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1. Purpose

This standard operating procedure describes how the MRIN Ethics Committee (MRIN EC) manages to review an initially submitted protocol.

2. Scope

This SOP applies to the review process of the study protocol package submitted for the first time.

3. Responsibility

It is the responsibility of the assigned reviewers to thoroughly review the study protocols delivered to them, give their decision, observation and comments to the MRIN EC in the Assessment Form and return to the Secretariat Office on the date due.

The MRIN EC Secretariat is responsible for receiving, verifying and managing the contents of both the hard copies and the electronic version of the received packages. In addition, the secretariat should create a protocol specific file, distribute the packages and get them reviewed by the MRIN EC and deliver the review results to the applicants.

4. Flow chart

No.	Activity	Responsibility
1	Receive the initial review submission package	EC Secretariat
	↓	
2	Review and Assign reviewers	Chairperson/Vice Chairperson/Secretary of MRIN EC
	↓	
3	Receive and verify the content of the package	EC Members/Reviewer
	↓	
4	Review the protocol	EC Members /Reviewers
	↓	

5	MRIN EC Meeting	EC Members / Secretariat/ Chairperson
	↓	
6	Communication of the decision	EC Members / Secretariat/ Chairperson

5. Detailed instructions

5.1 Receive the initial review submission package

- ☐ For Initial Review Submission, verify the contents of the protocol submitted package to include (AF/01-007/2020/01.4)
- ☐ Check the completeness of necessary information in the Initial Review Submission Form (AF/01-010/2020/01.4)
- ☐ Check the Summary Sheet of the Study Protocol for inclusion of all items mentioned in the Summary Sheet (AF/02-010/2020/01.4)
- ☐ Check the submitted Protocol and Related Documents for the following contents:
  - ☐ Subjects Information sheets
  - ☐ Informed Consent Form
  - ☐ Case Record Form (if applicable)
  - ☐ Study budget and budget justification
  - ☐ Agreement of the study (e.g. from collaborators, sponsor, etc)
  - ☐ Curriculum Vitae of investigator
  - ☐ Study related brochure (Changed)

5.2 Review and Assign Reviewers

- ☐ The Secretary of the MRIN EC decides whether the protocol should be exempted, expedited or needs a full board meeting to review.
- ☐ Check the Initial Review Submission Form (AF/01-010/2020/01.4)
- ☐ The Secretary assign two reviewers who may include him/ her
- ☐ An independent consultant can be appointed as third reviewer when none of the MRIN EC members has the specific expertise
- ☐ Fill out the reviewer assignation form (AF/01-010/2020/01.4)

5.3 Receive and Verify the content of the packages

- ☐ Check the distributed packages.
- ☐ Sign and date an acknowledgement form upon receiving the packages.
- ☐ Return the receipt form back to the delivery person / MRIN EC Secretariat.
- ☐ Look for an Assessment Form (AF/01-008/2020/01.5)

SOP/008/2020/01.5

- ☐ Look for the due date for the review.
- ☐ If the review will require a full board meeting, check the meeting date to see if he/she is available to attend the meeting.
- ☐ Notify the MRIN EC Secretariat if there are documents missing, or the specified date cannot be met.

5.4 Review the Protocol

5.4.1 Initial Review Application Form

- ☐ Check the form for completeness of the information and signatures of the principal investigator

5.4.2 Assessment Form

- ☐ Use the Assessment Form (AF/01-008/2020/01.5) to guide the review and deliberation process.
- ☐ Complete and return the form to Secretariat within 7 (seven) working days

  Note: The completed Assessment Form is the official record of the decision reached by the EC for the specific protocol.

- ☐ Consider the following criteria when performing the review:
  - ☐ minimize risks to participants;
  - ☐ risks must be reasonable in relation to anticipated benefits;
  - ☐ participants are selected equitably;
  - ☐ informed consent is adequate, easy to understand and properly documented;
  - ☐ the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate;
  - ☐ there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate; and
  - ☐ appropriate safeguards are included to protect vulnerable participants.
- ☐ Make comments where appropriate.
- ☐ Sign and date the reviewer's name.
- ☐ Refer to SOP/008/2020/01.5 when performing the review

5.4.3 Request for an Appeal Procedures

5.4.3.2 Inquiry or Appeals of MRIN EC Decisions

- Investigators can submit an inquiry or appeal of board recommendations within the allowable resubmission period of ninety (90) days by submitting the letter to MRIN EC including the reason of requesting of appeal.
- Processing of inquiries or appeals will follow the regular cut off dates of submissions described above in SOP 010/2020/01.4, Item 5.2 Study protocol submissions will be assigned to Primary reviewers.

