Office of Non-clinical and Clinical Compliance, Pharmaceuticals and Medical Devices Agency

Ver. 3.2 (prepared on July 1, 2022)

**Checklist for GCP[[1]](#footnote-1) On-site Inspection for New Drug (for Medical Institution)**

|  |  |
| --- | --- |
| Name of medical institution |  |
| Name of product to be inspected  <Nonproprietary name> | < > |
| Name of sponsor (company) |  |
| Name of document  to be inspected |  |
| Date of inspection | MMM DD, YYYY |
| Name of inspector |  |

**\* When electromagnetic methods are used to store, prepare, circulate, or provide documents, they shall be processed in accordance with related laws, regulations, notifications, etc.**

<<Reference>> Partial Revision of the New “Standard Forms for requesting clinical trials, etc.”

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

• Use of the Standard Forms at the time of inspection

Used

Not used (Reason for not being used: )

# [I] Outline of Medical Institution

## 1. Qualifications for Medical Institution [Article 35: Also applied retrospectively to clinical trials requested before April 1, 1997][[2]](#footnote-2)

Compliant

Institution Department: , Number of beds:

Number of inpatients: ( ) /year, month or day

Number of outpatients: ( ) /year, month or day

Personnel Number of physicians: ( )

Number of dentists:

Number of pharmacists: , Number of nurses:

Number of laboratory technologists: , Number of radiological technologists:

\* Numbers in the parentheses indicate the situation in the department in charge of the clinical trial.

⚫ Being well equipped with facilities and having sufficient personnel to conduct the necessary clinical observations and laboratory tests.

⚫ Being capable of taking necessary measures for the subject in the event of an emergency.

⚫ Having an institutional review board (IRB) (excluding cases applicable to the exceptional provisions) **Until March 2008** [[3]](#footnote-3).

⚫ Having adequate necessary personnel including investigator, subinvestigators, pharmacists, and nurses, etc.

Other ( )

## 2. Implementation Status of Clinical Trials

\* Numbers in the parentheses indicate the situation in the department in charge of the clinical trial.

While the clinical trial was conducted (YYYY ) Phase I: ( ), Phase II: ( ), Phase III: ( )

Clinical trials conducted in the past 3 years (YYYY ) Phase I: ( ), Phase II: ( ), Phase III: ( )  
(YYYY ) Phase I: ( ), Phase II: ( ), Phase III: ( )  
(YYYY ) Phase I: ( ), Phase II: ( ), Phase III: ( )

## 3. Management System for Clinical Trial Operations

1) Preparation of written operating procedures for the duties related to the clinical trial **[Article 36, Paragraph 1]** **From April 1998**

Compliant

Name:

Effective date of the written operating procedures applicable to the clinical trial period:

MMM DD, YYYY

Administrative procedure

Clinical trial office

Control/Accountability of investigational product(s) (drug[s] used in the clinical trial)

Record keeping

Establishment of a procedure necessary to select an appropriate IRB  
 **[Article 27, Paragraph 1]** From April 2008 (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

Other

Other ( )

2) Necessary measures to ensure that the clinical trial is conducted properly and smoothly  
 **[Article 36, Paragraphs 2 and 3]** **From April 1998**

Compliant

Designation of subinvestigators and clinical research coordinators (see GCP Ministerial Ordinance Article 43, Paragraph 1)

Until March 31, 2012

Approval of the list of subinvestigators and clinical research coordinators   
 From April 1, 2012 (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

Appropriate communication system within the medical institution (see GCP Ministerial Ordinance Article 32, Paragraphs 1, 2, 6, and 7)

Prior communication to the sponsor in case of change in the investigators, etc.   
 From October 2008 (PFSB/ELD Notification No. 1001001 dated October 1, 2008)

Other

Other ( )

3) Appointment of a clinical trial office **[Article 38]** **From April 1997**

Compliant

Organization:

Person in charge:

Involvement of a CRC(s) in the clinical trial: Yes / No

\* If a clinical research core hospital, etc. forms a network with other medical institutions, it is acceptable for the heads of multiple medical institutions to jointly establish a clinical trial office; however, the responsibility shall be borne by the head of each medical institution.

From December 28, 2012 (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

Other ( )

4) Appointment of a person(s) who performs clerical work of the IRB   
 **[From April 1997 until March 2008: Article 28, Paragraph 3; From April 2008: Article 28, Paragraph 4]** From April 1997

Compliant

Person in charge:

Other ( )

5) Outsourcing of part of the duties related to conducting the clinical trial

**[Article 39-2]** **From July 30, 2003**

a Contract

Not applicable

Compliant

Name of contractor: (Date of contract: )

Scope of the duties outsourced (scope of duties: )

Description of the operating procedures for the duties outsourced

Statement that the medical institution can ascertain whether the duties outsourced are conducted properly and smoothly in compliance with the operating procedures specified in the preceding item

Description of the instructions to the contractor

Statement that if the instructions specified in the preceding item are given, the medical institution is entitled to ascertain whether appropriate measures are taken in response to the instructions

Description of the reports to be submitted by the contractor to the medical institution

Other necessary matters related to the duties outsourced

Documents or records (including data) to be retained by the contractor continuously after the completion of the operations and the period of retention

From April 1, 2012 (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

Provision of direct access to all the documents and records (including data) to be retained by the contractor for regulatory inspection(s)

From April 1, 2012 (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

Other ( )

b Preparation of a written procedure(s) by contractor for compensation for trial-related injuries attributable to the duties outsourced

**From July 22, 2004** (PFSB/ELD Notification No. 0722014 dated July 22, 2004)

Not applicable

Compliant

Storage of the written procedures (copy) for compensating the cost necessary for trial-related injuries specified by the contractor and other losses at the medical institution  
 From October 18, 2004 until February 13, 2013 (PFSB Administrative Notice dated October 18, 2004)

Other ( )

6) Cooperation in monitoring, auditing, and investigation by the IRB   
 **[Article 37, Paragraphs 1 and 2]** From April 1998

Compliant

Other ( )

**[II] Institutional Review Board (IRB)**

## 1. Establishment of IRB

While the clinical trial was conducted: Board name

At present:　　　　　　　　　　　 Board name

\* Rationale for establishment:

Until March 2008 **[Until March 2006: Article 27; From April 2006 until March 2008: Article 27, Paragraph 1]**

IRB established inside the medical institution where the clinical trial was conducted **[Article 27]**

IRB established outside the medical institution where the clinical trial was conducted

Established jointly with the head of another medical institution **[proviso in Article 27]**

Established by an organization (public-service corporation) established pursuant to the provisions of Article 34 of the Civil Code **[proviso in Article 27]**

Established by a specified non-profit organization  
 **[proviso in Article 27, Paragraph 1]** From April 2006

Established by an academic society composed of healthcare professionals  
 **[proviso in Article 27]**

Established by the head of another medical institution **[proviso in Article 27]**

IRB established for each clinical trial to be conducted newly  
 **[Article 27, Paragraph 1]** From April 2006 (PFSB/ELD Notification No. 0401001 dated April 1, 2006)

From April 2008 **[Article 27, Paragraph 1]**

IRB established inside the medical institution where the clinical trial was conducted (including an IRB established jointly by the heads of multiple medical institutions and by the head of another medical institution) (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

Established by the head of the medical institution where the clinical trial was conducted

Established jointly by the heads of multiple medical institutions

Established by the head of another medical institution

IRB established outside the medical institution where the clinical trial was conducted

Established by a general incorporated association or general incorporated foundation

Established by a specified non-profit organization

Established by an academic society composed of healthcare professionals

Established by an incorporated educational institution (private university) having a medical institution

Established by an incorporated administrative agency mainly providing medical care.

Established by an incorporated national university having a medical institution

Established by a local incorporated administrative agency (e.g., public university) having a medical institution

## 2. Utilization of Other Institutional Review Boards From April 1997

Not applicable

1) If any IRB other than the IRB established inside the medical institution where the clinical trial was conducted is used, obtainment of the written operating procedures of the board and the list of board members  
**[From April 1997 until March 2006: Article 30, Paragraph 3; From April 2006 until March 2008: Article 30, Paragraph 11; From April 2008: Article 30, Paragraph 8]**

Compliant

Name of the board:

Obtainment of the written operating procedures of the board

Obtainment of the list of board members

\* When seeking opinions of two or more IRBs

Opinions may be sought from other IRBs in addition to the IRB established inside the medical institution where the clinical trial was conducted. **[Article 30, Paragraph 2]** **From April 1997**

The head of the medical institution may seek opinions of two or more IRBs.

