

Provisional Translation (as of March 2026)*

Administrative Notice
November 27, 2025

To: Pharmaceuticals and Medical Devices Agency

Research and Development Division,
Health Policy Bureau,
Ministry of Health, Labour and Welfare

Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare

Utilization of Sample Informed Consent Form and Assent Form in Pediatric Clinical
Trials (Request)

Please be informed that the notification on the topic in the title has been sent to the directors of prefectural health departments (bureaus) and heads of pharmaceutical organizations as shown in the attached copy.

* This English document has been prepared for reference purposes only. In the event of any inconsistency and discrepancy between the Japanese original and the English translation, the Japanese text shall prevail.



HPB/RDD Notification No. 1127-1
PED/PSB Notification No. 1127-3
November 27, 2025

To: Directors of Prefectural Health Departments (Bureaus)

Director, Research and Development Division,
Health Policy Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Director, Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Utilization of Sample Informed Consent Form and Assent Form in Pediatric Clinical
Trials (Request)

Thank you very much for your cooperation in the pharmaceutical administration.

The Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare is promoting the development of pediatric drugs through the "Pediatric Drug Development Network Support Project" to resolve the drug lag/drug loss of pediatric drugs that becomes serious.

This project has been implemented as a project of the Ministry of Health, Labour and Welfare from 2020. The purpose of the project is to compile a list to support the development of pediatric drugs, make requests for development to pharmaceutical companies, etc., support the conduct of clinical trials at companies (selection of study sites, advice on consultation, etc.), and support the smooth conduct of clinical trials through the utilization of various networks related to pediatric clinical trials, based on the situation where the development of pediatric drugs is desired in our country.

Now, the Japan Pediatric Society, National Center for Child Health and Development, and Pediatric Clinical Trials Network's Pediatric CRC Working Group have revised and released the "Sample Informed Consent Form and Assent Form in Pediatric Clinical Trials" based on the opinions of not only medical institutions (CRCs, etc. familiar with pediatric clinical trials) and experts (ethics and Japanese-language education) but also children (elementary and junior high school students), etc. in order to standardize informed consent forms and assent forms for pediatric clinical trials (see the following URL). The effort for standardization of Informed Consent Form/Assent Form for Pediatric Study (hereinafter "Pediatric ICF/IAF") has no precedent in the world, and Japan takes the lead in this effort.

Common formats of written information and informed consent form have been notified in the "Utilization of common formats of written information and informed consent form in clinical trials (Request)" (HPB/RDD Notification No. 0704-1/PSB/PED Notification No. 0704-2 dated July 4, 2024. Joint notification issued by the Directors of the Research and

Development Division, Health Policy Bureau and Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare). On the other hand, the Pediatric ICF/IAF is composed from the viewpoint of patients, and it provides useful sample documents to conduct pediatric clinical trials, such as preparing the documents in pairs assuming that a legally acceptable representative and a patient hear the explanation together. So, please use an appropriate template depending on the clinical study to be conducted.

Medical institutions, pharmaceutical companies, etc. that are not members of the Pediatric Clinical Trials Network can also use the templates on a voluntary basis. So, please inform medical institutions and related business operators under your jurisdiction of the sample documents so that they can consider their active use.

○ Where to post "Sample Informed Consent Form and Assent Form in Pediatric Clinical Trials" (website of the Pediatric Clinical Trials Network)

<https://pctn-portal.ctdms.ncchd.go.jp/service/agree/>



HPB/RDD Notification No. 1127-2
PSB/PED Notification No. 1127-4
November 27, 2025

To:

President of the Federation of Pharmaceutical Manufacturers' Associations of JAPAN
President of the Japan Pharmaceutical Manufacturers Association
Chairperson of the Japan-Based Executive Committee of the Pharmaceutical Research and Manufacturers of America
President of the European Federation of Pharmaceutical Industries and Associations
Chairman of the Japan CRO Association
Chairman of the Japan Association of Site Management Organizations

Director, Research and Development Division,
Health Policy Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Director, Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Utilization of Sample Informed Consent Form and Assent Form in Pediatric Clinical Trials (Request)

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Medical institutions, pharmaceutical companies, etc. that are not members of the Pediatric Clinical Trials Network can also use the templates on a voluntary basis. So, we would like to ask your special consideration to inform corporate members, companies, etc. under your jurisdiction of the sample documents so that they can consider their active use.

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