

HEALTH
SCIENCES
AUTHORITY

REGULATORY GUIDANCE

01 JUL 2021

CLINICAL TRIALS GUIDANCE

CONSENT REQUIREMENTS FOR CLINICAL TRIALS
INVOLVING COLLECTION AND USE OF HUMAN TISSUE

GN-IOCTB-15 Rev. No. 001



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.

CONTACT INFORMATION

For further information, please contact:

Innovation Office & Clinical Trials Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way, #11-01, Helios
Singapore 138667

Email: HSA_CT@hsa.gov.sg

Website: www.hsa.gov.sg

REVISION HISTORY

Guidance Version (Version Date)

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

SUMMARY OF AMENDMENTS

This section is not applicable.

TABLE OF CONTENTS

1. INTRODUCTION	4
1.1. Purpose.....	4
1.2. Background	4
1.3. Scope	5
2. DEFINITIONS	5
3. CONSENT ELEMENTS FOR CLINICAL TRIALS INVOLVING COLLECTION AND USE OF HUMAN TISSUE FROM CLINICAL TRIAL PARTICIPANTS	6
4. IMPLEMENTATION TIMELINES	7

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 research 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 has been developed to specify the consent elements for clinical trials that involve the collection and use of human tissue. This ensures 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.

1.3. Scope

This guidance applies to clinical trials regulated by HSA:

- (i) Clinical trials of Therapeutic Products¹ 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 Products³ 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 CLINICAL TRIALS INVOLVING COLLECTION AND USE OF HUMAN TISSUE FROM CLINICAL TRIAL PARTICIPANTS

Regulation 19(1) of the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations prescribe consent elements for clinical trials. This includes specific consent elements [Regulation 19(1)(a) to (t)] (“Specific Consent Elements”), as well as any other information that HSA may require to be given to potential trial participants, trial participants or their legal representatives [Regulation 19(1)(u)].

For the purposes of Regulation 19(1)(u) of the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations, the following information should be provided to potential trial participants or their legal representatives for **clinical trials involving the collection of human tissue, in addition to** the Specific Consent Elements:

- (a) 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 use of the tissue;
- (b) whether the tissue taken from the trial participant will be destroyed, discarded or stored and used for future research⁴;
- (c) where applicable, whether the trial participant’s individually-identifiable information will be used for future research⁴;
- (d) whether the trial participant would wish to be re-identified in the case of an incidental finding relating to the collected tissue if the research expressly provides for such re-identification;
- (e) whether the tissue will be exported or removed from Singapore to a place outside Singapore.

⁴ Please note that tissue banking activities for future unspecified research are required to comply with the relevant requirements of the Human Tissue Framework under the Human Biomedical Research Act (HBRA), administered by the Ministry of Health. Please refer to the HBRA webpage (<https://www.moh.gov.sg/policies-and-legislation/human-biomedical-research-act>) for more information.

Clinical trial sponsors and investigators should ensure that the subsequent use of the tissue is in accordance with the consent provided.

4. IMPLEMENTATION TIMELINES

This guidance applies to new clinical trial applications submitted to HSA from 1 August 2021.

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

CONTACT INFORMATION:

Innovation Office & Clinical Trials Branch
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03, Helios
Singapore 138667
Email: HSA_CT@hsa.gov.sg
Website: www.hsa.gov.sg