**From April 2008** (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

In this case, opinions on continuing review of the clinical trial should also be sought. (PFSB/ELD Notification No. 1001001 dated October 1, 2008)

Expert IRB (reviews and deliberations of specific specialized matters, which are the prerequisites for the determination of the appropriateness of conducting the clinical trial) **[Article 30, Paragraph 4]** **From April 2006**

Report of opinions of the expert IRB to the IRB established inside the medical institution where the clinical trial was conducted. The IRB providing the final opinion is the IRB specified in GCP Ministerial Ordinance Article 30, Paragraph 1. **[Article 32, Paragraph 5]**

Third-party IRB in addition to the IRBs described above **[Article 30, Paragraph 8]** **From April 2006 until March 2008**

2) Conclusion of a contract with the founder of another IRB  
**[From April 2006 until March 2008: Article 30, Paragraphs 2, 6, and 9; From April 2008: Article 30, Paragraphs 2 and 6]** From April 2006

From April 2006 until March 2008

Contract is concluded between the head of the medical institution and the founder of another IRB

From April 2008

Contract is concluded between the head of the medical institution and the founder of another IRB (e.g., IRB established by the head of another medical institution, a general incorporated association or general incorporated foundation, a specified non-profit organization, an academic society composed of healthcare professionals, an incorporated educational institution, an incorporated administrative agency, an incorporated national university, or a local incorporated administrative agency)

\* No contract is required for an IRB established by a corporation having the medical institution where the clinical trial was conducted (e.g., an incorporated educational institution, an incorporated administrative agency, an incorporated national university, or a local incorporated administrative agency) or an IRB established jointly by the head of the medical institution where the clinical trial was conducted and the head of another medical institution.

\* Contents of the contract

Date of concluding the contract: MMM DD, YYYY

Names and addresses of the medical institution and the founder of the IRB

Procedures for the duties related to the contract

Due date when the IRB should give its opinion

Description of maintaining the confidentiality of the subject

Other necessary details

Documents or records (including data) to be retained by the IRB continuously after the completion of the operations and the period of retention  
 From April 1, 2012 (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

Provision of direct access to all the documents and records (including data) to be retained by the IRB for regulatory inspection(s)  
 **From April 1, 2012** (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

\* Prior agreement with the medical institution and the founder of the IRB if the sponsor audits the IRB **[Article 30, Paragraph 2]** From December 28, 2012 (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

From April 2006 until March 2008

Contract is concluded between the head of the medical institution and the founder of an expert IRB

From April 2008

Contract is concluded between the head of the medical institution and the founder of an expert IRB (e.g., IRB established by the head of another medical institution, a general incorporated association or general incorporated foundation, a specified non-profit organization, an academic society composed of healthcare professionals, an incorporated educational institution, an incorporated administrative agency, an incorporated national university, or a local incorporated administrative agency)

\* No contract is required for an IRB established by a corporation having the medical institution where the clinical trial was conducted (e.g., an incorporated educational institution, an incorporated administrative agency, an incorporated national university, or a local incorporated administrative agency) or an IRB established jointly by the head of the medical institution where the clinical trial was conducted and the head of another medical institution.

\* Contents of the contract

Date of concluding the contract: MMM DD, YYYY

Names and addresses of the medical institution and the founder of the expert IRB

Procedures for the duties related to the contract

Scope of specific specialized matters which the expert IRB reviews/deliberates and the due date when the IRB should give its opinion

Description of maintaining the confidentiality of the subject

Other necessary details

Documents or records (including data) to be retained by the expert IRB continuously after the completion of the operations and the period of retention

From December 28, 2012 (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

Provision of direct access to all the documents and records (including data) to be retained by the expert IRB for regulatory inspection(s)

From December 28, 2012 (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

\* If the sponsor audits the expert IRB, prior agreement with the medical institution and the founder of the expert IRB should be made. **[Article 30, Paragraph 6]** From December 28, 2012 (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

3) Satisfying the requirements for establishing an IRB established by a general incorporated association or general incorporated foundation (a corporation established pursuant to the provisions of Article 34 of the Civil Code before November 2008), a specified non-profit organization, or an academic society composed of healthcare professionals **[Article 27, Paragraph 2]** From April 2006

**\* Details shall be confirmed with the GCP Ministerial Ordinance and the Notification of Operation.**

Compliant

The founder of the IRB has provisions that stipulate the establishment of an IRB.

The executive directors of the IRB include at least one healthcare professionals such as physicians, dentists, pharmacists, nurses.

Employees of a certain medical institution and a certain juridical person respectively account for no more than one third of all the executive directors.

The founder of the IRB has a sufficient financial basis to establish and operate the IRB adequately.

The founder of the IRB retains its financial documents in its office and provides the public with access to such documents.

There is no risk of impairment of fair and proper execution of the duties of the IRB.

Other ( )

## 3. Composition of Institutional Review Board [Article 28, Paragraph 1]

Compliant

Being capable of performing fully reviewing the proposed clinical trial from ethical and scientific viewpoints **From April 1998**

Review from ethical, scientific, and medical viewpoints From April 1, 1998 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Review from ethical, scientific, medical, and pharmaceutical viewpoints  
From October 1, 2008 (PFSB/ELD Notification No. 1001001 dated October 1, 2008)

Being composed of at least five members

Having a person(s) other than those who have expertise in medicine, dentistry, pharmaceutical science, other medical care, or clinical trials

Having a person(s) independent of the medical institution **From April 1998**

The head of the medical institution cannot be a member of the IRB established by himself/herself. **From April 1998** (PAB Notification No. 430 dated March 27, 1997)

Having a person(s) independent of the founder of the IRB  
(It may be the same person as the person independent of the medical institution, but it is desirable to have another person or multiple persons.) **From April 2006**

Preferably being composed of both sexes **From April 2006** (PFSB/ELD Notification No. 0401001 dated April 1, 2006)

Other ( )

## 4. List of Members, Written Operating Procedures, Records of IRB Meetings, etc. to be Prepared by Founder of Institutional Review Board

1) Preparation of a list of members **[Article 28, Paragraph 2]** From April 1997

Compliant

The member list includes the professional qualification and affiliation of the members. **[Article 34]** From May 29, 1997 until March 31, 2009 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

The member list includes the occupation, qualification, and affiliation of the members. **[Article 28, Paragraph 3]** From April 1, 2009 (PFSB/ELD Notification No. 1001001 dated October 1, 2008)

If appropriate members are selected from among many candidate members for each clinical trial, the members shall be capable of conducting consistent review and deliberation from the start to the end of each trial **[Article 28, Paragraph 2]** From September 21, 2006 (PFSB/ELD Notification No. 0921001 dated September 21, 2006)

- A majority of the members in the list shall attend the meeting and meet the qualifications stipulated in GCP Ministerial Ordinance Article 28, Paragraph 1. From December 28, 2012 (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

Other ( )

2) Preparation of written operating procedures specifying the following information and implementation of operations in compliance with the written operating procedures **[Article 28, Paragraph 2**]

Compliant

Name:

Effective date of the written operating procedures applicable to the clinical trial period:  
MMM DD, YYYY

\* Provisions From April 1997

Method of appointing a chairperson

Conditions for a regular IRB meeting (The handling of attendance of persons other than medical experts and independent persons shall be clarified.)

Attendance of non-expert members and external members is essential for the conditions for a meeting in principle.  
 From April 1997 until September 15, 2004 (PAB Notification No. 430 dated March 27, 1997)

Attendance of non-expert members and external members is essential for the conditions for a meeting. From September 16, 2004 (PFSB/ELD Notification No. 0916004 dated September 16, 2004)

Attendance of more than half, but at least five, members is required for deliberation and voting.

From July 22, 2004 until August 31, 2020 (PFSB/ELD Notification No. 0722014 dated July 22, 2004)

Attendance of more than half, but at least five, members in the member list is required for deliberation and voting.