5.5 MRIN EC meeting

In the case that the Chairperson/Vice Chairperson/Secretary decided that the protocol requires a full board meeting to review:

- ☐ The primary reviewer presents a brief oral or written summary of the study design and his/her comments.
- ☐ The Chairperson or designee entertains discussion on each document under consideration (e.g., protocol, informed consent, investigator's and site qualifications, advertisements).
- ☐ Recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the Committee are noted in the meeting minutes as 'with modifications made by MRIN EC' and will be communicated to the investigator.
- ☐ The Committee decide to either:
  - ☐ Approve the study to start as presented with no modifications
  - ☐ Require minor modifications to item(s) noted at the convened meeting and to be followed-up by the Primary Reviewers after receiving the requested modifications
  - ☐ Require major modifications and/or request further information to be resubmitted and subjected to review in the next full Board meeting.
  - ☐ Disapprove the study and state the reason
- ☐ If the study is approved, the Committee determines the frequency of Continuing Review from each investigator.

- ☐ If the Committee decide not to approve the study, the Secretariat notifies the investigator in writing about the decision and the reason for not approving the study.
- ☐ If the investigator wishes to appeal to the decision, he/she may do so by contacting the EC Secretariat. The appeal process is stated in the action letter to the investigator.
- ☐ If the Committee requires modifications to any of the documents, the Secretariat sends a written request of the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the MRIN EC.

5.6 Final Communication of the Decision

- ☐ The Secretariat sends an action letter within 7 (seven) days after the meeting along with the approved documents to the investigator. The letter contains, at a minimum, a listing of each document approved, the date set by the MRIN EC for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- ☐ If the MRIN EC arrive at the decision that require modifications (minor or major revision) to any of the documents, the Secretariat sends a written request of the specific changes to the Investigator to make the necessary changes and resubmit the documents to the MRIN EC within 7 (seven) working days. Resubmission should be made not later than 7 (seven) days before the next schedule EC Meeting.
- ☐ If the Board votes not to approve the study, the Chairperson or Vice Chairperson or Secretary notifies the investigator in writing of the decision and the reason for disapproving the study. If the investigator wishes to appeal this decision, he or she may do so by contacting MRIN EC within 7 (seven) working days. This process is stated in the action letter provided to the investigator.

6. Glossary

Initial Review	The first time review of that protocol made by two or three individual reviewers (MRIN EC members or non-members) in advance of the full Committee meeting, and comments of the reviewers will be reported to the full Committee meeting.

Phase I studies	Initial introduction of an investigational new drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses.
Phase II study	A Study of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.
Phase III study	A Study expands controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.
Phase IV study	A study that seeks to expand an approved medication's use into a new population, new indication, or new dose.
Stipulation	Specify as terms of or condition for an agreement, contract, etc. state, put forward for a necessary condition.
Gift	An item given to someone without the expectation of payment or anything in return.
Compensation	Compensation for the inconvenience of the participant (Reimbursement, insurance,items)

7. Annex

Annex 1	AF/01-010/2020/01.4	Protocol Submission Form for Clinical Trial
Annex 2	AF/02-010/2020/01.4	Protocol Submission Form for Health Related Research Survey, Registry, Surveillance, Epidemiology, Stored Biological Specimen, Non Clinical
Annex 3	AF/03-010/2020/01.4	Informed Consent Form & checklist
Annex 4	AF/04-010/2020/01.4	Document History

