HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

1 NOV 2026

CLINICAL TRIALS GUIDANCE

CONSENT REQUIREMENTS FOR CLINICAL TRIALS INVOLVING COLLECTION OF HUMAN TISSUE

GN-CT-15 Rev. No. 003

HSA Health Sciences Authority

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action / decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

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REVISION HISTORY

Guidance Version (Version Date)

GN-IOCTB-15 Rev. No. 001 (01 Jul 2021)

GN-IOCTB-15 Rev. No. 002 (01 Oct 2021)

GN-CT-15 Rev. No. 003 (1 Nov 2026)

SUMMARY OF AMENDMENTS

- Administrative changes due to HSA re-organisation

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1. INTRODUCTION

1.1. Purpose

The purpose of this document is to provide guidance to sponsors and investigators on the information to be provided to trial participants as part of the informed consent process, prior to collecting human tissue in clinical trials regulated under the Health Products Act and the Medicines Act.

1.2. Background

Informed consent is a fundamental ethical and legal requirement in clinical trials. Freely given informed consent should be obtained from every trial participant prior to clinical trial participation. The Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations specify the consent requirements for clinical trials.

In most clinical trials, human tissue (e.g., blood, biopsy samples) is collected from trial participants and used for various trial-related purposes, including eligibility assessment, safety monitoring and to meet trial objectives as specified in the clinical trial protocol. To safeguard the rights, safety and well-being of trial participants, it is good ethical practice to ensure that informed consent for tissue collection is obtained and the subsequent use of the tissue is in accordance with the consent provided.

This guidance was first developed to specify the additional information to be provided to trial participants prior to obtaining consent for the collection of human tissue in a clinical trial, and had applied to new clinical trial applications submitted to HSA from 1 August 2021. This was to ensure that trial participants are fully informed prior to giving consent to provide tissue in clinical trials. The Human Biomedical Research Act (HBRA), in part, articulates the general principles of proper consent for tissue collection and use to safeguard the rights, safety and well-being of trial participants. For consistency, and as far as is relevant and appropriate to clinical trials, the consent elements stipulated in this guidance are aligned with the consent elements prescribed in the HBRA.

The Health Products (Clinical Trials) Regulations was subsequently amended to specify the additional information to be provided to trial participants prior to obtaining consent for the collection of tissue, for the purposes of the regulated clinical trial, with effect from 1 October 2021.

In some instances, additional tissue samples are collected from trial participants for purposes outside of the regulated clinical trial (e.g., for biobanking or for future unspecified research). The Health Products (Clinical Trials) Regulations and this guidance do not cover the consent requirements for leftover tissue, or additional tissue collected, from trial participants for such purposes outside of the regulated clinical trial. Sponsors and investigators who plan to collect, store, supply or use leftover tissue samples, or collect and store additional tissue samples, from trial participants for research purposes outside of the regulated trial should additionally comply with the relevant requirements of the Human Tissue Framework under the Human Biomedical Research Act..

1.3. Scope

This guidance applies to the collection of tissue from trial participants for the purposes of the following clinical trials (referred to in this guidance as "regulated clinical trials"):

(i) Clinical trials of Therapeutic Products[1] or Class 2 Cell, Tissue and Gene Therapy Products (CTGTPs)[1,2] that are subject to the requirements of a Clinical Trial Authorisation (CTA) or a Clinical Trial Notification (CTN);

(ii) Clinical trials of Medicinal Products[3] that are subject to the requirements of a Clinical Trial Certificate (CTC).

2. DEFINITIONS

"Human tissue" or "tissue", for the purposes of this guidance, means any human biological material obtained from the human body, consisting of or including human cells, but excludes the following:

- hair shaft, cut without dermal hair root or follicle,
- nail plate, cut without underlying dermal tissue,
- naturally excreted bodily fluids and waste products such as saliva, sweat, urine and faeces.

[1] Therapeutic Product and CTGTP are defined in the First Schedule of the Health Products Act.

[2] Class 1 and Class 2 CTGTP are defined in the Health Products (Cell, Tissue and Gene Therapy Products) Regulations.

- Class 1 CTGTP means a CTGTP that —
  (a) is the result of only minimal manipulation of human cell or tissue;
  (b) is intended for homologous use;
  (c) is not combined or used with a therapeutic product or a medical device; and
  (d) is assigned by HSA as a Class 1 CTGTP due to a lower health risk to a user of the product.
- Class 2 CTGTP means a CTGTP other than a Class 1 CTGTP.

[3] Medicinal Product is defined in the Medicines Act.

3. CONSENT ELEMENTS FOR THE COLLECTION OF HUMAN TISSUE FROM CLINICAL TRIAL PARTICIPANTS FOR THE PURPOSES OF THE REGULATED CLINICAL TRIAL

Regulation 19(1) of the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations prescribe consent elements for clinical trials.

Regulation 19(1)(a) to (t) specify consent elements for all clinical trials. **In addition,** the following information should be provided to potential trial participants or their legal representatives for **clinical trials involving the collection of human tissue** [Regulation 19(1)(ta)]:

(a) that the provision of the tissue is voluntary, and the renunciation of the trial participant's rights to the tissue and any intellectual property rights that may be derived from the tissue;

(b) whether the trial participant would wish to be re-identified in the case of an incidental finding relating to the collected tissue if the clinical trial expressly provides for such re-identification;

(c) whether the tissue will be exported or removed from Singapore to a place outside Singapore.

4. COLLECTION, STORAGE, SUPPLY OR USE OF ADDITIONAL HUMAN TISSUE / LEFTOVER HUMAN TISSUE FOR PURPOSES OUTSIDE OF THE REGULATED CLINICAL TRIAL

The collection, storage, supply or use of additional/leftover human tissue from trial participants for purposes outside of the regulated clinical trial (e.g., for biobanking or for future unspecified research) should comply with the relevant requirements of the Human Tissue Framework under the Human Biomedical Research Act (HBRA). Please refer to the HBRA webpage (https://go.gov.sg/hsa-hbra) for more information.

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