



PRIVACY NOTICE FOR CLINICAL TRIALS

This privacy notice specifically applies to individuals who participate in clinical trials conducted by or under the auspices of Gertrude's Children's Hospital.

Introduction

Gertrude's Children's Hospital ("Gertrude's," "we," "us," or "our") is committed to protecting the privacy of clinical trial participants and handling your personal data responsibly, in accordance with the Data Protection Act, 2019, the Health Act, 2017, and other applicable laws and regulations in Kenya. This privacy notice explains how we collect, use, store, and process your personal data in the context of clinical trials.

The Kind of Personal Data We Collect

We collect the following types of personal data from clinical trial participants and related parties:

- **Personal details:** Name, title, gender, nationality, marital status, date of birth, place of birth, age, national identification/passport number, addresses, telephone numbers, personal email addresses.
- **Health data:** Current and previous medical conditions, treatment details, medical records, allergies, health reports, research/clinical trial information, test results, genetic information, biometric information, vaccination history.
- **Study-specific data:** Data collected as part of the clinical trial protocol, including measurements, observations, and responses to interventions.
- **Informed consent data:** Records of informed consent forms and related documentation.

Purposes of Processing

We process clinical trial data for the following purposes:

- **Conducting clinical trials and research.**
- **Recruiting and managing study participants.**
- **Obtaining informed consent.**
- **Ensuring compliance with research protocols and regulatory requirements.**
- **Analyzing research data and publishing findings** (in anonymized or aggregated form where applicable).
- **Monitoring safety and efficacy.**

Lawful Basis for Processing

We process clinical trial data based on one or more of the following lawful bases:



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- **Research purposes:** Processing is necessary for scientific and historical research purposes and statistical purposes, in accordance with the Data Protection Act, 2019.
- **Consent:** You have given explicit consent for us to process your data for the specific purpose of participating in the clinical trial.
- **Contract:** Processing is necessary for the performance of a contract with the study sponsor.
- **Legal obligation:** Processing is necessary for us to comply with legal and regulatory requirements related to clinical trials.
- **Legitimate interests:** Processing is necessary for our legitimate interests or the legitimate interests of the study sponsor, provided your interests and rights do not override those interests.
- **Medical purposes:** Processing is necessary for medical purposes and carried out by healthcare professionals.

Disclosure of Your Personal Data

We may disclose your personal data to the following categories of recipients:

- **Study sponsors and CROs.**
- **Regulatory authorities.**
- **Research institutions.**
- **Other healthcare providers.**
- **Ethics committees.**

Data Security

We have implemented appropriate technical and organizational measures to protect your personal data against unauthorized access, use, disclosure, alteration, or destruction.

Data Retention

We will retain your personal data only for as long as necessary to fulfill the purposes for which it was collected, or as required by law and study protocols.

Your Data Protection Rights

You have rights under the Data Protection Act, 2019, including the right to access, rectify, erase, restrict processing, object to processing, and data portability. To exercise your rights, please contact our Data Protection Committee.

Contact Us



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If you have any questions or concerns about this privacy notice or our data processing practices, please contact our Data Protection Committee dpc@gerties.org