



**THE INDONESIAN FOOD AND DRUG AUTHORITY
OF THE REPUBLIC OF INDONESIA**

DISCLAIMER:

The Original document is written in Bahasa Indonesia, and subsequently translated into English.

In the event of a discrepancy between the two versions, Bahasa Indonesia version shall take precedence.

REGULATION OF THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG
AUTHORITY
NUMBER 21 OF 2015
ON
THE PROCEDURE OF CLINICAL TRIAL APPROVALS

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY

- Considering :
- a. that the public need to be protected from the use of drugs, herbal medicines, health supplements, processed food and cosmetics that do not meet the requirements of safety, efficacy/ benefits and quality;
 - b. that under certain conditions, the truth of the safety and efficacy/ benefits of medicines, herbal medicines, health supplements, processed food and cosmetics must be scientifically evidenced through clinical trials;
 - c. that the provisions of the Procedures on the Clinical Trial Approval as regulated in the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 9 of 2014 on the Procedures on the Clinical Trial Approval and guidelines for clinical trials of herbal medicines as regulated in the Regulation of the the Chairperson of the Indonesian Food and Drug Authority 1 Number 13 of 2014 on the Guidelines for Clinical Trials of Herbal Medicines need to be

adapted to the development of science and most recent technology;

- d. that based on considerations as referred to in point a, point b and point c, it is necessary to issue a Regulation of the the Chairperson of the Indonesian Food and Drug Authority on the Procedures of the Clinical Trial Approval;

- Observing : 1. Law Number 8 of 1999 on Consumer Protection (State Gazette of the Republic of Indonesia of 1999 Number 42, Supplement to State Gazette of the Republic of Indonesia Number 3821);
2. Law Number 36 of 2009 on Health (State Gazette of the Republic of Indonesia of 2009 Number 144, Supplement to the State Gazette of the Republic of Indonesia of 2009 Number 5063);
3. Law Number 18 of 2012 on Food (State Gazette of the Republic of Indonesia of 2012 Number 227, Supplement to the State Gazette of the Republic of Indonesia of 2012 Number 5360);
4. Government Regulation Number 72 of 1998 on the Security of Pharmaceutical Preparations and Health Equipment (State Gazette of the Republic of Indonesia of 1998 Number 138, Supplement to the State Gazette Number 3781);
5. Government Regulation Number 69 of 1999 on Labels and Food Advertisements (State Gazette of the Republic of Indonesia of 1999 Number 131);
6. Government Regulation Number 28 of 2004 on the Safety, Quality and Food Nutrition (State Gazette of the Republic of Indonesia of 2004 Number 107, Supplement to the State Gazette of the Republic of Indonesia Number 4424);
7. Government Regulation Number 48 of 2010 on Types and Tariffs on Non-tax State Revenues applicable to the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2010 Number 67, Supplement to the State Gazette Number 5131);

8. Decision of the President Number 103 of 2001 on Positions, Duties, Functions, Authorities, Organizational Structure and Work Procedures of Non-departmental Government Institutions as several times amended, last by Presidential Regulation Number 3 of 2013;
9. Decision of the President Number 110 of 2001 on Organizational Units and Duties of Non-departmental Government Institutions, as several times amended, last by Presidential Regulation Number 4 of 2013;
10. Regulation of the Minister of Health Number 1010/Menkes/Per/XI/2008 on Drug Registration as amended by the Regulation of the Minister of Health Number 1120/Menkes/Per/XII/2008;
11. Regulation of the Minister of Health Number 1176/Menkes/Per/VIII/2010 on Notification of Cosmetics (State Bulletin of the Republic of Indonesia of 2010 Number 397);
12. Regulation of the Minister of Health Number 007 of 2012 on Traditional Medicine Registration (State Bulletin of the Republic of Indonesia of 2012 Number 226);
13. Regulation of the Minister of Health Number 66 of 2013 on the Implementation of Clinical Research Registry (State Bulletin of the Republic of Indonesia of 2013 Number 1319);
14. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.3.4991 of 2004 on Inspection of Clinical Trials;
15. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.4.2411 of 2004 on Basic Provisions on Grouping and Labeling on Indonesian Natural Medicines;
16. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.41.1381 of 2005 on the System on the Registration of Food Supplements;
17. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.41.1384 of 2005 on the Criteria and System on the Registration of Traditional Medicines, Standardized Herbal Drugs and Phytopharmaca;

18. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23. 12. 10.11983 of 2010 on the Criteria and Procedures on Filing the Notification of Cosmetics (State Bulletin the Republic of Indonesia of 2010 Number 598);
19. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.10.11.08481 of 2011 on the Criteria and System of Drug Registration (State Gazette The Republic of Indonesia of 2011 Number 634) as amended by the Regulation of the the Chairperson of the Indonesian Food and Drug Authority Number 3 of 2013 (State Bulletin of the Republic of Indonesia of 2013 Number 540);
20. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.11.11.09909 of 2011 on Control of Claims on Processed Food Labels and Advertisements (State Bulletin of the Republic of Indonesia of 2011 Number 18);
21. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.5.12.11.09956 of 2011 on the Procedures on the Registration of Processed Food (State Bulletin of the Republic of Indonesia of 2011 Number 811) as amended by the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 43 of 2014 (State Bulletin of the Republic of Indonesia of 2014 Number 964);
22. Decision of the Chairperson of the Indonesian Food and Drug Authority Number 02001/SK/KBPOM of 2001 on the Organization and Work Procedure of the Indonesian Food and Drug Authority as amended by the Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.21.4231 of 2004;

