Updates to the Health Products Act

Required Consent Elements for Clinical Trials Involving the Collection of Tissue From The Subject for Use in the Trial

Group Research

National Healthcare Group

v22 Oct 2021

You are strongly advised to:

- **Read the Health Products Act, Health Products (Clinical Trials) Regulations 2016 – version in force from 1 October 2021, the Regulatory Guidance and other applicable regulations/Acts/guidance (where applicable).**
- **Follow/ seek advise from your respective IRBs with regards to the submissions and the application processes for your research applications.**

Consent Elements for the Collection of Human Tissue In Clinical Trials (1/3)

Background

In most clinical trials, human tissue (e.g., blood, biopsy samples) is collected from subjects and used for various trial-related purposes. To safeguard the rights, safety and well-being of subjects, 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.

In July 2021, HSA first developed a **Clinical Trials Guidance – Consent Requirements For Clinical Trials Involving Collection of Human Tissue** to specify the additional information to be provided to subjects prior to obtaining consent for the collection of human tissue in clinical trials, and had applied to new clinical trial applications submitted to HSA **from 1 Aug 2021**.

Consent Elements for the Collection of Human Tissue In Clinical Trials (2/3)

Background

The new consent requirements applies to the following studies regulated by HSA:

(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).

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.

The **Clinical Trials Guidance – Consent Requirements For Clinical Trials Involving Collection of Human Tissue** was also updated (Version: 01 Oct 2021) to align with the HPA updates.

Consent Elements for the Collection of Human Tissue In Clinical Trials (3/3)

References:

i) Health Products (Clinical Trials) Regulations 2016, Regulation 19(1)(ta)

ii) HSA Clinical Trials Guidance - Consent Requirements for Clinical Trials Involving Collection of Human Tissue (GN-IOCTB-15 Rev. No.002, 01 Oct 2021)

The following information should be provided to potential trial participants or their legal representatives **for clinical trials involving the collection of human tissue**:

> (*ta*) where the trial involves the collection of tissue from the subject for use in the trial —
>
> (i) that the provision of the tissue is voluntary, and the renunciation of the subject's rights to the tissue and any intellectual property rights that may be derived from the tissue;
>
> (ii) whether the tissue will be exported or removed from Singapore to a place outside Singapore; and
>
> (iii) whether the subject would wish to be re-identified in the case of an incidental finding, if the clinical trial expressly provides for such re-identification;
>
> *[S 731/2021 wef 01/10/2021]*

Note: For consistency, and as far as is relevant and appropriate to clinical trials, the consent elements stipulated in the HPA and HSA Clinical Trials Guidance are aligned with the consent elements prescribed in the HBRA.

Definition of Human Tissue

References:

i) HPA (Clinical Trials) Regulations 2016 (Version in force 01 Oct 21), section 19(4)

ii) HSA Clinical Trial Guidance - Consent Requirements for Clinical Trials Involving Collection of Human Tissue [GN-IOCTB-15 Rev. No. 002, 1 October 2021]

"tissue" means any human biological material but does not include —

(*a*) any hair shaft that is cut without the dermal hair root or follicle;

(*b*) any nail plate that is cut without the underlying dermal tissue; or

(*c*) any naturally excreted bodily fluid or waste products.

[S 731/2021 wef 01/10/2021]

NHG DSRB Informed Consent Template (1/3)

Required Consent Element	Location of Sample Statements in the NHG DSRB Informed Consent Form Template
Provision of the tissue is voluntary, and the renunciation of the subject's rights to the tissue and any intellectual property rights that may be derived from the tissue **References: HPA (Clinical Trials) Regulations 2016 (Version in force 01 Oct 21), section 19(1)(ta)(i);** **HSA Clinical Trial Guidance - Consent Requirements for Clinical Trials Involving Collection of Human Tissue [GN-IOCTB-15 Rev. No. 002, 1 October 2021]**	Investigators can refer to **Section 11. Voluntary Participation** *Example:* ➢ **Voluntary -**"Your participation in this study is voluntary. You may stop participating in this study at any time…" ➢ **Renunciation of rights to tissue –** "The biological samples collected for the study will be deemed to be gifted to *(name of institution/sponsor)* and will not be returned to you. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if the biological sample(s) is individually-identifiable and has not been used…" ➢ **Renunciation of any intellectual Property rights -** "You will also not have any right or claim to any share in the commercial gain derived from the research (if any)…"

***Note:** If the collection of tissue is an **optional** component of the current research study, then investigators should highlight this clearly to participants and obtain their separate consent.