8. References

- Peraturan Pemerintah Republik Indonesia Nomor 39 Tahun 1995 tentang Penelitian dan Pengembangan Kesehatan, http://www.litbang.depkes.go.id/unduh_pp
- Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization, 2000, Geneva.
- Surveying and Evaluating Ethical Review Practices, World Health Organization, 2002, Geneva.
- International Conference on Harmonisation (ICH) Harmonised Tripartite : Guideline for Good Clinical Practice E6(R1), Current Step 4 version dated 10 June 1996, November 2005, November 2016
- Undang-undang Kesehatan No. 36 Tahun 2009 pasal 44.
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011, World Health Organization,
- Pedoman Nasional Etik Penelitian Kesehatan, Komisi Nasional Etik Penelitian Kesehatan, 2011.
- SIDCER Self-Assessment Tool, http://www.fercap-sidcer.org/selftool.php, accessed January 2013.
- Associated SOPs: SOP/007/2020/01.4, SOP/008/2020/01.5, SOP/010/2020/01.4.
- Pedoman Cara Uji Klinik Yang Baik Di Indonesia, Edisi III, 2016, Badan Pengawas Obat dan Makanan , Republik Indonesia
- SOP University of the Philippines Manila Research Ethics Board, 2019

Annex 1
Form AF/01-010/2020/01.4

PROTOCOL SUBMISSION FORM FOR CLINICAL TRIAL

To be filled by Principal Investigator (copy of 2)

Please fill out the form completely and return to the Secretariat of MRIN Ethics Committee (MRIN-EC), Jalan Boulevard Jendral Sudirman 1688, Lippo Karawaci, Tangerang 15810, Tel. +62 21 54210123, Fax. +62 21 542 10110, Email : mrin.ec@mrinstiute.org

Protocol No. (to be filled up by Secretariat of EC)

STUDY TYPE: (Mark "✓ " whichever apply to the study)
☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

STUDY POPULATION:: ☐ Healthy ☐ Patient ☐ Vulnerable groups

CHARACTERISTICS of PARTICIPANTS PARTICIPATED :

Age Range:	☐ 0 -17 yrs	☐ 18 - 44 yrs	☐ 45 - 65 yrs	☐ ≥ 66 yrs
Pediatric	☐ None	☐ < 1 yr	☐ 1-3 yrs	☐ 4 -14 yrs
Impaired	☐ None	☐ Physically	☐ Cognitively	☐ Mentally

REQUESTED EXCLUSION OF PARTICIPANTS:
☐ None ☐ Male ☐ Female ☐ Children ☐ Other (specify)_____)

SPECIAL RESOURCE REQUIREMENTS (check all that apply):
☐ Intensive Care ☐ Isolation unit ☐ Surgery
☐ Pediatric Intensive Care ☐ Transfusion ☐ CAT scan
☐ Gene therapy ☐ Controlled substances (Narcotics/Psychotropics)
☐ Prosthetics ☐ Gynecological services ☐ Others, specify…….
☐ Organ transplantation, specify…… ……..

IONIZING RADIATION USE (X-rays, radioisotopes, etc):
☐ None ☐ Medically indicated only

INVESTIGATIONAL NEW DRUG (IND) / DEVICE (IDE):

☐ None	☐ IND	☐ IDE
	No.Reg BPOM.:……	No.Reg BPOM:……
	Name:…….	Name:……
	Sponsor:…….	Sponsor:……...
	Holder:……	Holder:……...

HAS PRE-CLINICAL STUDY IN ANIMALS BEEN PERFORMED :
☐ No ☐ Yes, if yes please attach the result of study.....

PROCEDURE USE: ☐ Invasive ☐ Non-invasive

Annex 1
Form AF/01-010/2020/01.4

MULTI-SITE COLLABORATION: ☐ YES ☐ NO

FINANCIAL DISCLOSURE: ☐ YES ☐ NO

Conflict of Interest Declaration (Relationship with sponsor)	Are you a regular employee of the sponsor?	☐ Yes	☐ No
	Other ties with the sponsor	☐ Yes	☐ No

INSTITUTE RESEARCH CONTACT
Name:……
Address:……
Telephone:……
Fax:……
E-mail:……..

PARTICIPATING INVESTIGATORS (add extra pages if necessary):

First / Last Name	Institution	Telephone / Fax No.	E-mail
1.			
2.			
3.			
4.			
5.			