HAS DECIDED:

to Issue : REGULATION OF THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON SYSTEMS AND PROCEDURES ON CLINICAL TRIAL APPROVALS.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Regulation by:

1. Clinical Trials mean research activities involving human subjects with interventional Investigational Products, to discover or confirm clinical effects, pharmacologic and/or other pharmacodynamic, and/or identify any adverse reactions, and/or study the absorption, distribution, metabolism and excretion with the purpose to ensure the safety and/or effectiveness of the product being investigated.
2. Drug means a finished medicine including Biological Products, which is an ingredient or combination of ingredients used to influence or investigate the physiological system or state of pathology in order to establish diagnosis, prevention, healing, recovery, and improvement of health, and contraception for humans.
3. Herbal/Natural Drugs mean substances or ingredients that may originate from plants, animals and minerals.
4. Health Supplement means a product designed to supplement nutrient intake, to maintain, to increase, and/or to improve health functions, to have nutritional value and/or a physiological effect, to contain one or more materials in the form of vitamins, minerals, amino acids and/or other non-plant materials combinable with plants.
5. Processed Food means food or beverage that is processed in a certain way or method with or without food additives
6. Cosmetic means a material or dosage form designed for topical use on the human body (epidermis, hair, nails, lips, and external genital organs) or teeth and the oral mucosa mainly to clean, to perfume, to alter the appearance, and/or to improve body odor or to protect or to maintain the body in good condition.
7. Pre-marketing Clinical Trials mean Clinical Trials using Investigational Products that do not have marketing authorization in Indonesia, including Clinical Trials with Investigational Products that already have marketing authorizations to identify new indications/ posology.
8. Pre-marketing Clinical Trials mean Clinical Trials using Investigational Products that already pass Pre-marketing Clinical Trials and have marketing

- authorizations in Indonesia, to obtain safety data and/or to confirm the approved efficacies/ benefits.
9. Good Clinical Practice, hereinafter referred to as GCP, mean standards for designs, implementation, achievements, monitoring, auditing, recording, analysis and reporting of Clinical Trials that assures that the data and results reports are accurate and reliable, and that the rights, integrity and confidentiality of the Clinical Trial Subject is protected.
 10. Agreement of the Clinical Trial Implementation, (*Persetujuan Pelaksanaan Uji Klinik*) hereinafter referred to as PUK mean Agreements of the Clinical Trial Implementation issued by the Chairperson of the Agency.
 11. Ethics Committee means an independent institution, consisting of medic/scientific and non-medic/non-scientific professionals in the Clinical Trial sector, which is responsible for the protection, rights, safety and welfare of the Clinical Trial Subjects.
 12. Sponsors means individuals, companies, institutions or organizations that are responsible to initiate, manage and/or finance Clinical Trials.
 13. Contract Research Organizations, hereinafter referred to as CRO, are persons or organizations (commercial or others) who are contracted by the Sponsor to implement one or more duties and functions of the Sponsor in Clinical Trials.
 14. Inspections of Good Clinical Practice, hereinafter referred to as GCP Inspections, mean acts of the regulator/ the Indonesian Food and Drug Authority to implement official inspections on documents, facilities, records and other sources which are considered by the regulatory authorities are related to Clinical Trials (including bioequivalence trials), in the Clinical Trial Center, Sponsor and/or at the Contract Research Organization, and/or other sites related to the implementation of the intended Clinical Trial.
 15. Investigational Products mean Drugs, Herbal Medicines, Health Supplements, Processed Food and Cosmetics that will be used in Clinical Trials, either as investigational products or products used as comparators.
 16. The Principal Investigator means a person who has the capability and leads the team in research centers which may involve sub-investigators and others and is responsible for the entire conduct of the Clinical Trial in Clinical Trial centers or sites.
 17. Serious Adverse Events, hereinafter referred to as SAE, means every medical incidents occurring in Clinical Trial, regardless of causality resulting in death, life-threatening, requires hospitalization or extension of hospitalization,

- resulting in disabilities/ permanent and significant disabilities or results in congenital defects/ birth defects.
18. Adverse Product Reactions mean responses to products that are harmful and undesirable that occurs at the prevention, diagnosis/ disease treatments or for modification of physiological functions doses.
 19. Serious Adverse Product Reactions mean Adverse Product Reactions that result in deaths, is life-threatening, and requires hospitalization or extended hospitalization, resulting in disabilities / permanent and significant disabilities or results in congenital defects / birth defects.
 20. Clinical Trial Protocol means a complete and detailed document that among others outlines Clinical Trials, backgrounds, objectives, designs, methodologies and statistical considerations.
 21. Clinical Trial Subjects mean individuals participating in Clinical Trials who have rights and obligations during their participation in Clinical Trials.
 22. Informed Consent, hereinafter referred to as PSP (*Persetujuan Setelah Penjelasan*), mean a process to obtain consent from the subject; after receiving explanations regarding all relevant aspects of the Clinical Trial, the subject without coercion of any kind voluntarily states the willingness to participate in a Clinical Trial.
 23. Clinical Trial Centers or Clinical Trial Sites mean health facilities, university facilities or Government or private research institutions that qualify for the implementation of Clinical Trials.
 24. Chairperson of the Agency means the Chairperson of the Indonesian Food And Drug Authority.

