This Informed Consent Form is for patients who undergo percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) by Japanese experts.
The title of our research project is**" *Japanese CTO-PCI Expert Registry"***

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Japanese board of CTO interventional specialist
(General Incorporated Association)

Introduction

Clinical research is the scientific examination of both preventative and therapeutic treatments, carried out with the co-operation of members of the public, including patients. Almost all therapies available in modern medicine have undergone this process and are, for the most part, gradually improved upon as trials progress over a period of months or years. For efficacious therapy to be available to a wide patient demographic, clinical investigation is still required in areas yet to be clarified. As a result, the cooperation of a large amount of individuals is essential, starting with you.

The purpose of the CTO- PCI expert registry

This registered study aims to establish a standardised treatment protocol for chronic total occlusion (CTO) by percutaneous coronary intervention (PCI), through a case registry of patients with CTO treated by PCI by Japanese physicians both domestically and abroad.

Participation eligibility

Eligibility is limited to patients with CTO who underwent PCI treatment from July 2013 and thereafter, by a physician certified by the Japanese Specialist Association on Chronic Total Occlusion Intervention (General Incorporated Association) (Approximately 1000 – 2000 cases annually).

Study involvement for participants

Following treatment with PCI, your clinical data will be registered. In this instance, we may contact the facility, at which you received PCI treatment, to obtain information about your medical condition.

Study duration

July 2013 to December 2027 inclusive

Ethics

This registered study is an investigator-initiated, multi-centre study of PCI treatment for patients with CTO, undertaken with the cooperation of approximately 30 expert Japanese physicians, under the coordinating research body, the Japanese Specialist Association on Chronic Total Occlusion Intervention (General Incorporated Association). This study, to be conducted with patient welfare as first priority, is in adherence with the internationally recognised Declaration of Helsinki guidelines regarding ethical principles for medical research involving human subjects, and Japanese ethical guidelines for clinical and epidemiological studies.

Your personal information

Information about participating patients in this registered study (e.g. the patient's name) will be stored by the research administrator under strict safeguards. The results of this study will be provided to other organisations; however the utmost care will be taken to prevent the disclosure of personal information.

Announcement of results

The results of this trial will be announced publicly (e.g. to academic societies). However, any information leading to the possible identification of participants will not be released.

Sources of funding and conflict of interest

Conflict of interest refers to a position of vested interest that influences the outcomes of research, may it be financial, personal or otherwise. Funding for this study includes membership dues and medical-related corporate donations to the coordinating research body; however in no way does this affect the planning, implementation or the announcement of results for this study.

Patent rights

In the instance where the outcomes of this study result in the acquisition of a patent, such rights will belong to the coordinating research body.

Secondary utilisation of data

In the instance where further research is established based on the results of this study (data from participants), the ethical compliance of the new research body will be investigated. Furthermore, the objectives, methods and other details of the new study will be publicised on the website of the coordinating research body (see below). For those who do not wish for their data to be utilised, we require your notification.

Freedom to withdraw from research

Your decision to consent and offer your cooperation for this study must be based entirely on your own free will. You will not be coerced against your will. Non-consent will not result in any harm to your welfare. You are free to withdraw your consent at any time throughout the study without penalty.

If you wish to participate in this study, please complete the attached letter of consent.

Researcher and contact details

Name of operator:_____

Facility: _____

Coordinating research body

Japanese board of CTO interventional specialist

(General Incorporated Association)

Website: https://www.ctopci.com/

Research administration

Kurashiki Clinical Research Institute

1-1-1 Miwa, Kurashiki, Okayama 710-8602

Japanese CTO- PCI Expert Registry Office

Email: cto.e.registry@gmail.com

Facility _____

ID _____

Participant name _____

Certificate of Consent

I have read and thoroughly understand the information in this informed consent document for ***"Registry for CTO-PCI by Japanese Experts".*** I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care. I hereby voluntarily wish to participate in this study, decided upon without coercion.
I also agree to accept a copy of this document.

Printed Name of Participant _____

Signature of Participant _____

Date _____ (Day/month/year)

CONSENT FOR STUDY PARTICIPANT WHO CANNOT READ OR WRIGHT

The study participant has indicated that he/she is unable to read or write. I have witnessed the accurate reading of the consent form to the patient, and the patient has had the opportunity to ask questions. I confirm that the patient has given consent freely.

Printed Name of witness _____

Signature of witness _____

Date _____ (Day/month/year)

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the following:

☐ The purpose of the CTO- PCI expert registry	☐ Participation eligibility & Study duration
☐ Study involvement for participants	☐ Ethics
☐ Your personal information	☐ Announcement of results
☐ Sources of funding and conflict of interest	☐ Patent rights
☐ Secondary utilisation of data	☐ Freedom to withdraw from research

I confirm that the patient was given an opportunity to ask questions about the study, and he/she gave consent freely and voluntarily.
A copy of this Informed Consent Form has been provided to the participant.

Printed Name of Physician _____

Signature of Physician _____

Date: _____ (Day/month/year)