meaning that personal data can flow from the EU/EEA to the UK without additional safeguards.

6.2. Transfers From the EU/EEA to Non-Adequate Countries

Where we conduct trials in the EU/EEA and personal data is transferred to countries outside the EU/EEA that do not benefit from an EU adequacy decision (including the United States), we use the EU Standard Contractual Clauses approved by the European Commission as the transfer mechanism.

6.3. Supplementary Safeguards

In addition to the contractual safeguards above, we have carried out Transfer Impact Assessments and Transfer Risk Assessments in line with applicable regulatory guidance. These assessments evaluate the legal framework and government access practices in each recipient country and identify supplementary measures we apply, which include:

- Pseudonymisation of trial data (the site holds the identity key, not the Sponsor)

- Encryption of data in transit and at rest
- Access controls limiting who can view your data
- Contractual restrictions on onward transfers

Copies of the relevant transfer instruments and impact assessments are available on request from our Data Protection Officer.

7. Automated Decision-Making

We do not use automated decision-making (including profiling) that produces legal or similarly significant effects on you based on your personal data collected in this trial.

8. How Long We Keep Your Data

How long we retain your personal data will depend on the specific Trial. However, we will not retain your personal data any longer than necessary to fulfil the purposes the personal data was collected for or to fulfil our legal obligations, in line with our data retention policy.

If you wish to receive further specific information on the applicable retention periods, please reach out to us at DPO@avacta.com.

9. What Happens If You Withdraw From the Trial

You are free to withdraw from the clinical trial at any time.

However, please be aware that:

- **Data already collected** up to the point of your withdrawal will be retained and may continue to be processed. This is necessary to maintain the scientific integrity of the trial, to comply with regulatory requirements (including safety reporting) and to fulfil our legal obligations as trial Sponsor. We are permitted to do this under data protection law because our legal basis for processing is public interest and scientific research, not your consent.
- **No new data** will be collected about you after withdrawal, unless required by law (for example, to follow up on an ongoing adverse event for safety purposes).

US sites – HIPAA Authorisation: if you revoke your HIPAA Authorisation at a US site, this will prevent the site from making further disclosures of your Protected Health Information. However, it will not affect data already transmitted to us or other trial parties. We will continue to process that data in accordance with this notice.

10. Your Rights

You have rights over the personal data we hold about you. Because we are subject to UK data protection law, the rights set out below apply to all participants regardless of location. If your trial site is in the EU/EEA, you may also have equivalent rights under the EU GDPR.

Please note that some of these rights are subject to limitations in the context of scientific research, where appropriate safeguards are in place and the exercise of the right would seriously impair the research. We will consider each request on its merits and explain our reasoning if we need to rely on a research exemption.

Right	What This Means

Access	You can ask us for a copy of the personal data we hold about you. Because your data is coded, we may need to work with the clinical site to verify your identity.
Correction	You can ask us to correct any personal data that is inaccurate or incomplete. In practice, corrections to clinical data are usually made through the clinical site.
Deletion	You can ask us to delete your personal data. However, this right is significantly limited in the clinical trial context – we are likely to need to retain your data for regulatory compliance and scientific research purposes.
Restriction	You can ask us to restrict how we process your personal data in certain circumstances (for example, while we verify its accuracy).
Objection	You can object to our processing of your data where it is based on public interest. We will consider your objection, but we may need to continue processing where there are compelling grounds or regulatory obligations.
Data portability	This right is limited in the clinical trial context because our processing is based on public interest and scientific research, not on your consent or a contract.

To exercise any of these rights, please contact our Data Protection Officer using the details in Section 2. We will respond within one month. We may need to verify your identity before acting on your request.

11. Additional Information for Participants at US Sites

If you are participating in the trial at a clinical site in the United States, the following additional points apply to you:

- **HIPAA:** your health information may be protected under the US Health Insurance Portability and Accountability Act (HIPAA). The HIPAA Authorisation you signed at the clinical site governs the use and disclosure of your Protected Health Information by the site. We are not a HIPAA covered entity or business associate. Once we receive your coded data, we protect it under UK data protection law as described in this notice.
- **Revoking HIPAA Authorisation:** you may revoke your HIPAA Authorisation at any time by notifying the clinical site in writing. This will not affect data already collected or disclosed and the Sponsor may continue to process data received before revocation.
- **State privacy laws:** depending on the state in which you reside, you may have additional privacy rights under state law. If you believe you have rights under any state privacy law, please contact our Data Protection Officer.

12. Additional Information for Participants at EU/EEA Sites

If you are participating in the trial at a clinical site in the European Union or European Economic Area, the following additional points apply to you:

- **EU GDPR:** the EU General Data Protection Regulation applies to the processing of your personal data by the clinical site (as a controller or joint controller). As a UK based Sponsor, we process your data under the UK GDPR, but the rights and protections available to you are substantially equivalent. Where the laws of the member state in which your site is located provide additional data protection requirements, we will comply with them.
- **Supervisory authority:** in addition to the UK Information Commissioner's Office, you have the right to lodge a complaint with the data protection supervisory authority in the EU member state where your trial site is located, or where you reside.

- **EU Clinical Trials Regulation:** trials conducted in the EU are subject to Regulation 536/2014, which includes specific provisions on data protection and the retention of clinical trial data.

13. How to Raise a Concern or Make a Complaint

If you have concerns about how your personal data has been handled, we encourage you to contact our Data Protection Officer in the first instance (see Section 2 for contact details).

You also have the following formal complaint routes:

13.1. UK Information Commissioner's Office

As we are a UK based controller, the ICO has jurisdiction over our data processing activities:

- Website: www.ico.org.uk
- Telephone: +44 303 123 1113
- Address: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF, United Kingdom

13.2. EU/EEA National Supervisory Authorities

If your trial site is in an EU/EEA member state, you may also lodge a complaint with the data protection supervisory authority in the country where your site is located or where you reside.

13.3. Clinical Trial Concerns (All Participants)

If your concern relates to the conduct of the trial rather than data protection specifically, you may also contact:

- Your clinical trial site's Principal Investigator or study team
- The Ethics Committee or Institutional Review Board (IRB) that approved the trial at your site
- The relevant regulatory authority (MHRA, FDA, or the national competent authority in the country where your site is located)

14. Changes to This Privacy Notice

We may update this privacy notice from time to time to reflect changes in how we process your data or to comply with legal or regulatory requirements.

15. Contact Us

If you have any questions about this privacy notice or about how your personal information is handled in connection with a clinical trial, please contact the Data Protection Officer using the details provided in section 2.