CHAPTER II CLINICAL TRIAL

Part One Scope and Type of Clinical Trial

Article 2

The scope of this Regulation includes Clinical Trials implemented in Indonesia for :

- a. Drugs;
- b. Herbal Medicine;
- c. Health Supplements;

- d. Processed Food; and
- e. Cosmetics

Article 3

The Clinical Trials as referred to in Article 2 consists of :

- a. Premarketing Clinical Trials; and
- b. Post-marketing Clinical Trials;

Part Two Requirements

Article 4

Clinical Trials implemented must provide actual benefits for the development of science and public interest as well as referring to the Guidelines of GCP in Indonesia.

Article 5

- (1) The implementation of Clinical Trials as referred to in Article 3 point a prior to commencement is required to obtain approval of the Chairperson of the Agency.
- (2) The implementation of Clinical Trials as referred to in Article 3 point b prior to commencement is required to submit a notification to the Chairperson of the Agency.
- (3) Excluded from the provisions as referred to in section (1) and section (2), for processed food and cosmetics a request for approval may be filed or the submission of a notification.

Article 6

- (1) The submission for approval or notification as referred to in Article 5 are not intended for research in the framework of education.
- (2) Clinical Trials for educational purposes as referred to in section (1) may use test products that do not yet have marketing authorization in Indonesia.
- (3) Clinical Trials for educational purposes as referred to in section (1) is obligated to comply with the provisions of premarketing Clinical Trials.

Article 7

The implementation of Clinical Trials as referred to in Article 5, must priory obtain the approval of the Ethics Committee.

Article 8

- (1) The Principal Investigator implementing Clinical Trials must have a GCP certificate.
- (2) Provisions regarding the GCP certificate as referred to in section (1) will be stipulated separately.

CHAPTER III

FILING FOR APPROVAL OF CLINICAL TRIALS

Part One

Filing for the Approval of Premarketing Clinical Trials

Article 9

- (1) The filing for approval of premarketing Clinical Trials is implemented in writing by the sponsor or CRO to the Chairperson of the Agency.
- (2) The filing as referred to in section (1) uses the form as contained in Annex I which is an integral part of this Regulation.
- (3) The flow of filing for the approval of premarketing Clinical Trials and the necessary documents are as contained in Annex II which is an integral part of this Regulation.

Part Two

Submission of the Post-marketing Clinical Trial Notification

Article 10

- (1) The submission of post-marketing Clinical Trial notifications are performed in writing by the sponsor or CRO to the Chairperson of the Agency.
- (2) Submission of the notification as referred to in section (1) uses the sample form as referred to in Annex I which is an integral part of this Regulation.
- (3) The flow of submitting the post-marketing Clinical Trial notification together with the necessary documents are as contained in Annex III which is an integral part of this Regulation.

Part Three
Contract Research Organization

Article 11

- (1) CRO as referred to in Article 9 section (1) and Article 10 section (1) must be located in Indonesia.
- (2) CRO personnel must have proper understandings of the GCP.
- (3) In the event that the sponsor who will perform the Clinical Trials is from overseas, then the sponsor must delegate part or all the duties to the representative or CRO domiciled in Indonesia.

Part Four

Costs

Article 12

On the filing of approval for Clinical Trials as referred to in Article 9, costs are imposed as Non Tax State Revenues (PNBP) in accordance with the provisions of legislation.

CHAPTER IV
EVALUATION AND DECISIONS

Part One

Evaluation of Documents

Article 13

- (1) Evaluation of Clinical Trial documents will be performed on the filing of approval for clinical trials as referred to in Article 9 and the submission of notifications as referred to in Article 10.
- (2) An evaluation team on Clinical Trial documents as referred to in section (1) is established an Evaluation Team for Clinical Trials Documents .
- (3) The evaluation team as referred to in section (2), is established by the Chairperson of the Agency.
- (4) In implementing evaluations on Clinical Trial documents as referred to in section (1), the evaluation team may request opinions of experts on Clinical Trials.

Part Two
Premarketing Clinical Trials

Article 14

- (1) On the filing of approval for Clinical Trials as referred to in Article 9 section (1), the Chairperson of the Agency may issue decisions in the form of:
 - a. approval;
 - b. rejection; or
 - c. request for amendment of the Clinical Trial documents.
- (2) The Decisions in the form of approvals, rejections or request for amendment of the Clinical Trial documents as referred to in section (1) for premarketing clinical trials is be issued no later than 20 (twenty) work days from the date of receipt of the document.

Part Three
Post-marketing Clinical Trials

Article 15

- (1) The Chairperson of the Agency may response to the submission of post-marketing clinical trial notifications as referred to in Article 10 not later than 20 (twenty) work days from the date of receipt of the document.
- (2) The applicant may implement post-marketing clinical trials as referred to in section (1) if within a period of 20 (twenty) work days no response is received from the Chairperson of the Agency.

Part Four
Validity Period

Article 16

- (1) The approval as referred to in Article 14 section (1) point a is valid for 2 (two) years from the date of issue.
- (2) In the event that the implementation of Clinical Trials exceed the approval period provided as referred to in section (1), the sponsor or CRO must submit a request for extension of approval to the Chairperson of the Agency.
- (3) Filing of the request for extension of approval as referred to in section (2) must be accompanied by reasons.

Part Five
Follow-up

Article 17

- (1) The Chairperson of the Agency performs GCP inspections on the centers of Clinical Trial implementations and/or other locations related to the implementation of clinical trials.
- (2) In the implementation of GCP inspections as referred to in clause (1), the Chairperson of the Agency assigns the implementation to the GCP inspector of the Indonesian Food And Drug Authority.
- (3) The GCP inspection as referred to in section (2) may be performed prior, during and/or after Clinical Trials are implemented.
- (4) Provisions regarding GCP inspections are implemented according to the rules and regulations.

