

Provisional Translation (as of April 2019)*

HPB/RDD Notification No. 0710-4
PSEHB/PED Notification No. 0710-2
PSEHB/MDED Notification No. 0710-2
July 10, 2018

To: Commissioner of the Prefectural Health Department (Bureau)

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

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

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

Partial Revision of New “Standard Forms for requesting clinical trials, etc.”

Regarding New “Standard Forms for Requesting Clinical Trials, etc.” (hereinafter, “Standard Forms”), we previously issued “Partial Revision of ‘New Standard Forms for requesting clinical trials, etc.’” (HPB/RDD Notification No. 0701-1/PFSB/ELD Notification No. 0701-1 issued by the Director of the Research and Development Division, Health Policy Bureau and the Director of the Evaluation and Licensing Division of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated July 1, 2014; hereinafter, the “former notification”) to simplify and standardize the forms as well as to ensure efficient conducting of clinical trials and other related activities by promoting compliance with the Standard Forms. To ensure further efficiency of the procedures for clinical trials and other related activities, we have partially revised the Standard Forms as shown in the attachments, including the addition of forms for clinical trials of regenerative medical products in response to the enforcement of “Ordinance on

* This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Good Clinical Practice of Regenerative Medical Products, etc.” (Ordinance of the Ministry of Health, Labour and Welfare No. 89 of 2014) and decided their handling as described below. Please notify the related organizations under your jurisdiction of this Notification.

Description

1. The Standard Forms can be found, along with major changes from the former notification shown in the appendix on “Clinical Trials,” the website of the Ministry of Health, Labour and Welfare (<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/chiken.html>) or on “Standard Forms,” the website of the Center for Clinical Trials, Japan Medical Association (<http://www.jmacct.med.or.jp/plan/gcp.html#panel3>).
2. Revised Standard Forms will be effective on the day of issue of the present notification.
3. All documents specifying Standard Forms may be prepared, issued, and retained as electromagnetic records. Regarding the use of electromagnetic records, see also “Partial Revision of Basic Principles Regarding Utilization of Electromagnetic Records in Clinical Trial-related Documents” (Administrative Notice issued on July 1, 2014 by the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau).
4. Until the clinical trial support system and other related systems compliant with the former notification are ready for the revised Standard Forms, the documents prepared by these systems will also be regarded as those created in accordance with the present notification. For clinical trials of regenerative medical products, the term of Standard Forms should be read as forms based on the former notification, as appropriate.

[Reference]

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“Clinical Trials” page on the website of Ministry of Health, Labour and Welfare
<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/chiken.html>

“Standard Forms” page on the website of the Center for Clinical Trials, Japan Medical Association
<http://www.jmacct.med.or.jp/plan/gcp.html#panel3>

Major Changes from the Former Notification

Major changes from the former notification are as follows:

- 1 Company-sponsored clinical trials/post-marketing clinical studies
 - (1) Revision/abolishment and usage of forms
 - (a) A category for regenerative medical products has been added in Forms 1 to 6, 8 to 11, and 16 to 18 and Reference Forms 1 and 2.
 - (b) Form 12-2 (Serious Adverse Event Report [Clinical Trials of Drugs: For Detailed Description]) and Form 13-2 (Adverse Event Reports [Post-Marketing Clinical Studies of Drugs: For Detailed Description]) have been abolished and integrated into other forms (see [f]).
 - (c) Form 19 (Serious Adverse Event and Malfunction Report [Clinical Trials of Regenerative Medical Products]) and Form 20 (Serious Adverse Event and Malfunction Report [Post-Marketing Clinical Studies of Regenerative Medical Products]) have been added.
 - (d) Form 13-1 (Adverse Event Report [Post-Marketing Clinical Studies of Drugs]) has been replaced by Form 13 (Serious Adverse Event Report [Post-Marketing Clinical Studies of Drugs]), with the scope of reporting modified.
 - (e) Form 15 (Serious Adverse Event and Medical Device Malfunction Report [Post-Marketing Clinical Studies of Medical Devices]) has been replaced by Form 15 (Serious Adverse Event and Medical Device Malfunction Report [Post-Marketing Clinical Studies of Medical Devices]), with the scope of reporting modified.
 - (f) Addition of form for detailed description
In the event of any serious adverse event, an applicable form for detailed description should be attached to Forms 12, 13, 14, 15, 19, and 20 for reporting of detailed information on the subject.
 - (2) Change of information to be included in each form

(a) Both the date of onset of the adverse event and the date on which the event is determined to be serious are now required.

- Applicable forms: Forms 12, 13, 14, 15, 19, and 20

(b) The causal relationship with the adverse event has been changed to “related”/“not related.”

- Applicable forms: Forms 12 and 13 and forms for detailed description

(c) Fully revised and newly created forms

- Applicable forms: Forms 14, 15, 19, and 20

(3) Precautions for completing the Standard Forms

- Revision and description adjustment associated with form revision

2 Investigator-initiated clinical trials

(1) Revision/abolishment and usage of forms

(a) A category for regenerative medical products has been added in (Investigator) Forms 1 to 6, 8, 10, 11, and 16 to 18 and Reference Forms 1 and 2.

(b) (Investigator) Form 12-2 (Serious Adverse Event Report [Clinical Trials of Drugs: For Detailed Description]) has been abolished and integrated into other forms (see [d]).

(c) (Investigator) Form 19 (Serious Adverse Event and Malfunction Report [Clinical Trials of Regenerative Medical Products]) have been added.

(d) Addition of form for detailed description

In the event of any serious adverse event, an applicable form for detailed description should be attached to (Investigator) Forms 12, 14, and 19 for reporting of detailed information on the subject.

(2) Change of information to be included in each form

(a) Both the date of onset of the adverse event and the date on which the event is determined to be serious are now required.

- Applicable forms: (Investigator) Forms 12, 14, and 19

(b) The causal relationship with the adverse event has been changed to

“related”/“not related.”

- Applicable forms: (Investigator) Form 12 and form for detailed description

(c) Fully revised and newly created forms

- Applicable forms: (Investigator) Forms 14 and 19

(3) Precautions for completing the Standard Forms

- Revision and description adjustment associated with form revision