

Provisional Translation (as of August 2025).

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

PSEHB Notification No. 0831-7

August 31, 2020

To: Prefectural Governors

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

Notifications of Clinical Trial Plans, etc. for Processed Cells, etc.

Notifications, etc. of the plans, etc. of clinical trials for processed cells, etc. to be conducted by persons who intend to sponsor clinical trials or persons who intend to be sponsor-investigators have been handled in accordance with the “Notifications, etc. of Clinical Trial Plans, etc. for Processed Cells, etc.” (PFSB Notification No. 0812-26 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated August 12, 2014, hereinafter referred to as the “previous Director-General Notification”). With the enforcement of the Ministerial Ordinance on the Development of Related Ministerial Ordinances in Accordance with Enforcement of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Ordinance No. 155 of Ministry of Health, Labour and Welfare in 2020), the following provisions have been developed for the notifications of the plans, etc. of clinical trials for processed cells, etc. to be conducted by persons who intend to sponsor clinical trials and persons who intend to be sponsor-investigators. Please inform related businesses, medical institutions, etc. under your jurisdiction of this matter and provide instructions to them for proper implementation of operations with attention to the following content.

Note

1 Notifications of clinical trial plans

- (1) Persons who intend to sponsor clinical trials or persons who intend to be sponsor-investigators must submit notifications for plans for clinical trials related to processed cells, etc. that are expected to be regenerative medical products (cells of humans or animals cultured or processed in any other way or cells of humans or animals that contain genes transferred into them and expressed in their bodies; the same applies hereinafter) in compliance with Article 80-2, Paragraph 2 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and

Medical Devices (Act No. 145 of 1960; hereinafter referred to as the “Act”) and Article 275-2 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Ministry of Health and Welfare Ordinance No. 1 of 1961; hereinafter referred to as the “Regulation”).

- (2) Notifications of plans for clinical trials to be conducted by persons who intend to sponsor clinical trials or persons who intend to be sponsor-investigators shall be made by using Attached Form 1, in accordance with the provisions of Article 269 of the Regulation that are applied with modifications in Article 275-4 of the Regulation and by attaching a summary of study results related to the safety, indications, performance, etc. of the test product concerned, other information on the test product concerned, and the reason for judging the request for the clinical trial as scientifically valid. However, when foreign manufacturers request clinical trials in Japan, the clinical trial plans shall be notified using Attached Form 2.
- (3) When the notifier of a clinical trial plan has changed matters related to the notification pursuant to the provisions of Article 270, which are applied with modifications in Article 275-4 of the Regulation, or has discontinued or completed the clinical trial related to the notification, the notifier should submit the notification of the change, discontinuation, or completion using Attached Forms 3, 5 or 7, respectively. When a foreign manufacturer who submitted a clinical trial notification as described in (2) above has changed matters related to the notification or has discontinued or completed the clinical trial related to the notification, the manufacturer should submit the notification of the change, discontinuation, or completion using Attached Forms 4, 6 or 8, respectively.
- (4) A person who intends to sponsor a clinical trial or a person who intends to be a sponsor-investigator is allowed to submit the notification for a clinical trial plan after the start of the trial based on the provisions of Article 272 of Regulation that are applied with modifications in Article 80-2, Paragraph 2 of the Act and Article 275-4 of Regulation, if the clinical trial meets all the following criteria. However, for this clinical trial, the notification of the clinical trial plan must be submitted within 30 days after the start of the clinical trial pursuant to Article 80-2, Paragraph 2 of the Act.
 - A The processed cells, etc. concerned need to be urgently used to prevent diseases that may significantly affect the life and health of subjects and other health hazards, and there is no appropriate method other than the use of the processed cells, etc. concerned.
 - B Marketing, etc. of the processed cells, etc. concerned have been approved in countries with approval system, etc. for regenerative medical products considered to be at the level equivalent to that in Japan, or the Minister of Health, Labour and Welfare has judged that discontinuation of the clinical trial of the processed cells, etc. concerned is unnecessary after conducting investigations required to prevent the occurrence of health hazards.
 - C A notification of a plan of another clinical trial has been submitted and the clinical trial is being conducted in Japan for the processed cells, etc. concerned. In this case, the person who intends to sponsor the clinical trial or the person

who intends to be the sponsor-investigator should contact the Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare before conducting the clinical trial.

(5) The cells in the description in (4) A above, “processed cells, etc. concerned need to be urgently used to prevent diseases that may significantly affect the life and health of subjects and other health hazards,” shall be processed cells, etc. used in urgent medical care and others considered to be urgently necessary in medical practice.