CHAPTER V
TEST PRODUCTS

Article 18

- (1) Test products to be used in Clinical Trials must have initial safety data and quality requirements in accordance with the clinical trial phases.
- (2) In the event that test products as referred to in section (1) need to be imported into the territory of Indonesia, the sponsor must obtain an approval of the Chairperson of the Agency.
- (3) Filing of the request to import test products as referred to in section (2) is performed in writing together with the filing of the request for approval of the Clinical Trials.
- (4) The approval as referred to in section (2) is issued together with the approval for the implementation of Clinical Trials, by using the format of approved import as contained in Annex IV which is an integral part of this Regulation.

Article 19

In the event that the test product as referred to in Article 18 contains specific ingredients that cause sensitivity to the beliefs of particular public groups ,it must be described in the PSP.

CHAPTER VI
SUSPENSION OR TERMINATION OF CLINICAL TRIALS

Article 20

The Chairperson of the Agency may instruct the clinical trial sponsor to suspend or terminate ongoing clinical trials, if:

- a. Clinical trial safety problems occur and after consultation with Clinical Trial experts; and/or
- b. Clinical trials are implemented without the approval of the Ethics Committee.

CHAPTER VII
REPORTING OF CLINICAL TRIALS

Part One

Serious Adverse Events and Serious Adverse Test Products

Article 21

- (1) The Principal Investigator is obligated to report all Serious Adverse Events in Clinical Trials in Indonesia to the:
 - a. Sponsor; and
 - b. Ethics Committee.
- (2) Reporting of Serious Adverse Events as referred to in section (1) point a is conducted as soon as possible, no later than 24 (twenty four) hours since first identified.
- (3) Reporting of Serious Adverse Events as referred to in section (1) point b is conducted no later than 3 (three) calendar days.
- (4) In the event that Serious Adverse Events as referred to in section (2) and section (3) are still ongoing, then follow-up reporting shall be conducted as soon as possible up till the series of events is concluded.
- (5) Excluded from the provisions as referred to in section (2) and section (3), Serious Adverse Events that since the start were predicted to occur based on the protocol or other documents as Serious Adverse Events do not require immediate reporting.

Article 22

- (1) The sponsor is obligated to report Serious Adverse Test Products of Clinical trials in Indonesia to the Chairperson of the Agency.
- (2) Reporting of adverse reactions as referred to in section (1) is conducted immediately, no later than :
 - a. 7 (seven) calendar days since first identified for initial reporting that is life-threatening and/or death and followed by a complete report within a period of the next 8 (eight) calendar days; and
 - b. 15 (fifteen) calendar days since first identified for other serious adverse reactions.
- (3) Reporting as referred to in section (2) uses the format as contained in Annex V which is an integral part of this Regulation.

Article 23

- (1) The sponsor is obligated to report Serious and Unexpected Adverse Test Products (Unexpected Serious Adverse Drug Reaction) of clinical trials in other countries that involve Clinical Trial centers in Indonesia to the Ethics Committee and the Chairperson of the Agency.
- (2) In the event as referred to in section (1) is still ongoing, follow-up reporting is conducted as soon as possible until the series of events is concluded.
- (3) Reporting as referred to in section (1) must use the Indonesian or English languages.

Part Two

Reporting the Implementation of Clinical Trials

Article 24

- (1) The sponsor is obligated to report the progress of the Clinical Trials implemented to the Chairperson of the Agency:
 - a. every 6 (six) months;
 - b. at the end of the Clinical Trial implementation; and/or
 - c. in the event that the Clinical Trial implementation is terminated prematurely together with the reasons.
- (2) Reporting as referred to in section (1) point b is performed no later than 30 (thirty) work days since the end of the Clinical Trial implementation.
- (3) Reporting as referred to in section (1) point c is performed no later than 15 (fifteen) work days since the termination of the Clinical Trial implementation.

- (4) Reporting as referred to in section (1) shall use the format as contained in Annex VI, Annex VII, and Annex VIII which is an integral part of this Regulation.

CHAPTER VIII
AMENDMENT OF DOCUMENTS

Article 25

- (1) The sponsor is obligated to submit amended Clinical Trial documents.
(2) Amended Clinical Trial documents that affect the safety of clinical trial subjects must obtain the approval of the Chairperson of the Agency.

CHAPTER IX
ADMINISTRATIVE SANCTION

Article 26

Violations on the provisions in this Regulation can be subject to the following administrative sanctions:

- a. warnings;
- b. suspension of Clinical Trials; and/or
- c. termination of the Clinical Trial implementation.

CHAPTER X
TRANSITIONAL PROVISIONS

Article 27

All provisions regarding Clinical Trials prior to the issuance of this Regulation remain effective as long as it is not contrary to the provisions in this Regulation.

CHAPTER XI
CLOSING PROVISION

Article 28

At the time this Regulation comes into force:

- a. The Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 9 of 2014 on the Procedures for the Approval of Clinical Trials; and

b. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 13 of 2014 on Guidelines for Clinical Trials of Herbal Drugs; are repealed and declared ineffective.

Article 29

This Regulation comes into force on the date its promulgation.

In order that every person may know hereof, it is ordered to promulgate this Agency Regulation by its placement in the State Bulletin of the Republic of Indonesia.