From September 1, 2020 (PSEHB/PED Notification No. 0831-15 dated August 31, 2020)

Description of operation of the meeting

Conditions for expedited review of a minor change(s) in an ongoing clinical trial (scope of expedited review, person who makes a judgment, review method, reporting to the next IRB, etc.) (PAB Notification No. 430 dated March 27, 1997)

Determination and notification of the meeting schedule and administration of the meeting From May 29, 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Matters related to opinions of the IRB (approved, approved with modification, rejected, cancelled) From May 29, 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Description of the timing of review on the appropriateness of continuing the clinical trial conducted for more than one year **[Article 31, Paragraph 1]**

Description of records of IRB meetings

Description of records of IRB meetings From April 1997 until March 2008

Description of records and summaries of IRB meetings **From April 2008** (PFSB Notification No.0229011 dated February 29, 2008)

Description of record keeping

Other necessary details

\* Approval of a clinical trial which is a non-therapeutic clinical trial where subject’s consent is difficult From May 29, 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

\* Approval of a life-saving clinical trial in case of emergency  
 From May 29, 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

\* It is appropriate to clarify the matters for which opinions must be given promptly due to the urgency of the matters. **[Article 28, Paragraph 2; Article 32, Paragraph 3]**

From April 2006 (PFSB/ELD Notification No. 0401001 dated April 1, 2006)

Other ( )

3) Preparation of “records of IRB meetings” and “summaries of IRB meeting records” **[Article 28, Paragraph 2]**

Compliant

A “records of IRB meetings” includes not only the results of deliberation (approval, disapproval, etc.) but also a list of members participating in the deliberation and voting and a summary of proceedings. From April 1997 (PAB Notification No. 430 dated March 27, 1997)

Preparation of “summaries of IRB meeting records” From April 2008 (PFSB Notification No.0229011 dated February 29, 2008; PFSB/ELD Notification No. 0326001 dated March 26, 2008)

A “summaries of the IRB meeting records” includes the date and time of the meeting, the place of the meeting, the names of the attending members, the agenda (ingredient code, sponsor name, development phase, target disease name [only for phase III studies]), and a summary of the major discussion including the results of deliberation. (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

A summary of the major discussion shall include not only the results of deliberation but also the main contents such as questions and answers. If there is no particular discussion, it may include only the results of deliberation.

\* For expedited review of a minor change(s) in an ongoing clinical trial, it is not necessary to prepare a summary of the IRB meeting records if it is stipulated in the written operating procedures that the results should be reported to the IRB. (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

Other ( )

## 5. Disclosure of Written Operating Procedures, List of Members, and Summaries of Meeting Records of IRB by its Founder

\* Applicable to the products reviewed by an IRB in and after April 2009 even if the clinical trial was started before April 2009 **[Article 28, Paragraph 3]**

Compliant

\* Matters to be checked (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

Procedures necessary for disclosure have been defined.

The written operating procedures, the list of members, and the summaries of IRB meeting records are disclosed (for public viewing on the website or office of the medical institution).

The list of members includes occupation, qualification, and affiliation.  
However, it is not necessary to describe any qualification for a member who has no special qualification, etc.

The summaries of the IRB meeting records are disclosed after taking measures such as masking if necessary.

If there is any change, the disclosed information is immediately updated and a record is kept so that a history of the change can be checked.

The summaries of the IRB meeting records are disclosed within approximately 2 months after each IRB meeting.

It is desirable to disclose the scheduled date of IRB meetings in advance so that the head of the medical institution can select an appropriate IRB.

Other ( )

## 6. Operation Status of Institutional Review Board

1) Consultation with the IRB about the appropriateness of conducting the clinical trial **[Article 30, Paragraph 1: Also applied retrospectively to data collected or documents prepared before April 1, 1997]**

Compliant

(Date of request: MMM DD, YYYY)

Date of IRB meeting: MMM DD, YYYY

Attendance of non-expert members and external members is essential for the conditions of a meeting in principle. **[Article 28, Paragraph 2]** From April 1997 until September 15, 2004   
 (PAB Notification No. 430 dated March 27, 1997)

Attendance of non-expert members and external members is essential for the conditions for a meeting. **[Article 28, Paragraph 2]** From September 16, 2004   
 (PFSB/ELD Notification No. 0916004 dated September 16, 2004)

Attendance of more than half, but at least five, members is required for deliberation and voting. **[Article 28, Paragraph 2]** From July 22, 2004 until August 31, 2020  
 (PFSB/ELD Notification No. 0722014 dated July 22, 2004)

Attendance of more than half, but at least five, members in the member list is required for deliberation and voting. From September 1, 2020 (PSEHB/PED Notification No. 0831-15 dated August 31, 2020)

Executives or employees of the sponsor, persons who have a close relationship with the sponsor, the head(s) of the medical institution(s), investigators/subinvestigators, and clinical research coordinators shall not participate in the deliberation or voting regarding a clinical trial to be reviewed. **[Article 29, Paragraph 1]** From April 1997

Members who have not participated in the IRB deliberation shall not vote.  
 **[Article 29, Paragraph 2]** From April 1997

Other ( )

2) Review of the appropriateness of the clinical trial and opinions in writing   
 **[Article 32, Paragraph 1]**

Compliant

Date of review: MMM DD, YYYY 　　　(Time of material distribution: )

\* To be reviewed promptly according to the urgency of the matter consulted   
 **[Article 32, Paragraph 3]** From April 2006

\* It is desirable that the trial subject to deliberation is explained by the investigator/subinvestigator.   
 **[Article 29, Paragraph 1]**

From April 2008 (PFSB/ELD No. 0326001 Notification dated March 26, 2008)

Conclusion:  Approved  Approved with modification  Rejected

Description:

Records of the IRB meetings is prepared

Summary of the IRB meeting records is prepared **From April 2008**

\* Documents for review **[Article 10; Article 32, Paragraph 1]** From April 1997

Protocol

Investigator’s Brochure Until August 31, 2020

Investigator’s Brochure and documents describing the scientific knowledge of the drug(s) used in the clinical trial (excluding the test drug)\* **From September 1, 2020**\* Package inserts, interview forms, academic papers, etc. of approved drugs From September 1, 2020 (PSEHB/PED Notification No. 0831-15 dated August 31, 2020)

Sample of the case report form  
(If the information to be entered in the case report form can be provided sufficiently in the protocol, the protocol may be considered to include the information related to the sample case report form. From April 1, 2012 (PFSB/ELD Notification No. 1024-1 dated October 24, 2011))

Written information (i.e., informed consent document) (written information and informed consent form are an integrated document or a set of documents **From May 29, 1997** (PAB/ELD　Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997))

List of prospective investigators and subinvestigators

Documents on the burden of expenses for the clinical trial Until March 31, 2012

Documents on the burden of expenses for the clinical trial (documents on payment to the subject (if any)) From April 1, 2012 (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

Document explaining the compensation to subjects in the event of trial-related injury

Documents concerning subject recruitment procedures

Documents describing important information necessary to conduct the clinical trial properly, such as information on the quality, efficacy, and safety of the test drug **Until July 31, 2021**

Documents describing important information necessary to conduct the clinical trial properly, such as information on the quality, efficacy, and safety of the drug(s) used in the clinical trial From August 1, 2021

Curriculum vitae of each prospective investigator and subinvestigator From April 1997 until September 30, 2008

Curriculum vitae of each prospective investigator (curriculum vitae of each subinvestigator if necessary for review and deliberation) From October 1, 2008 (PFSB/ELD Notification No. 1001001 dated October 1, 2008)

Other documents that the IRB considers necessary

- Documents concerning the payment to the subject and expected expenses for the clinical trial and documents concerning the compensation to the subject in the event of trial-related injury **From May 29, 1997 until March 31, 2012** (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

- Documents concerning the expenses for the clinical trial planned to be paid by the sponsor to the head of the medical institution From April 1, 2012 (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

Documents to examine whether or not the medical institution can appropriately conduct the clinical trial through sufficient clinical observations, necessary measures in case of emergency, etc. From May 29, 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Other ( )

3) Notification of the opinion of the IRB in writing

**[From April 1997 until July 29, 2003: Article 32, Paragraphs 1 and 3]  
 [From July 30, 2003 until March 2006: Article 32, Paragraphs 1 and 4]  
 [From April 2006: Article 32, Paragraphs 1 and 6]**