CONTACT PERSON:
Name:
Institute/ Address:
Telephone
E-mail:

Annex 1
Form AF/01-010/2020/01.4

CurriculumVitae of Researchers

1. Principal investigator	
Name	
Home address	
Education Background	
Research Experiences (at least the last 2 years)	
Publication (at least the last 2 years)	
Training on Ethics and GCP Training the last 3 years (attach Ethics and GCP Training certificate)	
Duties on the research	
2. Research Team Members	
Name	
Home address	
Education Background	
Research Experiences (at least the last 2 years)	
Publication (at least the last 2 years)	
Training on Ethics and GCP Training (the last 3 years and attach GCP and Ethics Training certificate)	
Duties on the research	
3. Research Team Members	
Name	
Home address	
Education Background	
Research Experiences (at least the last 2 years)	
Publication (at least the last 2 years)	
Training on Ethics and GCP Training (the last 3 years and attach GCP and Ethics Training certificate)	
Duties on the research	

Note : at least one of the research team provides GCP Training

Annex 1
Form AF/01-010/2020/01.4

Abstract*

Type of Protocol (Screening, Survey, Clinical Trial, etc)* delete

Aims*

Anticipated Outcome*

Annex 1
Form AF/01-010/2020/01.4

Mode of Intervention to the Human*

Methodology (Synopsis of Study Design)*

Analysis method*

Timeline*

* indicates required field. Describe in details (What , Where, When, How)

Annex 1
Form AF/01-010/2020/01.4

3.	Type of Research:	☐ Non-Cooperation ☐ National Collaboration ☐ International Collaboration (Attach ethical approval from corresponding country) ☐ Involvement of Foreign Researcher (Attach approval from the State Ministry for Science and Technology)
4	Description of the Study in brief: Mark whatever applied to the study. ☐ Randomized ☐ Stratified Randomized ☐ Open-labeled ☐ Double blinded ☐ Placebo controlled ☐ Single Blinded ☐ Cross-over ☐ Parallel ☐ Interim Analysis ☐ Use of Tissue samples ☐ Use of Blood samples ☐ Use of genetic materials ☐ Multicenter study ☐ Screening ☐ Treatment controlled ☐ Descriptive	
5	Type of Proposal:	☐ New Protocol ☐ Continued Protocol ☐ Modified Protocol ☐ Amendment Protocol If continued or modified, please state previous SP3 No.:
6	Institution	
7	Funding Resources	☐ Investigator Initiated, specify source of funding…… ☐ Sponsor ,specify name of sponsor……..
8	Total of Research Funding	Rp
9	Research Location	
10	Research Period	Start : End :

Annex 1
Form AF-01-010/2020/01.4

11	Has this protocol been submitted to other Ethics Committee before	☐ Yes; ☐ accepted ☐ rejected ☐ No
12	Type of Research: (Tick more than one when appropriate)	
	☐ Explorative/Descriptive ☐ Quantitative (Deductive)	
	☐ Cross-sectional ☐ Case-control ☐ Pre-Post test ☐ Cohort ☐ Clinical Experiment	
	☐ Quantitative (Inductive)	
13	Clinical Trial Phase ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV	
14	Purpose of Clinical Trial:	
15	Subject Inclusion Procedures:	
	a. Number of Subjects	
	b. Inclusion Criteria	
	c. Exclusion Criteria	
	d. Withdrawal/Drop Out Criteria	
	e. Acquisition of Subject's Informed Consent	
	e.1 Summarize information disclosure procedure to subject (Materials conveyed; Speaker; Means of information delivery; Self-informing through provided manuscripts/Group Session/Accompanied by family/Close acquaintance/Private session; Compensation; Q&A session, etc.)	
	e.2 Detail relationship between information giver with observed subject ☐ Physician – Patient ☐ Teacher- Student ☐ Employer-Employee ☐ No Relationship ☐ Others : (please specify)	

Annex 1
Form AF01-010/2020/01.4

17	Information on subtance or medical intervention on trial (Has such clinical trial taken place before, are safety data and benefits of previous identical/similar study or studies from other countries available?)		
18	Information about the drugs		
		Investigational Drug	Standard Drug
	a. Generic Name :		
	b. Product Name :		
	c. Chemical Name :		
	d. Pharmacology Class :		
	e. Dossage Form and strenght of a Drug		
	f. Package :		
	g. Delivery route :		
	h. Expired Date :		
	i. Batch No :		
	j. Certificate of Analysis :		
	k. GMP Certificate :		
	l. Type and Quantity imported drug,if any		
	m. Name and address of manufacturer :		
	n. Name and address of importir :		
	o. Approved drugs or not in marketed overseas) :		
19	Will biological samples be sent abroad? ☐ Yes ☐ If Yes, Please include Material Transfer Agreement		