2 Investigations of clinical trial plans

The former part of Article 80-2, Paragraph 3 of the Act shall apply to the person who intends to sponsor a clinical trial or the person who intends to be a sponsor-investigator for processed cells, etc. expected to be regenerative medical products who makes the notification for the processed cells, etc. (to be studied in the clinical trial subject to this notification) for the first time. In this case, the clinical trial is subject to the investigations of clinical trial plans pursuant to the provisions of the latter part of the same paragraph.

A violation of this provision shall be established when the clinical trial contract is concluded less than 30 days after the date of notification.

3 Application timing

This notification shall apply from September 1, 2020. Until August 31, 2022, notifications may be submitted according to the previous regulations.

4 Abolition of notification

With the application of this notification, the previous Director-General Notification shall be abolished as of August 31, 2022.

Clinical Trial Notification

Clinical trial identification code	Type of clinical trial	Date of initial notification	Number of notifications
	1: Company-sponsored clinical trials 2: Clinical trials conducted by sponsor-investigators		

Category				
Generic name				
Name and address of the manufacturing site or investigational product provider				
Name of component cells and transgenes				
Shape, structure, components, quantity, or nature				
Manufacturing process				
Proposed indication or performance				
Proposed dosage and administration or directions for use				
Outline of clinical trial plan	Objective			
	Planned number of subjects			
	Target disease			
	Dosage and administration or directions for use			
	Study period			
	Reason for the fee			
	Party that bears clinical trial expenses			
	Name and address of medical institution	Name of investigator		
	Name and address of the founder of the IRB			
	Name of subinvestigator	Quantity of study product to be delivered (received)	Planned number of subjects at each medical institution	Other (name of the notifier, etc. of the same plan to be conducted jointly, if any)
	Name of coordinating investigator or member physicians of coordinating committee			
	Name and address of the party entrusted with the conduct (including request and preparation) and management operations of the study and range of operations entrusted			
Remarks				

I hereby notify the clinical trial plan as described above.

Month DD, YYYY

Address: (for a corporation, location of its main office)

Name: (for a corporation, its name and the name of the representative)

(vendor code)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. If the product concerned is an imported one, enter the name of the exporting country, the name of the manufacturer, and the brand name in the exporting country in the manufacturing process column.
3. When all of the required information cannot be entered in the specified column, enter "as per appendix ()" in the column and attach the appendix.
4. Enter the name of the person in charge of the notification and the contact telephone number/fax number in the remarks column.

Clinical Trial Notification (for foreign manufacturers)

Clinical trial identification code	Date of initial notification	Number of notifications

Category				
Generic name				
Name and address of the manufacturing site or investigational product provider				
Name of component cells and transgenes				
Shape, structure, components, quantity, or nature				
Manufacturing process				
Proposed indication or performance				
Proposed dosage and administration or directions for use				
Outline of clinical trial plan	Objective			
	Planned number of subjects			
	Target disease			
	Dosage and administration or directions for use			
	Study period			
	Reason for the fee			
	Party that bears clinical trial expenses			
	Name and address of medical institution		Name of investigator	
	Name and address of the founder of the IRB			
	Name of subinvestigator	Quantity of study product to be delivered (received)	Planned number of subjects at each medical institution	Other (name of the notifier, etc. of the same plan to be conducted jointly, if any)
	Name of coordinating investigator or member physicians of coordinating committee			
	Name and address of the party entrusted with the conduct (including request and preparation) and management operations of the study and range of operations entrusted			
	Clinical trial in-country representative	Address (for a corporation, location of its main office)		
Name (for a corporation, its name and the name of the representative)				
Remarks				

I hereby notify the clinical trial plan as described above.
 Month DD, YYYY

Address: (for a corporation, location of its main office)
 Japanese
 Foreign language
 Name: (for a corporation, its name and the name of the representative)
 Japanese
 Foreign language
(vendor code)
 Clinical trial in-country representative
 Address: (for a corporation, location of its main office)
 Name: (for a corporation, its name and the name of the representative)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When all of the required information cannot be entered in the specified column, enter “as per appendix ()” in the column and attach the appendix.

3. Enter the contact telephone number/fax number of the clinical trial in-country representative in the remarks column.

Notification of Changes in Clinical Trial Plan

Clinical trial identification code	Type of clinical trial	Date of initial notification	Number of notifications
	1: Company-sponsored clinical trials 2: Clinical trials conducted by sponsor-investigators		

Category					
Generic name					
Date of clinical trial notification and number of changes					
Reason for change	Item	Before change	After change	Date of change	Reason for change
Remarks					

I hereby notify the change in the clinical trial plan.