Compliant

From IRB to the head of the medical institution Date of report: MMM DD YYYY

From the head of the medical institution to the sponsor Date of notification: MMM DD, YYYY

to the investigator From April 1997 Date of notification: MMM DD, YYYY

Other ( )

4) Obtainment of the latest documents to be reviewed by the IRB  
 **[Article 31, Paragraph 2, Note)]** From May 29, 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

\* Excluding revisions of a separate protocol (information specific only to an individual medical institution), changes in the layout of the case report form, and changes in the specifications of the case report form due to the use of an electronic information processing system   
 From October 2008 until March 31, 2012 (PFSB/ELD Notification No. 1001001 dated October 1, 2008)

Compliant

Other ( )

5) Review of the appropriateness of continuing the clinical trial for more than one year (at least once a year) and notification of the opinion in writing From April 1997

**[From April 1997 until July 29, 2003: Article 31, Paragraph 1; Article 32, Paragraphs 2 and 3]  
 [From July 30, 2003 until March 2006: Article 31, Paragraph 1, Article 32, Paragraphs 2 and 4]  
 [From April 2006: Article 31, Paragraph 1; Article 32, Paragraphs 3 and 6]**

a Report of a summary of the clinical trial status in writing **[Article 48, Paragraph 1]**

Not applicable

Compliant

At least once a year or more frequently at the request of the IRB   
 From May 29, 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

From the investigator to the head of the medical institution Date of report: MMM DD, YYYY

Other ( )

b Review

Not applicable

Compliant

Date of review: MMM DD, YYYY

(Clinical trial period: to )

\* To be reviewed promptly according to the urgency of the matter consulted   
 **[Article 32, Paragraph 3]** From April 2006

\* It is desirable that the trial subject to deliberation is explained by the investigator/subinvestigator.  
 **[Article 29, Paragraph 1]** From April 2008 (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

Conclusion:  Approved  Approved with modification  Cancellation of matters previously approved

Description:

Preparation of records of the IRB meetings

Preparation of summary of the IRB meeting records From April 2008

From IRB to the head of the medical institution Date of report: MMM DD YYYY

From the head of the medical institution to the sponsor Date of notification: MMM DD, YYYY

to the investigator Date of notification: MMM DD, YYYY

Other ( )

6) Review of the appropriateness of continuing the clinical trial when obtaining information on serious and unexpected adverse drug reactions from the sponsor, and notification of the opinion in writing

a Report of “unknown and serious adverse drug reactions,” in writing **From April 1997**

**[From April 1997 until July 29, 2003: Article 31, Paragraph 2; Article 32, Paragraphs 2 and 3]  
[From July 30, 2003 until March 2006: Article 31, Paragraph 2; Article 32, Paragraphs 2 and 4]  
[From April 2006: Article 31, Paragraph 2; Article 32, Paragraphs 3 and 6]**

Not applicable

Compliant

From the sponsor to the head of the medical institution Date of notification: MMM DD, YYYY

From the head of the medical institution to the IRB **[Article 40, Paragraph 1]** Date of notification: MMM DD, YYYY

\* If an agreement among the sponsor, the IRB and the head of the medical institution has been obtained in advance, the sponsor may notify the IRB at the same time in addition to the investigator and the head of the medical institution of only notifications related to GCP Ministerial Ordinance Article 20, Paragraphs 2 and 3. In this case, it may be regarded that the head of the medical institution has notified the IRB in writing.   
 **[Article 40, Paragraph 1]** From December 28, 2012 (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

b Review

Not applicable

Compliant

Date of review: MMM DD, YYYY

\* To be reviewed promptly according to the urgency of the matter consulted   
 **[Article 32, Paragraph 3]** From April 2006

\* It is desirable that the trial subject to deliberation is explained by the investigator/subinvestigator.   
 **[Article 29, Paragraph 1]** From April 2008 (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

Conclusion:  Approved  Approved with modification  Cancellation of matters previously approved

Description of adverse drug reactions:

Preparation of records of the IRB meetings

Preparation of summary of the IRB meeting records **From April 2008**

From IRB to the head of the medical institution Date of report: MMM DD YYYY

From the head of the medical institution to the sponsor Date of notification: MMM DD, YYYY

to the investigator Date of notification: MMM DD, YYYY

\* If an agreement among the sponsor, the IRB and the head of the medical institution has been obtained in advance, the IRB may give its opinions only on the appropriateness of continuing the clinical trial, related to GCP Ministerial Ordinance Article 20, Paragraphs 2 and 3, to the investigator and the sponsor at the same time in addition to the head of the medical institution. In this case, it may be regarded that the head of the medical institution has notified the sponsor and the investigator of the opinion of the IRB in writing. **[Article 32, Paragraph 3]** From December 28, 2012 (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

Other ( )

7) Review of the appropriateness of continuing the clinical trial in relation to a revision of the written information and notification of opinions in writing **From April 1997**

**[From April 1997 until July 29, 2003: Article 31, Paragraph 2; Article 32, Paragraphs 2 and 3]  
[From July 30, 2003 until March 2006: Article 31, Paragraph 2; Article 32, Paragraphs 2 and 4]  
[From April 2006: Article 31, Paragraph 2; Article 32, Paragraphs 3 and 6]**

Not applicable

Compliant

Date of review: MMM DD, YYYY

\* To be reviewed promptly according to the urgency of the matter consulted   
 **[Article 32, Paragraph 3]** From April 2006

\* It is desirable that the trial subject to deliberation is explained by the investigator/subinvestigator.   
**[Article 29, Paragraph 1]** From April 2008 (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

Conclusion:  Approved  Approved with modification  Cancellation of matters previously approved

Description of the revision:

Preparation of records of the IRB meetings

Preparation of summary of the IRB meeting records From April 2008

From IRB to the head of the medical institution Date of report: MMM DD YYYY

From the head of the medical institution to the sponsor Date of notification: MMM DD, YYYY

to the investigator Date of notification: MMM DD, YYYY

Other ( )

8) In the case of a non-therapeutic clinical trial where no direct clinical benefit to subjects is expected based on the consent of their legally acceptable representative  
**[Article 28, Paragraph 2; Article 32, Paragraph 1]** **From May 29, 1997** (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Not applicable

Compliant

The protocol and other documents give due consideration to relevant ethical issues.

In compliant with GCP Ministerial Ordinance Article 7, Paragraph 2.

The document approved by the IRB clearly states that subjects are to be enrolled in the clinical trial although it would be difficult to obtain their own consent.

9) In the case of a life-saving clinical trial in an emergency situation where prior consent of subjects or their legally acceptable representative cannot be obtained  
**[Article 28, Paragraph 2; Article 32, Paragraph 1]** From May 29, 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Not applicable

Compliant

The protocol and other documents give due consideration to relevant ethical issues.

In compliant with GCP Ministerial Ordinance Article 7, Paragraph 3.

The document approved by the IRB clearly states the method to protect the human rights, safety, and welfare of subjects participating in the clinical trial without obtaining their consent or their legally acceptable representative’s consent.