Annex 1
Form AF/01-010/2020/01.4

20	Clinical Trial Process
	a. Administration of Intervention (Dose regimen, invasive measures, reference drugs, placebo) Provide explanatory guidance on procedure: dose and administration, frequency, interval, invasive measures taken, radiation, etc.
	b. Selection of Outcome Indicator
	c. Interim Analysis
	d. Clinical Trial Termination Procedure
	e. Time Estimate for Processing of One Subject (minute(s)/hour(s)/day(s)/week(s)/month(s)/year(s))
	f. Possible occurring subject involving ethical problem (e.g. inconvenience, please put to record)
21	Adverse Event (AE)
	a. Documentation (Details of events occurring during treatment)
	b. Analysis
	c. Emergency Rescue System
	d. Subject Withdrawal from Research at the Cause of AE
	e. Subject Compensation
22	Data Analysis
	a. Efficacy
	b. Safety
23	Post-Research Responsibility (Capacity building, benefits for local community, treatment maintenance on subjects, etc.)

Document Completeness (Tick box when appropriate)	
	One set cover letter from the referring institution
	2 Copies of original proposal approved by advisor or institute director
	2 Copies of Protocol Submission Form For Clinical Trial inlcluding supporting documents below
	Attachment 1. Information for Subject
	Attachment 2. Informed Consent Form & Check list
	Attachment 3. Memorandum of Understanding between Researcher, Sponsor and Research Institution (For Research Collaboration)
	Attachment 4. Ethical Approval from Other Institution (When Available)
	Attachment 5. Case Report Form/ Incidence Card
	Attachment 6. Forms: Questionnaire, Laboratory/Radiology Examination Request, Laboratory/Radiology Examination Results
	Attachment 7. Adverse Event Report Form
	Attachment 8. Investigator's Brochure (When Necessary)
	Attachment 9. Investigational Drugs Request Letter to or Approval from BPOM (New Drugs/Food Trial)
	Attachment 10. Result of the Pre-Clinical Study using of Animals (for Phase I and II)
	Attachment 11. Budgeting Details and Funding Resources
	Attachment 12. Others (e.g. Workflow)
Ethical Responsibility and COI Statement (please tick)	
	I hereby pledge to address all form of COI that I may have and perform my tasks objectively, protect the scientist integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator

Principal Investigator
Signature

_____ _____
Name Date

TYPE OF INITIAL REVIEW:*	**ASSIGNED REVIEWERS:***
☐ **Expedited Review** ☐ **Full Board Review**	**1.** **2.** **3.**
SIGNATURE*: _____ Date:…… ***to be filled by Chairperson/Vice Chairperson/Secretary MRIN EC**	

Annex 2
Form AF/02-010/2020/01.4

PROTOCOL SUBMISSION FORM FOR HEALTH RELATED RESEARCH SURVEY, REGISTRY, SURVEILLANCE, EPIDEMIOLOGY, HUMANIORA, STORED BIOLOGICAL SPECIMEN, NON-CLINICAL
To be filled by Principal Investigator (copy of 2)

Please fill out the form completely and return to the Secretariat of MRIN Ethics Committee (MRIN-EC), Jalan Boulevard Jendral Sudirman 1688, Tangerang 15810, Tel. +62 21 54210123, Fax. +62 21 54210110, Email : mrin.ec@mrinstitute.org

Protocol No. (to be filled up by Secretariat of EC) | | | | | | | | | | |

STUDY TYPE: (Mark "✓ " whichever apply to the study)
☐ Survey ☐ Social ☐ Medical ☐ Community based ☐ Individual based
☐ Screening ☐ Observational ☐ Epidemiology ☐ Intervention study
☐ Genetic Study ☐ Retrospective ☐ Prospective ☐ Others……..