NHG DSRB Informed Consent Template (2/3)

Required Consent Element	Location of Sample Statements in the NHG DSRB Informed Consent Form Template
Whether the tissue will be exported or removed from Singapore to a place outside Singapore; **References: HPA (Clinical Trials) Regulations 2016 (Version in force 01 Oct 21), section 19(1)(ta)(ii);** **HSA Clinical Trial Guidance - Consent Requirements for Clinical Trials Involving Collection of Human Tissue [GN-IOCTB-15 Rev. No. 002, 1 October 2021]**	Investigators can refer to **Section 13. Confidentiality of Study and Medical Records**. *Example:* ➢ **For studies with no tissue exported/removed from Singapore –** "Any biological samples and/or information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will not be transferred out of Singapore…" ➢ **For studies with anonymised tissue exported/removed from Singapore –** "Any biological samples and/or information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will be stored in Singapore. Only anonymised biological samples and/or data will be transferred out of Singapore to *(Insert Name of overseas collaborator/company)*…"

NHG DSRB Informed Consent Template (3/3)

Required Consent Element	Location of Sample Statements in the NHG DSRB Informed Consent Form Template
Whether the subject would wish to be re-identified in the case of an incidental finding, if the clinical trial expressly provides for such re-identification **References: HPA (Clinical Trials) Regulations 2016 (Version in force 01 Oct 21), section 19(1)(ta)(iii);** **HSA Clinical Trial Guidance - Consent Requirements for Clinical Trials Involving Collection of Human Tissue [GN-IOCTB-15 Rev. No. 002, 1 October 2021]**	Investigators can refer to **Section 3. What procedures will be followed in this study**. *Example:* ➢ **For studies with no anticipated or unanticipated incidental findings –** "Incidental findings" are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. There will not be any incidental findings arising in this research…" ➢ **For studies with incidental findings -** 'During the course of the study, there is a possibility that we might unintentionally come to know of new information about your/your child's health condition from *(e.g. the imaging scans etc.)* that is/are conducted as part of the study. These are called "incidental findings"…"

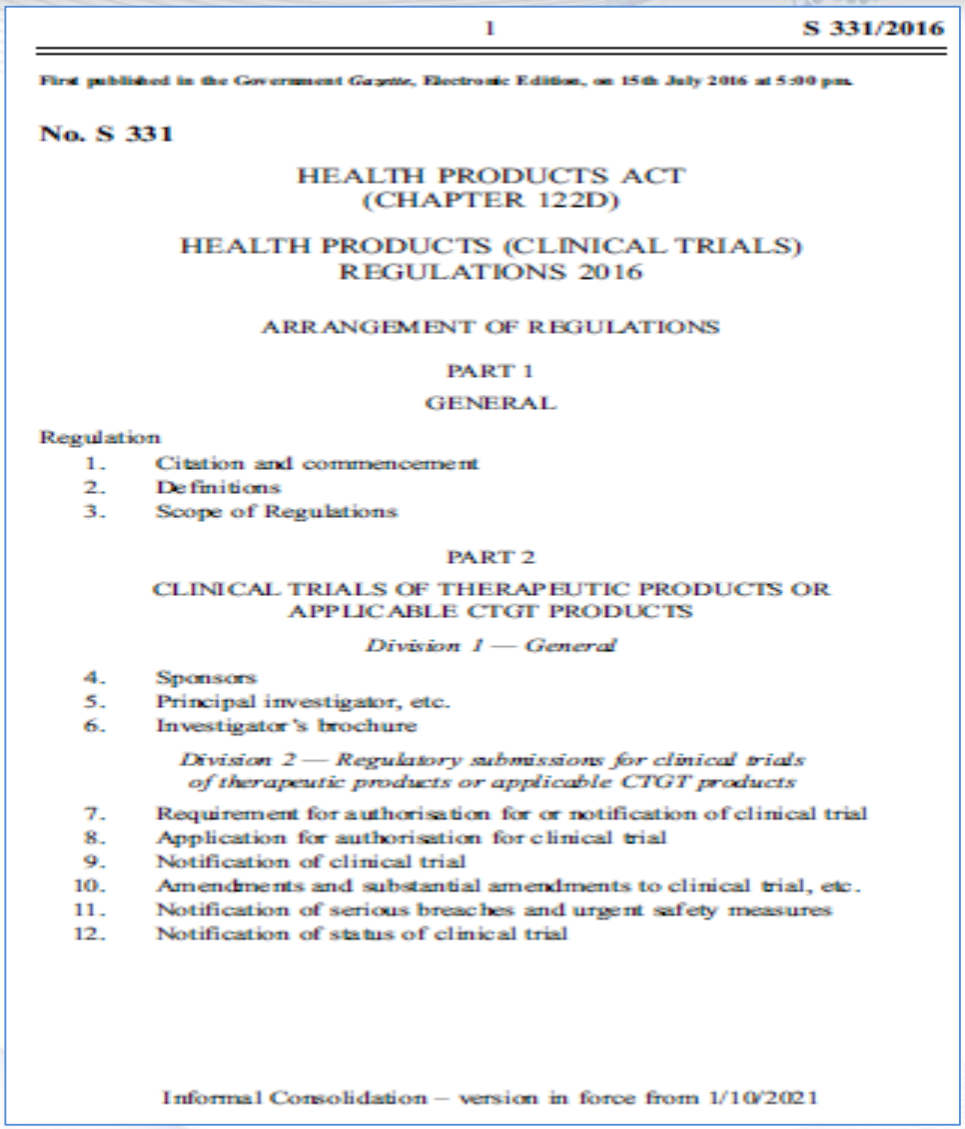
***Note:** Consent document should allow participants to indicate their preferences to be informed of incidental findings (if any).