## 7. Record Keeping by Founder of IRB **From April 1997**

Retention of the following records (until the later date of either the date of marketing approval of the test drug or 3 years after the date of premature termination/completion of the clinical trial) **[Article 34]**

Compliant

⚫ Written operating procedures of the IRB

⚫ List of IRB member (including the professional qualification and affiliation of the members: PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

⚫ Documents for review by the IRB

Protocol

Investigator’s Brochure Until August 31, 2020

Investigator’s Brochure and documents describing the scientific knowledge of the drug(s) used in the clinical trial (excluding the test drug) (package inserts, interview forms, academic papers, etc. of approved drugs) From September 1, 2020

Sample of the case report form

(If the information to be entered in the case report form can be provided sufficiently in the protocol, the protocol may be considered to include the information related to the sample case report form. From April 1, 2012 (PFSB/ELD Notification No. 1024-1 dated October 24, 2011))

Written information

List of prospective investigators and subinvestigators

Documents on the burden of expenses for the clinical trial

Document explaining the compensation to the subject in the event of trial-related injury

Documents concerning subject recruitment procedures

Documents describing important information necessary to conduct the clinical trial properly

Curriculum vitae of each prospective investigator (subinvestigator)

⚫ Written notifications to the IRB (adverse drug reaction reports, clinical trial completion/premature termination reports)

⚫ Records of IRB meetings

⚫ Summaries of IRB meeting records From April 2008

⚫ Contract with the head of the medical institution (if applicable) From April 2008

Other ( )

# [III] Investigators, etc. (Qualifications, Duties, etc.)

Investigator From April 1997

1) Qualifications for Investigator **[Article 42]**

Compliant

Name of the investigator:

⚫ Being fully qualified by education and training

⚫ Having adequate clinical experience

⚫ Being well versed in the protocol, Investigator’s Brochure, and appropriate administration of the investigational product From August 31, 2020

⚫ Being well versed in the protocol, Investigator’s Brochure, and appropriate administration of the drug(s) used in the clinical trial From September 1, 2020

⚫ Having sufficient time to conduct the clinical trial

Other ( )

2) Preparation of a list of assigned duties when the clinical trial is conducted with involvement of subinvestigators or clinical research coordinators **[Article 43, Paragraph 1]**

Not applicable

Compliant

Date of preparation: MMM DD, YYYY

Date of appointment: MMM DD, YYYY  
 From April 1998 until March 31, 2012 (PAB Notification No. 430 dated March 27, 1997)

Date of approval: MMM DD, YYYY  
 From April 1, 2012 (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

Other ( )

3) Provision of necessary information to subinvestigators and clinical research coordinators **[Article 43, Paragraph 2]**

Not applicable

Compliant

Explanation of the details of the clinical trial (protocol, Investigator’s Brochure, etc.)

Provision of information (adverse drug reaction information provided by the sponsor)

Guidance and supervision **From May 29, 1997** (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Other ( )

# [IV] Clinical Trial Management

## 1. Information on Adverse Drug Reactions

1) Report of “serious adverse events” in writing **From April 1997**

a

Not applicable

Compliant

A request for the provision of necessary information by the sponsor shall be responded to.

|  |  |
| --- | --- |
| From the investigator to the head of the medical institution **[Article 48, Paragraph 2]** | Date of report: MMM DD YYYY |
| to the sponsor **[Article 48, Paragraph 2]** | Date of notification: MMM DD, YYYY |

Details of adverse events:

Other ( )

b Review

**[From April 1997 until July 29, 2003: Article 31, Paragraph 2; Article 32, Paragraphs 2 and 3]  
[From July 30, 2003 until March 2006: Article 31, Paragraph 2; Article 32, Paragraphs 2 and 4]  
[From April 2006: Article 31, Paragraph 2; Article 32, Paragraphs 3 and 6]**

Not applicable

Compliant

Date of review: MMM DD, YYYY

\* To be reviewed promptly according to the urgency of the matter consulted   
 **[Article 32, Paragraph 3]** From April 2006

\* It is desirable that the trial subject to deliberation is explained by the investigator/subinvestigator.  
 **[Article 29, Paragraph 1]** From April 2008 (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

Conclusion:  Approved  Approved with modification  Cancellation of matters previously approved

Description:

Preparation of records of the IRB meetings

Preparation of summary of the IRB meeting records From April 2008

From IRB to the head of the medical institution Date of report: MMM DD YYYY

From the head of the medical institution to the sponsor Date of notification: MMM DD, YYYY

to the investigator Date of notification: MMM DD, YYYY

Other ( )

2) Report of “premature termination/suspension of the clinical trial” in writing (the reason shall be specified) From April 1997

Not applicable

Compliant

a Suspension or premature termination of the clinical trial based on notification pursuant to GCP Ministerial Ordinance Article 40, Paragraph 2

|  |  |
| --- | --- |
| From the sponsor to the head of the medical institution  **[Article 24, Paragraph 2]** | Date of notification: MMM DD, YYYY |
| From the head of the medical institution to the IRB  **[Article 40, Paragraph 2]** | Date of notification: MMM DD, YYYY |
| to the investigator **[Article 40, Paragraph 2]** | Date of notification: MMM DD, YYYY |
| From the investigator to the subject  **[Article 49, Paragraph 1]** | Date of notification: MMM DD, YYYY |

Provision of appropriate medical care (necessary measures)

b Suspension or premature termination of the clinical trial by the investigator

|  |  |
| --- | --- |
| From the investigator to the head of the medical institution  **[Article 49, Paragraph 2]** | Date of report: MMM DD YYYY |
| From the head of the medical institution to the IRB  **[Article 40, Paragraph 3]** | Date of notification: MMM DD, YYYY |
| to the sponsor **[Article 40, Paragraph 3]** | Date of notification: MMM DD, YYYY |

Detailed explanation in writing **From May 29, 1997** (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Other ( )

3) Report of “completion of the clinical trial” in writing (a summary of results shall be attached) From April 1997

Compliant

|  |  |
| --- | --- |
| From the investigator to the head of the medical institution  **[Article 49 Paragraph 3]** | Date of report: MMM DD YYYY |
| From the head of the medical institution to the IRB  **[Article 40, Paragraph 4]** | Date of notification: MMM DD, YYYY |
| to the sponsor **[Article 40, Paragraph 4]** | Date of notification: MMM DD, YYYY |

Other (

## 2. Deviations from Protocol

The investigator, etc. shall conduct the clinical trial in compliance with the protocol approved by the IRB in advance. **[Article 46, Paragraph 1]** From August 1, 2021

Compliant

Other ( )

## 3. Deviations from Protocol to Eliminate Immediate Hazards to Subjects

a-1 When the investigator has failed to comply with the protocol in order to eliminate immediate hazards to subjects, the investigator shall document all such deviations, and immediately submit the document describing those deviations and the reasons thereof to the sponsor and the head of the medical institution.

**[Article 46, Paragraph 1]** From April 1997 until July 31, 2021  
 **[Article 46, Paragraph 2]** From August 1, 2021

Not applicable

Compliant

Description of deviations:

From the investigator to the head of the medical institution  
 Date of submission: MMM DD, YYYY

to the IRB Date of submission: MMM DD, YYYY

**From May 29, 1997**

(PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

to the sponsor Date of submission: MMM DD, YYYY

Other ( )

a-2 Review **[Article 46]**

From April 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Not applicable

Compliant

Date of review: MMM DD, YYYY

Conclusion:  Approved  Other

Description:

From IRB to the head of the medical institution Date of notification: MMM DD, YYYY

From the head of the medical institution to the investigator Date of approval: MMM DD, YYYY

Sponsor’s agreement to the investigator Date of notification: MMM DD, YYYY

Other ( )

b-1 The investigator shall document all deviations from the protocol regardless of their reasons and submit the document describing the deviations and the reasons thereof to the sponsor. **[Article 46]**

**From May 29, 1997 until September 30, 2008** (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Not applicable

Compliant

Description of deviations:

From the investigator to the sponsor Date of submission: MMM DD, YYYY

Other ( )

b-2 The investigator or subinvestigator shall document all deviations from the protocol regardless of their reasons.

**[Article 46] From October 1, 2008** (PFSB/ELD Notification No. 1001001 dated October 1, 2008)

Not applicable

Compliant

Description of deviations.:

Other ( )

## 4. Control/Accountability of Investigational Product(s) (or Drug(s) Used in the Clinical Trial)

1) Appointment of an investigational product storage manager  
 **[Article 39]** From April 1997 (PAB Notification No. 430 dated March 27, 1997)

Compliant

Investigational product storage manager: (title)

Other ( )

2) Provision of the written operating procedures for control/accountability of investigational products (prepared by the sponsor)  
 **[Article 39, Paragraph 1]** **From July 1997 until December 27, 2012**

Compliant

Other ( )

3)-1 Proper control/accountability of investigational products in accordance with the procedures prepared by the sponsor  
 **[From July 1997 until December 27, 2012: Article 39, Paragraph 2]  
 [From December 28, 2012 until August 31, 2020: Article 39]**

Compliant

Storage place of investigational product:

Access control to the storage place:

From May 29, 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Record of receipt of investigational products supplied by the sponsor \*

Record of stock of investigational products at the medical institution\*

Record of use of investigational products by subject\*

Record of return to the sponsor or alternative disposal record of unused investigational products\*

Record of administration of investigational products to subjects at the dose specified in the protocol

Records of control/accountability of all investigational products received from the sponsor

The records above\* include date, quantity, manufacturing number or code, expiry date (if necessary), and investigational product code and subject identification codes.