Issued in Jakarta
on 21 December 2015
CHAIRPERSON OF THE INDONESIAN FOOD AND
DRUG AUTHORITY,

signed

ROY A. SPARRINGA

Promulgated in Jakarta
on 29 December 2015
DIRECTOR GENERAL OF
THE LEGISLATION OF THE MINISTRY OF LAW AND HUMAN RIGHTS OF
THE REPUBLIC OF INDONESIA,

Signed

WIDODO EKATJAHJANA

STATE BULLETIN OF THE REPUBLIC OF INDONESIA YEAR 2015 NUMBER 1987

ANNEX I

REGULATION OF THE CHAIRPERSON OF THE
INDONESIAN FOOD AND DRUG AUTHORITY NUMBER
21 OF 2015ON

THE PROCEDURE OF CLINICAL TRIAL APPROVALS

THE FORM FOR FILING PREMARKETING CLINICAL TRIAL APPROVALS

The Chairperson of the Indonesian Food and Drug Authority

Jln. Percetakan Negara 23

JAKARTA

- | |
|--|
| <input type="checkbox"/> Request for Approval of Premarketing Clinical Trial Implementation |
| <input type="checkbox"/> Request for Post-marketing Clinical Trial Implementation Notification |

I. GENERAL INFORMATION

1. Title of Clinical Trial Protocol;
2. Number/version and date of protocol (final protocol);
3. Clinical Trial Phase (I, II, III or IV);
4. Clinical Trial Design;
5. Purpose of Clinical Trial:
6. The use of comparisons in Clinical Trials Yes <input type="checkbox"/> No <input type="checkbox"/>

7. If the answer in number 6 is Yes, the comparison used in the Clinical Trial is :	
Placebo <input type="checkbox"/>	Positive Control <input type="checkbox"/>
8. Number of subjects:	
9.a. Clinical Trial Documents Submitted :	
	Yes No
- Clinical Trial Protocol	<input type="checkbox"/> <input type="checkbox"/>
- Informed Consent	<input type="checkbox"/> <input type="checkbox"/>
- Approval of the Ethics Committee	<input type="checkbox"/> <input type="checkbox"/>
- Investigator's Brochure	<input type="checkbox"/> <input type="checkbox"/>
- Other Documents	<input type="checkbox"/> <input type="checkbox"/>
Specify :	
.....	
.....	
.....	
.....	
9.b. Test Product Documents Submitted :	
- Information on Test Products	<input type="checkbox"/> <input type="checkbox"/>
- Certificate of Analysis (CoA)	<input type="checkbox"/> <input type="checkbox"/>
- Certificate of Good Manufacturing Practices	<input type="checkbox"/> <input type="checkbox"/>
- Summary of Batch Protocol (sequential 3 batches) specifically for biological products including vaccines	<input type="checkbox"/> <input type="checkbox"/>
- Lot Release specifically for vaccines	<input type="checkbox"/> <input type="checkbox"/>
9.c. Other Supporting Documents :	
- Investigator GCP Certificate	<input type="checkbox"/> <input type="checkbox"/>
- CRO Contract (describe the sponsor function delegated/contracted to CRO and CRO resources, if using CRO)	<input type="checkbox"/> <input type="checkbox"/>

- Insurance (if any)	<input type="checkbox"/>	<input type="checkbox"/>
- Laboratory Certificate specifically for biological products including vaccines	<input type="checkbox"/>	<input type="checkbox"/>
- Curriculum Vitae of the Principal Investigator/ Investigator	<input type="checkbox"/>	<input type="checkbox"/>

10. Category of Test Products used for Clinical Trials :

Category I
The test product is new and Clinical Trials are never done before

Category II
The test product is new and the Premarketing Clinical Trials phases (phase I, II or III) are still ongoing.

Category III
The test product already received marketing authorization in Indonesia and Clinical Trials are implemented for new indications, new usage methods and new dosages.

Category IV
The product already received marketing authorization in Indonesia and Clinical Trials are implemented to observe the aspects of efficacy/ further safety.

Category V
Others, please describe :

Note:
The above mentioned categories are not the phases in Clinical Trials, it is only intended to describe the status of the Test Products.

II. INFORMATION OF THE IMPLEMENTATION CENTER

Multicenter Clinical Trial Yes <input type="checkbox"/> No <input type="checkbox"/>
Domestic Center (specify) :
Foreign Center (specify) :
State the name of the Principal Investigator and Assistant Investigator in each implementing center: - Principal Investigator - Last involved in Clinical Trial in year with number of subjects

III. INFORMATION ON TEST PRODUCTS

Test Products are : imported <input type="checkbox"/> local <input type="checkbox"/>
1. Generic Name :
2. Trade Name :
3. Chemical Name :
4. Pharmacology Class (for drugs):
5. Form of supply and strength of Test Product:
6. Packaging :
7. Method of administration :

8. Date of Expiration :
9. Batch Number :
10. Type and quantity of imported Clinical Trial Products (if importation is required):
11. Type and quantity of Clinical Trial Products to be used (for local clinical trial products):
12. Name and address of manufacturer :
13. Name and address of importer (if importation is required) :
14. Status of Test Product circulation in other countries (if any) :
15. In the event it contains/uses herbs :
 - Name of plant (scientific name):

If the composition consists of several plants, describe plant names one by one together with the scientific names and information regarding the contained compounds.
 - Parts of the plants used :
 - Source of raw material acquisition :
 - Form of simplistic or extracts:
 - Evidence of traditional use history (if any) and/or based on research journal :
 - Standardization conducted includes :
 - extraction method/ material preparation method
 - qualitative and quantitative determining method of active compounds/ identity compounds

IV. INFORMATION OF COMPARATIVE PRODUCTS

Drugs are : imported <input type="checkbox"/>
local <input type="checkbox"/>
Name of product :
Composition of active ingredients and the quantity :
Indication / usage :
Form of supply :
Method of administration and dosage :
Packaging :
Date of expiration :
Batch number :
Certificate of analysis :
Type and quantity of comparative products to be imported (if importation is required) :
Type and quantity of comparative products to be used (for local comparator products) :
Name and address of manufacturer :
Name and address of importer (if importation is required) :
Status of comparative product circulation in other countries (if any) :
If the product contains/ uses plants :
- Name of product:

If the composition consists of several plants, describe plant names one by one together with the scientific names and information regarding the contained compounds.