Month DD, YYYY

Address: (for a corporation, location of its main office)

Name: (for a corporation, its name and the name of the representative)

(vendor code)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When all of the required information cannot be entered in the specified column, enter “as per appendix ()” in the column and attach the appendix.
3. Enter the name of the person in charge of the notification and the contact telephone number/fax number in the remarks column.

Notification of Changes in Clinical Trial Plan (for foreign manufacturers)

Clinical trial identification code	Date of initial notification	Number of notifications

Category					
Generic name					
Date of clinical trial notification and number of changes					
Reason for change	Item	Before change	After change	Date of change	Reason for change
Remarks					

I hereby notify the change in the clinical trial plan.

Month DD, YYYY

Address: (for a corporation, location of its main office)

Japanese

Foreign language

Name: (for a corporation, its name and the name of the representative)

Japanese

Foreign language

(vendor code)

Clinical trial in-country representative

Address: (for a corporation, location of its main office)

Name: (for a corporation, its name and the name of the representative)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When all of the required information cannot be entered in the specified column, enter “as per appendix ()” in the column and attach the appendix.
3. Enter the telephone number/fax number of the clinical trial in-country representative in the remarks column.

Clinical Trial Discontinuation Notification

Clinical trial identification code	Type of clinical trial	Date of initial notification	Number of notifications
	1: Company-sponsored clinical trials 2: Clinical trials conducted by sponsor-investigators		

Category					
Generic name					
Date of clinical trial notification					
Timing of discontinuation					
Reason for discontinuation					
Status of subsequent actions					
Status at each medical institution	Name of medical institution	Quantity delivered (received)	Quantity used	Quantity collected/disposed, etc.	Number of subjects
Remarks					

I hereby notify discontinuation of the clinical trial as described above.

Month DD, YYYY

Address: (for a corporation, location of its main office)

Name: (for a corporation, its name and the name of the representative)

(vendor code)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When all of the required information cannot be entered in the specified column, enter “as per appendix ()” in the column and attach the appendix.
3. Enter the name of the person in charge of the notification and the contact telephone number/fax number in the remarks column.

Clinical Trial Discontinuation Notification (for foreign manufacturers)

Clinical trial identification code	Date of initial notification	Number of notifications

Category					
Generic name					
Date of clinical trial notification					
Timing of discontinuation					
Reason for discontinuation					
Status of subsequent actions					
Status at each medical institution	Name of medical institution	Quantity delivered (received)	Quantity used	Quantity collected/disposed, etc.	Number of subjects
Remarks					

I hereby notify the discontinuation of the clinical trial as described above.

Month DD, YYYY

Address: (for a corporation, location of its main office)

Japanese

Foreign language

Name: (for a corporation, its name and the name of the representative)

Japanese

Foreign language

(vendor code)

Clinical trial in-country representative

Address: (for a corporation, location of its main office)

Name: (for a corporation, its name and the name of the representative)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When all of the required information cannot be entered in the specified column, enter “as per appendix ()” in the column and attach the appendix.
3. Enter the telephone number/fax number of the clinical trial in-country representative in the remarks column.

Clinical Trial Completion Notification

Clinical trial identification code	Type of clinical trial	Date of initial notification	Number of notifications
	1: Company-sponsored clinical trials 2: Clinical trials conducted by sponsor-investigators		

Category					
Generic name					
Date of clinical trial notification					
Status at each medical institution	Name of medical institution	Quantity delivered (received)	Quantity used	Quantity collected/disposed, etc.	Number of subjects
Remarks					

I hereby notify the completion of the clinical trial as described above.

Month DD, YYYY

Address: (for a corporation, location of its main office)

Name: (for a corporation, its name and the name of the representative)

(vendor code)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When all of the required information cannot be entered in the specified column, enter “as per appendix ()” in the column and attach the appendix.
3. Enter the name of the person in charge of the notification and the contact telephone number/fax number in the remarks column.

Clinical Trial Completion Notification (for foreign manufacturers)

Clinical trial identification code	Date of initial notification	Number of notifications

Category					
Generic name					
Date of clinical trial notification					
Status at each medical institution	Name of medical institution	Quantity delivered (received)	Quantity used	Quantity collected/disposed, etc.	Number of subjects
Remarks					

I hereby notify the completion of the clinical trial as described above.

Month DD, YYYY

Address: (for a corporation, location of its main office)

Japanese

Foreign language

Name: (for a corporation, its name and the name of the representative)

Japanese

Foreign language

(vendor code)

Clinical trial in-country representative

Address: (for a corporation, location of its main office)

Name: (for a corporation, its name and the name of the representative)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When all of the required information cannot be entered in the specified column, enter “as per appendix ()” in the column and attach the appendix.
3. Enter the telephone number/fax number of the clinical trial in-country representative in the remarks column.