Other ( )

3)-2 Proper control/accountability of drug(s) used in the clinical trial in accordance with the procedures prepared by the sponsor **[Article 39]** **From September 1, 2020**

\* For any drug used in the clinical trial, other than investigational products, which is not supplied by the sponsor and is stored in stock at the medical institution, the sponsor shall handle it according to the written operating procedures for handling, storage, control, prescription, etc. specified at the medical institution.   
 From September 1, 2020 (PSEHB/PED Notification No. 0831-15 dated August 31, 2020)

Compliant

Storage place of drug(s) used in the clinical trial:

Access control to the storage place:

From September 1, 2020 (PSEHB/PED Notification No. 0831-15 dated August 31, 2020)

Record of receipt of drug(s) used in the clinical trial supplied by the sponsor\*

Record of stock of drug(s) used in the clinical trial provided by the sponsor at the medical institution\*

Record of use of drug(s) used in the clinical trial provided by the sponsor by subject\*

Record of return to the sponsor or alternative disposal record of unused drug(s) used in the clinical trial provided by the sponsor\*

Record of administration of drug(s) used in the clinical trial to subjects at the dose specified in the protocol

Records of control/accountability of all drug(s) used in the clinical trial received from the sponsor

The records above\* include date, quantity, manufacturing number or code, expiry date (if necessary), and investigational product code and subject identification codes.

From August 1, 2021 (PSEHB/PED Notification No. 0730-3 dated July 30, 2021)

If a drug used in the clinical trial is delivered from the medical institution to the subject’s home, a procedure necessary to ensure the delivery of the drug used in the clinical trial to the subject in addition to the quality control of the drug used in the clinical trial during transportation

If a drug used in the clinical trial is delivered to the subject’s home using a carrier, a contract with the contractor of the duty is concluded pursuant to the provisions of GCP Ministerial Ordinance Article 39, Paragraph 2

Other ( )

3)-3 Prohibition of receipt of investigational products before concluding the clinical trial contract (see GCP Ministerial Ordinance Article 11) **From May 29, 1997** (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

Compliant

Date of receipt of investigational product: MMM DD, YYYY

Other ( )

## 5. Record Keeping

1) Appointment of a record keeping manager **[Article 41, Paragraph 1]**

Compliant

Record keeping manager:

Other ( )

2) Record keeping (until the later date of either the date of marketing approval of the test drug or 3 years after the date of premature termination/completion of the clinical trial) **[Article 41, Paragraph 2]**

Compliant

Storage place of records:

Access control to the storage place:

\* Documents to be retained

Source documents

- Source data should be attributable, legible, contemporaneous, original, accurate, and complete. **From January 1, 2020** (PSEHB/PED Notification No. 0705-3 dated July 5, 2019)

- Changes to source data should be traceable and should not obscure the original entry (e.g., via an audit trail). **From January 1, 2020** (PSEHB/PED Notification No. 0705-3 dated July 5, 2019)

Contract

Informed consent form and written information

Protocol

Documents obtained from the IRB

Record of the control/accountability of investigational products Until August 31, 2020

Record of the control/accountability of drug(s) used in the clinical trial From September 1, 2020

Records of letters, meetings, telephone communications, etc. with the sponsor about important matters related to the conduct of the clinical trial   
 From April 1, 2012 (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

Other

Other ( )

# [V] Communication with Subjects

## 1. Selection of Subjects and Responsibilities for Medical Care of Subjects

1) Requirements for subject selection **[Article 44: Also applied retrospectively to clinical trials requested before April 1, 1997]**

Compliant

The prospective subject’s health condition, symptoms, age, ability to give consent, etc. shall be carefully considered, in line with the objectives of the clinical trial, from ethical and scientific viewpoints.

Any prospective subject who is incapable of giving consent shall not be selected unless it is inevitable to enroll him or her in the clinical trial.

In selecting a subject who may unduly incur any disadvantage if the subject refuses to participate in the clinical trial, careful considerations shall be given so that he or she can voluntarily give consent to his or her participation.  
<Medical/Dental students, pharmaceutical students, nursing students, hospital personnel, employees of pharmaceutical companies, etc. From May 29, 1997 (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)>

Other ( )

2) Explanation and, as necessary, confirmation, of the appropriate use of investigational products to each subject **[Article 45, Paragraph 1]** From April 1997 until August 31, 2020Explanation and, as necessary, confirmation, of the appropriate use of drug(s) used in the clinical trial to each subject **[Article 45, Paragraph 1]** From September 1, 2020

Not applicable

Compliant

Appropriate explanation and instructions to the subject

Confirmation that the subject is properly following the instructions explained

Other ( )

3) If a subject is receiving treatment by another physician, notification to the physician of the fact that the subject will participate in the clinical trial with prior consent of the subject **[Article 45, Paragraph 2]** **From April 1997**

Not applicable

Compliant

Method of notification:

Other ( )

4) Establishment of preliminary measures to ensure that adequate medical care is provided to a subject for any adverse event **[Article 45, Paragraph 3]** **From April 1997**

Compliant

Other ( )

5) When a subject needs medical care for adverse event(s), the subject is informed about it **[Article 45, Paragraph 4]** **From April 1997**

Not applicable

Compliant

Other ( )

## 2. Explanation

1) Provision of written information describing the following information  
 **[Article 51, Paragraph 1]** From April 1997

Compliant

That the clinical trial involves research

The objectives of the clinical trial

The name, title, and contact information of the investigator Until July 31, 2021  
(Name, title, and contact information of the investigator or subinvestigator  
 **From May 29, 1997 until August 31, 2020** (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997))

The name and contact information of the investigator From August 1, 2021

Clinical trial design (including the experimental aspects of the clinical trial design, subject inclusion criteria, and the probability of being assigned to each treatment in the case of randomization (PAB Notification No. 430 dated March 27, 1997))

Expected benefits and disadvantages

- That there is no expected clinical benefit, if applicable   
 Until March 2006 (PAB Notification No. 430 dated March 27, 1997)

- That there is no expected clinical benefit to the subject, if applicable From April 2006

Description of alternative procedure(s) or course(s) of treatment (availability of alternative procedure(s) or course(s) of treatment and expected important benefits and risks associated with them (PAB Notification No. 430 dated March 27, 1997))

Duration of the subject’s participation in the clinical trial

That the subject may withdraw from the clinical trial at any time

That the subject’s refusal of or withdrawal from participation in the trial does not cause any disadvantage to the subject

That the monitors, auditors, IRB, and regulatory authorities are given direct access to the source documents on the condition that confidentiality of the subject is fully secured   
From April 1998

That the subject’s identity will be kept confidential

The contact information of the medical institution in the event of trial-related injury

That necessary treatment is available to the subject in the event of trial-related injury

Description of compensation in the event of any trial-related injury

Type of the IRB, matters subject to review and deliberation by the IRB, and other matters concerning the IRB involved in the clinical trial **From April 2006**

- Include the type of the IRB, matters subject to review and deliberation, the name and address of the founder of the IRB, and accessible information related to the founder of the IRB.

- Statement that the subject can confirm the written operating procedures and related documents of the IRB (written operating procedures of the IRB, list of members, summaries of IRB meeting records... See Article 28, Paragraph 3 of GCP Ministerial Ordinance in Notification of Operation (PFSB/ELD Notification No. 1001001 dated October 1, 2008))   
 From April 2009 (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

- Statement that the written operating procedures and related documents of the IRB are available for public viewing (disclosure of the website address, availability in the office, etc.)  
 **From April 2009** (PFSB/ELD Notification No. 0326001 dated March 26, 2008)

Matters concerning the subject’s burden of expenses for the clinical trial, if any **From January 22, 2016**

Other necessary matters concerning the clinical trial  
(Expected number of subjects, conditions/reasons for discontinuation of participation, burden of expenses, etc. PAB Notification No. 430 dated March 27, 1997)

Other ( )

2) Information not to be included in the written information   
 From April 1997 **[Article 51, Paragraph 2]**

Compliant

Language that causes the prospective subject to waive any legal rights

Language that eliminates or reduces the liabilities of the sponsor, the medical institution, or the investigator/subinvestigator

Other ( )

3) Preparation of written information using wording and expressions as plain as possible **[Article 51, Paragraph 3]** **From April 1997**

Compliant

Other ( )

4) Method of explanation

Compliant

Appropriate explanation to the subject in writing **[Article 50, Paragraph 1]**

Other ( )

5) Providing the subject or the subject’s legally acceptable representative with sufficient time and opportunities for questions and answers for thorough understanding of the trial **[Article 50, Paragraph 5]** **From April 1997**

Compliant

Time required for explanation: About minutes/person

Other ( )

## 3. Explanation in Special Situations From April 1997

Conditions for the life-saving clinical trial in case of emergency without obtaining the consent of the subject or the subject’s legally acceptable representative **[Article 55, Paragraph 1]**

Not applicable

Compliant

Subject No.:

The prospective subject is in an emergency and obviously at life-threatening risk.