- Parts of the plants used (if any) :
- Source of raw material acquisition (if any) :
- Form of simplistic or extracts (if any) :
- Evidence of traditional use history and/or based on research journal (if any):
- Standardization conducted includes (if any):
 - extraction method/ material preparation method
 - qualitative and quantitative determining method of active compounds/ identity compounds

V. INFORMATION ON THE SPONSOR AND CONTRACT RESEARCH ORGANIZATION (if any)

1. Name and address of sponsor:
2. Responsible person representing the sponsor (name and telephone number) :
3.1. Name and address of CRO (if there is a contract with CRO):
3.2. Type of authority delegated by the Sponsor to CRO: 3.2.1 3.2.2
Agreements related to number 3.2 between the Sponsor and CRO: Available <input type="checkbox"/> Not available <input type="checkbox"/> (attached)

VI. APPROVAL OF THE ETHICS COMMITTEE

Approval of the Ethics Committee (attached) - Name and address of the Ethics Committee : - Number and date of approval :
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VII. STATEMENT OF THE INVESTIGATOR

I/we will comply with the provisions contained in the Regulation of the Regulation of the Chairperson of the Indonesian Food And Drug Authority Number 21 on the Procedure of Clinical Trial Approvals.

(stamp)

Signature

Name (in block letters)

Date

*Note : the original is submitted to the POM Agency

VIII. STATEMENT OF THE SPONSOR

We will comply with the provisions stipulated in Regulation of the Chairperson of the Indonesian Food and Drug Authority on the Procedure on the Approval of Clinical Trials.

We declare that the information submitted is true on the date of submission of the dossier.

We will inform the Ethics Committee and the Chairperson of the Agency any information amendment that may occur.

We will guarantee claims incurred related to the occurrence of injuries or deaths in the implementation of Clinical Trials, unless the injury or losses incurred are due to non-compliance to the Clinical Trials.

(stamp)

Signature

Name (in block letters)

Date

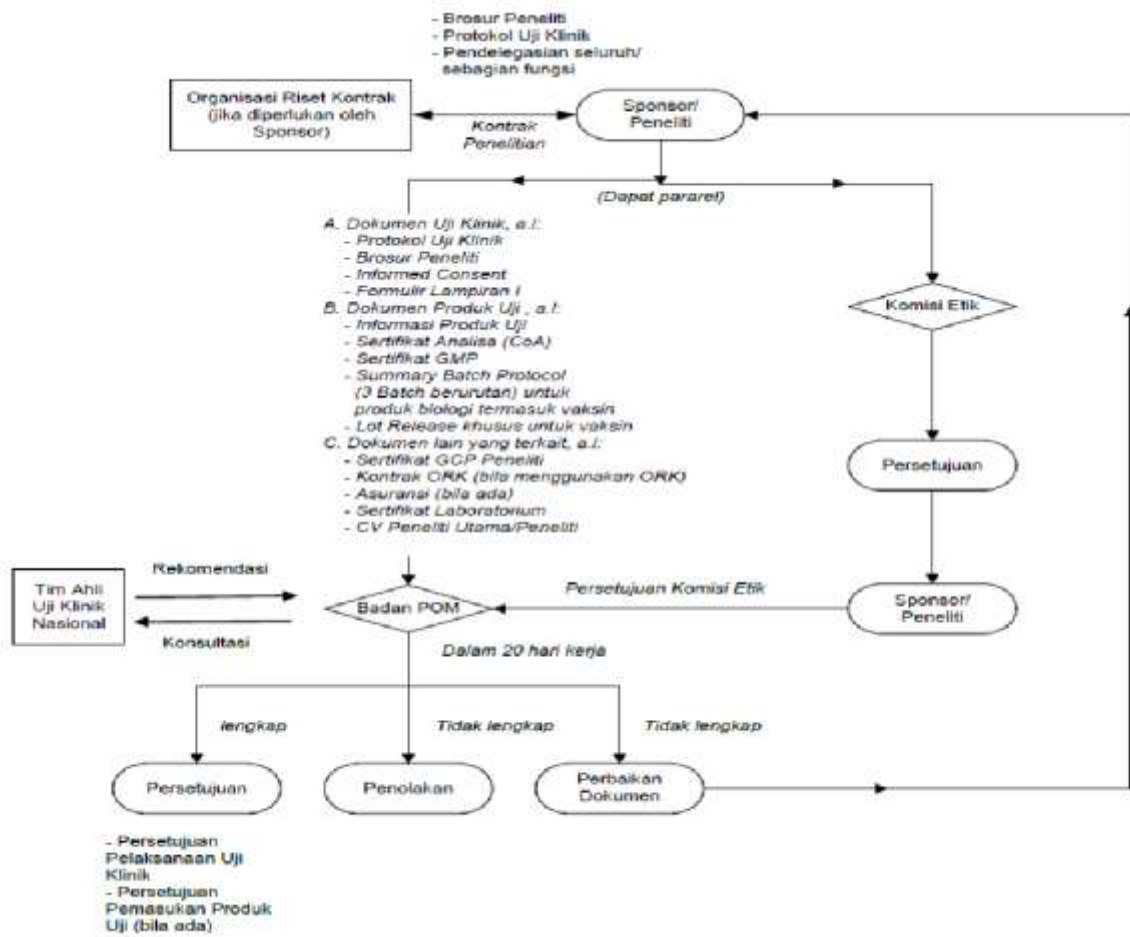
THE CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY ,

signed

ROY A.SPARRINGA

ANNEX II
REGULATION OF THE CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG
AUTHORITY NUMBER 21 OF 2015
ON
THE PROCEDURE OF CLINICAL TRIAL
APPROVALS