Important Note

Reference: HSA Clinical Trials Guidance - Consent Requirements for Clinical Trials Involving Collection of Human Tissue (GN-IOCTB-15 Rev. No.002, 01 Oct 2021)

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), 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.

Reference



1 S 331/2016

First published in the Government Gazette, Electronic Edition, on 15th July 2016 at 5:00 pm.

No. S 331

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (CLINICAL TRIALS) REGULATIONS 2016

ARRANGEMENT OF REGULATIONS

PART 1

GENERAL

Regulation

1. Citation and commencement
2. Definitions
3. Scope of Regulations

PART 2

CLINICAL TRIALS OF THERAPEUTIC PRODUCTS OR APPLICABLE CTGT PRODUCTS

Division 1 — General

4. Sponsors
5. Principal investigator, etc.
6. Investigator's brochure

Division 2 — Regulatory submissions for clinical trials of therapeutic products or applicable CTGT products

7. Requirement for authorisation for or notification of clinical trial
8. Application for authorisation for clinical trial
9. Notification of clinical trial
10. Amendments and substantial amendments to clinical trial, etc.
11. Notification of serious breaches and urgent safety measures
12. Notification of status of clinical trial

Informal Consolidation – version in force from 1/10/2021

For more information, download a copy of the HPA regulations from https://sso.agc.gov.sg/SL/HPA2007-S332-2016

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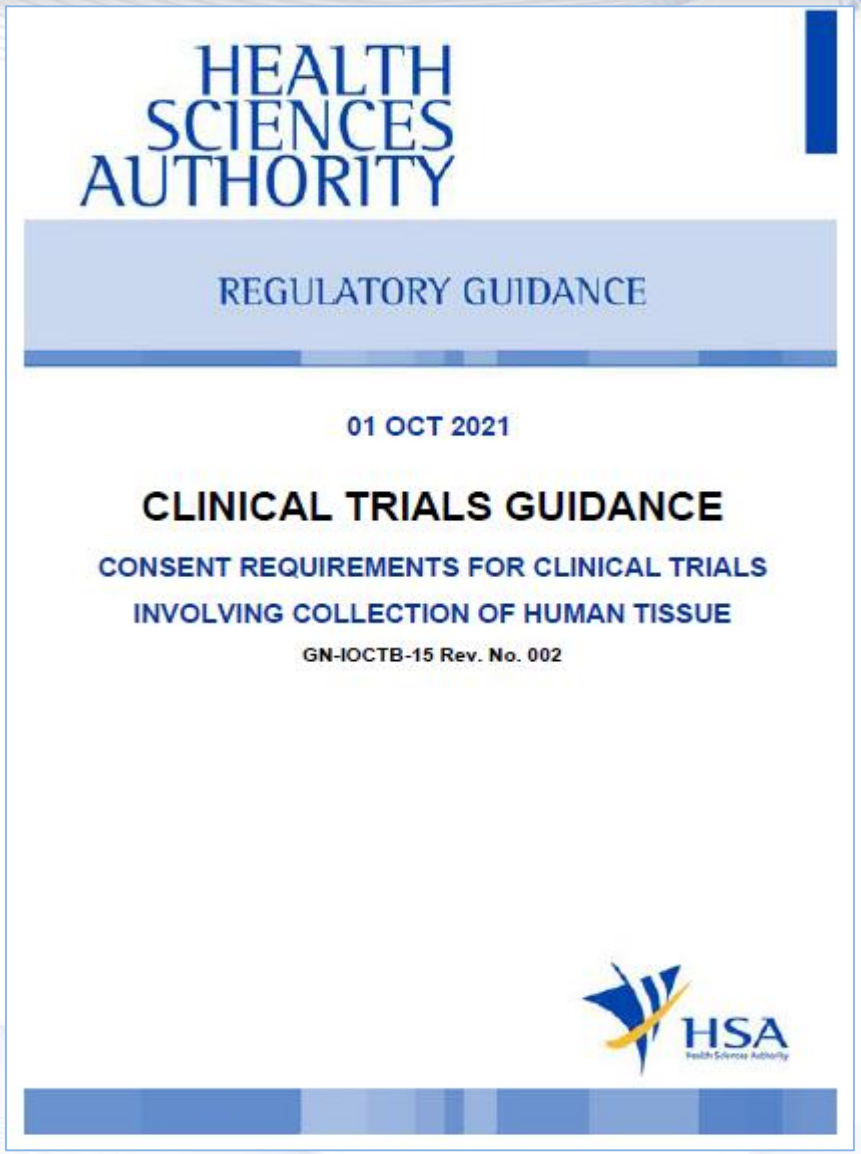
Reference



For more information, download a copy of the guidance from HSA website.

CONTACT INFORMATION

For further information, please contact:

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Credits

THANK YOU FOR YOUR KIND ATTENTION

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