Currently available treatments are unlikely to achieve sufficient therapeutic effects in the prospective subject.

There is a sufficient possibility of saving the life of the prospective subject in a life-threatening condition by using the test drug.

The potential disadvantages which the prospective subject may incur in the clinical trial are minimized.

The prospective legally acceptable representative cannot immediately be contacted for consent.

Other ( )

## 4. Response to Information Influencing Subject’s Willingness to Continue to Participate in Ongoing Clinical Trial From April 1997

1) Provision of the information to the subject, documentation of the communication of the information, and confirmation of the willingness to continue to participate in the clinical trial **[Article 54, Paragraph 1]**

Not applicable

Compliant

Has the information been provided immediately? (documentation of the communication of the information)

Has sufficient opportunity been given for questions and answers? (mutatis mutandis application of GCP Ministerial Ordinance Article 50, Paragraph 5)

Has there been no compulsory consent? (mutatis mutandis application of GCP Ministerial Ordinance Article 52, Paragraph 2)

Other ( )

2) Prompt revision of the written information as necessary **[Article 54, Paragraph 2]**

Not applicable

Compliant

Date of revision: MMM DD, YYYY

Other ( )

3) When the written information is revised, reporting of the revision to the head of the medical institution, and obtainment of the consent of the subject (or the subject’s legally acceptable representative) to continue participation in the clinical trial **[Article 54, Paragraph 3]**

Not applicable

Compliant

Reporting to the head of the medical institution (Date of report: MMM DD, YYYY)

Approval by IRB (Date of notification of direction/decision: MMM DD, YYYY)   
 From January 1, 2020 (PSEHB/PED Notification No. 0705-3 dated July 5, 2019)

Obtainment of informed consent

Other ( )

## 5. Obtainment of Informed Consent

1) Written consent of the subject **[Article 50, Paragraph 1]** From April 1997

Signature or name and seal of the informed consent form   
 **[Article 52, Paragraph 1]** From April 1997 to December 24, 2020

Signature of the informed consent form **[Article 52, Paragraph 1]** From December 25, 2020

\* For a subject who cannot sign the informed consent form by himself/herself, the form may be signed for the subject by a person equivalent to the subject’s legally acceptable representative or a person who is not equivalent to the subject’s legally acceptable representative in the presence of an impartial witness (in cases of absolute necessity).   
 From August 1, 2021 (PSEHB/PED Notification No. 0730-3 dated July 30, 2021)

Avoiding forced consent **[Article 52, Paragraph 2]** From April 1997

Provision of the informed consent form (copy) **[Article 53]** From April 1997

Compliant

Obtainment of the consent from the subject **[Article 50, Paragraph 1]** From April 1997

- The investigator providing an explanation and the subject shall date, and affix the name and seal or sign the consent form. **[Article 52, Paragraph 1]** From April 1997 to December 24, 2020

- The investigator providing an explanation and the subject shall date and sign the consent form. **[Article 52, Paragraph 1]** From December 25, 2020

- (When a clinical research coordinator provided a supplementary explanation) The clinical research coordinator shall affix the name and seal or sign, and date the consent form. **[Article 52, Paragraph 1]** From April 1997 until July 31, 2021 (PAB Notification No. 430 dated March 27, 1997)

- (If a clinical research coordinator provided a supplementary explanation) The clinical research coordinator shall sign and date the consent form.  
 **[Article 52, Paragraph 1]** From August 1, 2021 (PSEHB/PED Notification No. 0730-3 dated July 30, 2021)

The informed consent shall not be obtained in such a way that the investigators, etc. coerce or unduly influence the subject to give consent. **[Article 52, Paragraph 2]** From April 1997

Provision of a copy of the above informed consent form to the subject   
 **[Article 53]** From April 1997

Other ( )

2) For a subject who is incapable of giving consent, consent of the subject’s legally acceptable representative **[Article 50, Paragraph 2]** **From April 1997**

Records of the consent of the subject’s legally acceptable representative and the relationship of the legally acceptable representative to the subject  
 **[Article 50, Paragraph 3]** From April 1997

Signature or name and seal of the informed consent form   
 **[Article 52, Paragraph 1]** From April 1997 until December 24, 2020

Signature of the informed consent form **[Article 52, Paragraph 1]** From December 25, 2020

Elimination of forced consent **[Article 52, Paragraph 2]** From April 1997

Provision of the informed consent form (copy) **[Article 53]** From April 1997

Not applicable

Compliant

Obtainment of the consent from the legally acceptable representative   
 **[Article 50, Paragraph 2]** From April 1997

Records of the consent and the relationship of the legally acceptable representative to the subject **[Article 50, Paragraph 3]** From April 1997

- The investigator providing an explanation and the legally acceptable representative shall date, and affix the name and seal or sign the consent form.   
 **[Article 52, Paragraph 1]** **From April 1997 until December 24, 2020**

- The investigator providing an explanation and the legally acceptable representative shall date and sign the consent form. **[Article 52, Paragraph 1]** **From December 25, 2020**

- (When a clinical research coordinator provided a supplementary explanation) The clinical research coordinator shall affix the name and seal or sign, and date the consent form.   
 **[Article 52, Paragraph 1]** **From April 1997 until July 31, 2021**   
 (PAB Notification No. 430 dated March 27, 1997)

- (If a clinical research coordinator provided a supplementary explanation) The clinical research coordinator shall sign and date the consent form.   
 **[Article 52, Paragraph 1]** **From August 1, 2021** (PSEHB/PED Notification No. 0730-3 dated July 30, 2021)

The informed consent shall not be obtained in such a way that the investigators, etc. coerce or unduly influence the subject to give consent. **[Article 52, Paragraph 2]** From April 1997

Provision of a copy of the above informed consent form to the subject (or the subject’s legally acceptable representative) **[Article 53]** From April 1997

3) Presence of a witness if a subject is incapable of reading the written information **[Article 52, Paragraph 3]** **From April 1997**

Not applicable

Compliant

The witness shall neither be the investigators, etc. nor the clinical research coordinator.   
 **[Article 52, Paragraph 4]** From April 1997

Other (

4) Prompt explanation to the subject or the subject’s legally acceptable representative and obtainment written consent in the case of a life-saving clinical trial in an emergency situation **[Article 55, Paragraph 2]** **From April 1997**

Not applicable

Compliant

Prompt obtainment of the consent from the prospective subject or the prospective legally acceptable representative

The prospective subject’s identity is clear (PAB Notification No. 430 dated March 27, 1997).