FLOW OF REQUEST FOR PREMARKETING CLINICAL TRIALS



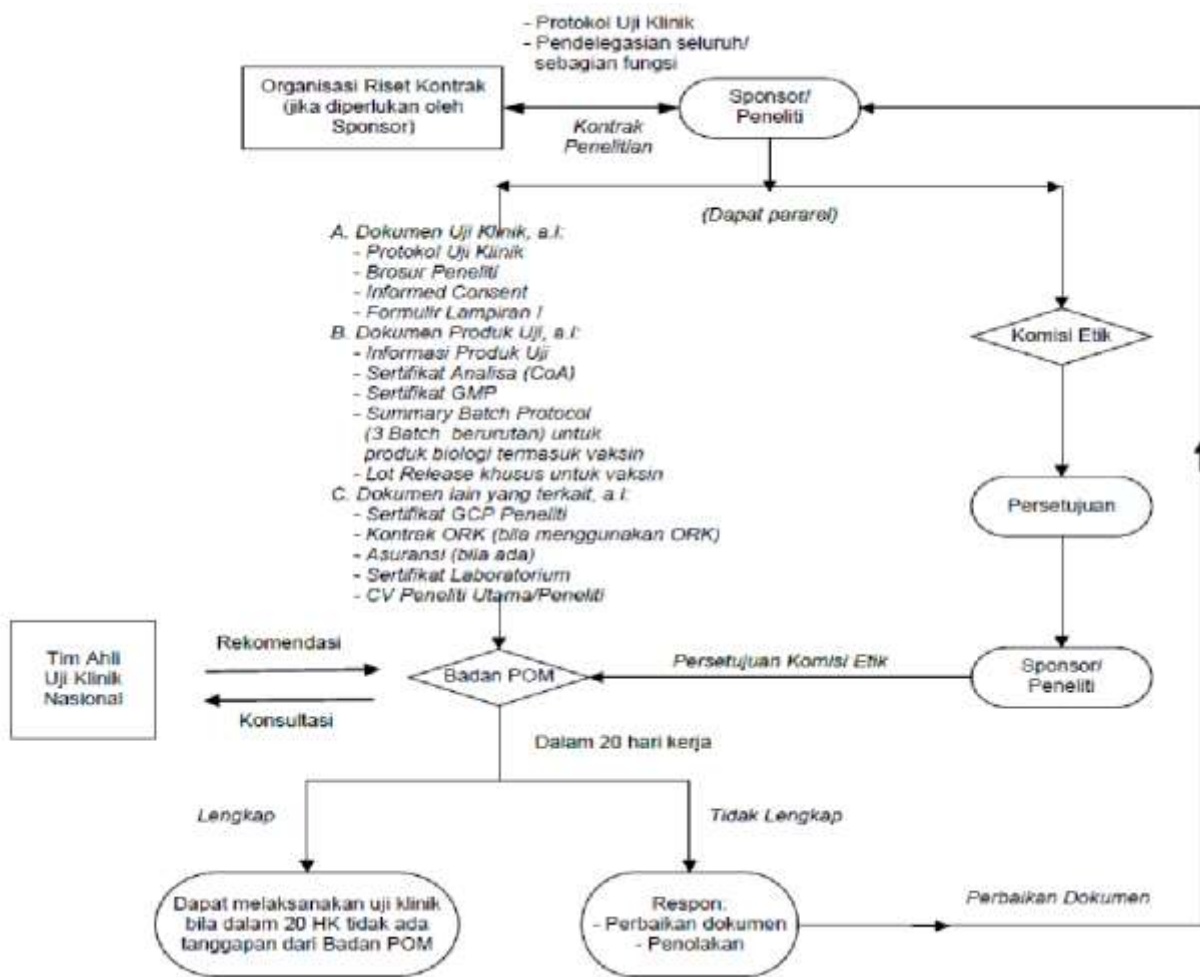
THE CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY ,

signed

ROY A.SPARRINGA

ANNEX III
REGULATION OF THE CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG
AUTHORITY NUMBER 21 OF 2015
ON
THE PROCEDURE ON THE CLINICAL
TRIAL APPROVAL

FLOW OF SUBMITTING THE POST-MARKETING CLINICAL TRIAL
NOTIFICATION



THE CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY ,

signed

ROY A.SPARRINGA

ANNEX IV
REGULATION OF THE CHAIRPERSON OF THE
INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 21 OF 2015
ON
THE PROCEDURE ON CLINICAL TRIAL APPROVALS

FORMAT OF THE APPROVAL FOR IMPORTING TEST PRODUCTS

Jakarta,

Number :
Attachment :
Subject : Approval for Import of Test Products
To :

Referring to your letter No..... dated.....
Subject request for the import of test products, we herewith inform you that in principle we approve your test product import with the protocol entitled "....."

1. Name and quantity of the test product :
2. Batch number of test product :
3. Manufacturer and source of origin

Test product:

Importer :

Based on the following provisions :

1. The test product is imported from country in above mentioned quantity.
2. The test product is used for above mentioned Clinical Trial based on the Clinical Trial Implementation Approval number and the Ethics Committee Approval number

Jakarta,

THE INDONESIAN FOOD AND DRUG
AUTHORITY

Chairperson,

.....
NIP.

THE CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY ,

signed

ROY A.SPARRINGA

ANNEX V
 REGULATION OF THE CHAIRPERSON OF
 THE INDONESIAN FOOD AND DRUG
 AUTHORITY
 NUMBER 21 OF 2015
 ON
 THE PROCEDURE ON CLINICAL TRIAL
 APPROVALS

FORM OF REPORTING SERIOUS TEST PRODUCT ADVERSE REACTIONS

REPORTING	
SERIOUS TEST PRODUCT ADVERSE REACTION	
When first identified : (Day/Date):	Initial of Subject : ID NO. of Subject :
Manifestation of incident (describe)	Clinical Trial Center : Code of Center : Principal Investigator :
Condition before the incident (describe)	Country : Title and Version of Protocol : Approval of Ethics Committee :
Handling of incident (describe)	
Consequence <input type="checkbox"/> Recovered <input type="checkbox"/> Passed away <input type="checkbox"/> Recovered with remaining symptoms <input type="checkbox"/> Not recovered yet <input type="checkbox"/> Others (Specify) 	

Participation in the clinical trial <input type="checkbox"/> continued, describe <input type="checkbox"/> terminated, describe

.....,

Acknowledged by,

(Sponsor)

(Principal Investigator)

THE CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY ,

Signed

ROY A. SPARRINGA

ANNEX VI
REGULATION OF THE CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG
AUTHORITY
NUMBER 21 OF 2015
ON
THE PROCEDURES ON CLINICAL TRIAL
APPROVALS

**REPORTS ON CLINICAL TRIAL IMPLEMENTATIONS EVERY 6 (SIX)
MONTHS**

No

Based on the Clinical Trial Implementation Agreement of the National Agency of Drug and Food Control Number ..., for the Clinical Trial with the Protocol entitled “.....””, we report the progress of the referred Clinical Trial as follows :

Number/Protocol Version :

Approval of the Ethics Committee :

Principal Investigator :

Sponsor :

Contract Research Organization (CRO) :

Clinical Trial Center :

Number of Monitoring by the Sponsor/CRO :

Commencement of Clinical Trial :

Number of Planned Subjects :

Number of Subjects Participating in the Clinical Trial :

Number of Subjects Completing the Clinical Trial :

Number of Subjects Withdrawing/Drop Out :
(describe reasons, if any)

Number of Serious Product Adverse Reactions :
(describe, if any, and describe the conclusion of the Serious Product Adverse Reactions)

Quantity of remaining Test Products :
(describe what is done with
the remaining Test Product)

Jakarta,
Sponsor of the Clinical Trial

Signature

Printed Name

Position

THE CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed

ROY A. SPARRINGA

ANNEX VII
REGULATION OF THE CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG
AUTHORITY
NUMBER 21 OF 2015
REGARDING
THE PROCEDURE ON CLINICAL TRIAL
APPROVALS

**REPORT ON THE COMPLETION OF THE CLINICAL TRIAL
IMPLEMENTATION
NO.**

Based on the Approval of the Clinical trial Implementation of the National Agency of Drug and Food Control Number, for the Clinical Trial with the Protocol entitled ".....", we report that the following Clinical Trial has been completed :

Number/Protocol Version :

Approval of the Ethics Committee :

Principal Investigator :

Sponsor :

Contract Research Organization (CRO) :

Clinical Trial Center :

Number of Monitoring by the Sponsor/CRO :

Commencement of Clinical Trial :

Number of Planned Subjects :

Number of Subjects participating in the Clinical Trial :

Number of Subjects Completing the Clinical Trial:

Number of Subjects Withdrawing/Drop Out :(describe reasons, if any)

Number of Serious Product Adverse Reactions :(describe, if any, and describe the end of the Serious Product Adverse Reactions)

Quantity of remaining Test Products :(specify what is done with the remaining Test Products)

Jakarta,

Sponsor Clinical trial

Signature

Printed Name

Position

THE CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed.

ROY A. SPARRINGA

ANNEX VIII
REGULATION OF THE CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG
AUTHORITY NUMBER 21 OF 2015
ON
THE PROCEDURE ON THE CLINICAL
TRIAL APPROVAL

**REPORT ON THE TERMINATION OF THE CLINICAL TRIAL
IMPLEMENTATION**

No.

Based on the Approval of the Clinical Trial Implementation from the National Agency of Drug and Food Control Number , for Clinical Trial with the protocol entitled “..... ”, we report that the implementation of the referred Clinical Trial has been prematurely terminated, as follows :

Number/Protocol Version :

Approval of the Ethics Committee :

Principal Investigator :

Sponsor :

Contract Research Organization (CRO) :

Clinical Trial Center :

Number of Planned Subjects :

Number of Subjects Participating in the Clinical Trial :

Number of Subjects Completing the Clinical Trial:

Number of Drop Out Subjects :

Commencement of Clinical Trial :

Quantity of remaining Test Products :
(specify what has been done
with the remaining Test
Products)

Reason of Termination :

Jakarta,
Sponsor of the Clinical Trial

Signature

Printed Name

Position

THE CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed

ROY A. SPARRINGA