Reporting of the course and result of obtaining the consent from the prospective subject or the prospective legally acceptable representative to the IRB (PAB Notification No. 430 dated March 27, 1997)

Other ( )

# [VI] Case Report Form

1)-1 The investigators, etc. shall prepare case report forms accurately in compliance with the protocol and affix their name and seal or sign the forms.   
 **[Article 47, Paragraph 1: Also applied retrospectively to studies requested before April 1, 1997]**  
 Until December 24, 2020

The investigators, etc. shall prepare CRFs accurately in compliance with the protocol and affix their name to the forms. **[Article 47, Paragraph 1]** **From December 25, 2020**

\* When the name of the investigators, etc. is entered in a case report form, its authenticity shall be ensured that the investigators, etc. themselves have completed the form. From August 1, 2021 (PSEHB/PED Notification No. 0730-3 dated July 30, 2021)

1)-2 When an interim report of the clinical trial is prepared to be used for a marketing approval application for a drug, the investigators, etc. shall inspect the CRFs and confirm the content thereof to affix their name and seal or sign the forms.   
 **[Article 47, Paragraph 1]** **From September 1, 2020 until July 31, 2021** (PSEHB/PED Notification No. 0831-15 dated August 31, 2020)

When an interim report of the clinical trial is prepared to be used for a marketing approval application for a drug, the investigators, etc. shall inspect the CRFs and confirm the content thereof to affix their name to the forms. **[Article 47, Paragraph 1]** **From August 1, 2021** (PSEHB/PED Notification No. 0730-3 dated July 30, 2021)

\* When the name of the investigators, etc. is entered in a case report form, its authenticity shall be ensured that the investigators, etc. themselves have completed the form. From August 1, 2021 (PSEHB/PED Notification No. 0730-3 dated July 30, 2021)

Consistency with source documents (collation/confirmation) **[Article 47, Paragraph 1: Also applied retrospectively to clinical trials requested before April 1, 1997]**

(If there is any inconsistency, a record explaining the reason shall be prepared. (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997))

2) Changes or corrections made to CRFs

– CRFs shall be dated and affixed with the seal or signed. (Significant change/correction shall be explained.) **[Article 47, Paragraph 2]** From April 1997 until December 24, 2020

– CRFs shall be dated and affixed with the name. (Significant change/correction shall be explained.) **[Article 47, Paragraph 2]** From December 25, 2020

\* When the name of the investigators, etc. is entered in a case report form, its authenticity shall be ensured that the investigators, etc. themselves have completed the form. From August 1, 2021 (PSEHB/PED Notification No. 0730-3 dated July 30, 2021)

Compliant

Other ( )

3) The investigator shall inspect the CRFs prepared by the subinvestigator(s) and confirm the content thereof to affix the name and seal or sign the forms.  
 **[Article 47, Paragraph 3]** **From April 1997 until December 24, 2020**

The investigator shall inspect the CRFs prepared by the subinvestigator(s) and confirm the content thereof to affix the name to the forms.  
 **[Article 47, Paragraph 3]** **From December 25, 2020**

\* When the name of the investigators, etc. is entered in a case report form, its authenticity shall be ensured that the investigators, etc. themselves have completed the form. From August 1, 2021 (PSEHB/PED Notification No. 0730-3 dated July 30, 2021)

Compliant

Other ( )

<<Reference>> Clinical Trial Contract

1. Consistency in the Contract from the Time of Request, IRB Meetings, until the Conclusion of the Contract

Compliant

Other ( )

2. Contents of the Contract **[Article 13, Paragraph 1]** From April 1997

Compliant

The contract includes the following matters: (It is not necessary to include all of them in one contract document. From December 28, 2012 (PSEHB/PED Notification No. 1228-7 dated December 28, 2012))

Date of concluding the contract

Name and address of the sponsor

When part of the duties is outsourced to a contractor, the name and address of the contractor and the scope of the duties outsourced **Until December 27, 2012**

- If part of the duties is outsourced to a contract research organization, a contract shall be concluded among the three parties, the sponsor, the contract research organization, and the medical institution. **From May 29, 1997** (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

- It is acceptable to conclude appropriate written contracts between the sponsor and the medical institution and between the sponsor and the contract research organization as long as the duties at the sponsor and the medical institution can be performed smoothly.

**From April 1, 2012** (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

When all or any of the duties are outsourced to a contractor, the name and address of the contractor and the scope of the duties outsourced **From December 28, 2012**

- If all or part of the duties are outsourced to a contract research organization, a contract shall be concluded among the three parties, the sponsor, the contract research organization, and the medical institution **From December 28, 2012** (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

- It is acceptable to conclude appropriate written contracts between the person who intends to sponsor the clinical trial and the medical institution and between the person who intends to sponsor the clinical trial and the contract research organization as long as the duties related to the preparation and management of the clinical trial by the person who intends to sponsor the clinical trial and duties related to the conduct of the clinical trial at the medical institution can be performed smoothly. **From September 1, 2020** (PSEHB/PED Notification No. 0831-15 dated August 31, 2020)

- As long as the duties at the sponsor and the medical institution can be performed smoothly, upon agreement among the three parties, i.e., the person who intends to sponsor the clinical trial, the contract research organization, and the medical institution, it is acceptable to conclude a contract between the two parties, i.e., the contract research organization and the medical institution. **From December 28, 2012** (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

Name(s) and address(es) of the medical institution(s)

Name(s) and title(s) of the person(s) in charge of the contract from each party

- It is acceptable that either of the head of the medical institution or a person appointed by the head of the medical institution serves as the contractor of the medical institution.

**From December 28, 2012** (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

Name and title of the investigators, etc. **Until December 27, 2012**

Name of the investigator **From December 28, 2012**

Duration of the clinical trial

Expected number of subjects **Until December 27, 2012**

Description of the control/accountability of investigational products   
 **From July 1997 until August 31, 2020** (PAB Notification No.430 dated March 27, 1997)

Description of the control/accountability of drug(s) used in the clinical trial   
 **From September 1, 2020**

Description of record (and data) keeping  
 **From July 1997** (PAB Notification No. 430 dated March 27, 1997)

Description of notifications given by the sponsor and the personnel of the medical institution **From July 1997** (PAB Notification No. 430 dated March 27, 1997)

Description of maintenance of the confidentiality of the subjects From April 1998 (PAB Notification No. 430 dated March 27, 1997) (Prohibition of leakage of secrets related to subjects **(Article 80-2, Paragraph 10 of the Act[[4]](#footnote-4)**))

Description of the expense for the clinical trial   
 From July 1997 (PAB Notification No. 430 dated March 27, 1997)

- It is acceptable to describe the amount of expenses that can be calculated.   
 **From December 28, 2012** (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

Statement that the medical institution conducts the clinical trial in compliance with GCP and the protocol

Statement that the medical institution will provide the sponsor with direct access to records (source documents, contract, informed consent form and written information, other documents prepared by the medical institution staff members, protocol, documents obtained from the IRB, records of investigational product control/accountability and other clinical trial-related duties) upon request by the sponsor   
 **From April 1998** (PAB Notification No. 430 dated March 27, 1997)

Statement that the sponsor may cancel the contract if it is found that the medical institution has violated GCP, the protocol, or the relevant contract, resulting in interference with the proper conduct of the clinical trial (excluding cases stipulated in GCP Ministerial Ordinance Article 46)

Description of compensation to the subject in the event of trial-related injuries

Other matters necessary to ensure that the clinical trial is conducted properly and smoothly  
(clinical trial title, contents of the clinical trial, matters related to the procedures for recording and reporting of data, matters related to the confidentiality of information belonging to the sponsor, etc.   
 **From May 29, 1997** (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

The investigator shall also affix the name and seal or sign the contract or a copy of the contract to confirm the contents of the contract   
 **From May 29, 1997 until March 31, 2012** (PAB/ELD Notification No. 445, PAB/SD Notification No. 68 dated May 29, 1997)

The investigator shall check the contents of the contract, but does not necessarily have to sign it. **From April 1, 2012** (PFSB/ELD Notification No. 1024-1 dated October 24, 2011)

\* It is acceptable for persons other than the medical institution staff, such as the secretariat of the network of the core clinical trial hospital, to perform the duties supporting the contract between the medical institution and the person who intends to sponsor the clinical trial. December 28, 2012 (PSEHB/PED Notification No. 1228-7 dated December 28, 2012)

Other ( )

1. The terms “GCP” and “GCP Ministerial Ordinance” in this checklist refer to the “Ministerial Ordinance on Good Clinical Practice for Drugs” i.e., the Ordinance of the Ministry of Health and Welfare No. 28 of March 27, 1997 (As last amended by the Ordinance of Ministry of Health, Labour and Welfare No. 161 of December 28, 2012). [↑](#footnote-ref-1)
2. Text enclosed in square brackets indicates relevant article/paragraph number of the GCP Ministerial Ordinance. [↑](#footnote-ref-2)
3. Date enclosed in a box indicates since/until when the relevant check item is effective. [↑](#footnote-ref-3)
4. The terms “Act” in this checklist refer to the “Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices” i.e., Act No. 145 of August 10, 1960. [↑](#footnote-ref-4)