STUDY POPULATION:: ☐ Healthy ☐ Patient ☐ Vulnerable groups

CHARACTERISTICS of PARTICIPANTS PARTICIPATED :

Age Range:	☐ 0 -17 yrs	☐ 18 - 44 yrs	☐ 45 - 65 yrs	☐ ≥ 66 yrs
Pediatric	☐ None	☐ < 1 yr	☐ 1-3 yrs	☐ 4 -14 yrs
Impaired	☐ None	☐ Physically	☐ Cognitively	☐ Mentally

REQUESTED EXCLUSION OF PARTICIPANTS:
☐ None ☐ Male ☐ Female ☐ Children ☐ Other (specify)_____)

SPECIAL RESOURCE REQUIREMENTS (check all that apply):
☐ Intensive Care ☐ Isolation unit ☐ Surgery
☐ Pediatric Intensive Care ☐ Transfusion ☐ CAT scan
☐ Gene therapy ☐ Controlled substances (Narcotics/Psychotropics)
☐ Prosthetics ☐ Gynecological services ☐ Others, specify…….
☐ Organ transplantation, specify…… ……

IONIZING RADIATION USE (X-rays, radioisotopes, etc):
☐ None ☐ Medically indicated only

PROCEDURE USE: ☐ Invasive ☐ Non-invasive

MULTI-SITE COLLABORATION: ☐ YES ☐ NO

FINANCIAL DISCLOSURE: ☐ YES ☐ NO

Annex 2
Form AF/02-010/2020/01.4

Conflict of Interest Declaration (Relationship with sponsor)	Are you a regular employee of the sponsor?	☐ Yes	☐ No
	Other ties with the sponsor	☐ Yes	☐ No

INSTITUTE RESEARCH CONTACT
Name:
Address:
Telephone:
Fax:
E-mail

PARTICIPATING INVESTIGATORS (add extra pages if necessary):

First / Last Name	Institution	Telephone / Fax No.	E-mail
1.			
2.			
3.			
4.			
5.			

CONTACT PERSON:
Name:
Institute/ Address:
Telephone
E-mail:

Annex 2
Form AF/02-010/2020/01.4

CurriculumVitae of Researchers

1. Principal investigator	
Name	
Home address	
Education Background	
Research Experiences (at least the last 2 years)	
Publication (at least the last 2 years)	
Training on Ethics	
Duties on the research	
2. Research Team Members	
Name	
Home address	
Education Background	
Research Experiences (at least the last 2 years)	
Publication (at least the last 2 years)	
Training on Ethics	
Duties on the research	
3. Research Team Members	
Name	
Home address	
Education Background	
Research Experiences (at least the last 2 years)	
Publication (at least the last 2 years)	
Training on Ethics	
Duties on the research	

Annex 2
Form AF/02-010/01.4

Abstract*

Aims*

Anticipated Outcome*

Mode of Intervention to the Human*

Annex 2
Form AF/02-010/01.4

Methodology (Synopsis of Study Design)*

Analysis method*

Timeline*

* indicates required field. Describe in details (What , Where, When, How)

Annex 2
Form AF/02-010/2020/01.4

3	Type of Research	☐ Survey ☐ Registry ☐ Surveillance ☐ Epidemiology ☐ Humaniora ☐ Stored/ Archived Biological Specimen ☐ Non-Clinical,specify : .....
		☐ Non-cooperation ☐ National collaboration ☐ International collaboration (Attach ethical approal from corresponding country) ☐ Involvement of foreign researcher (Attach approval from the State Ministry for Science and Technology)

4 Description of the Study in brief: Mark whatever applied to the study.

☐ Randomized	☐ Stratified Randomized	☐ Use of genetic materials
☐ Treatment controlled	☐ Parallel	☐ Descriptive
☐ Cross-over	☐ Preliminary Study	
☐ Use of Tissue samples	☐ Use of Blood samples	
☐ Multicenter study	☐ Screening	

Annex 2
Form AF/02-010/2020/01.4

5	Type of Proposal	☐ New Protocol ☐ Continued Protocol ☐ Modified Protocol ☐ Amendment Protocol If continued or modified, please state previous SP3 No.: ☐
6	Institution	
7	Funding Resources	
8	Total of Research Funding	
9	Research Location	
10	Period of Research	Start : End :

Annex 2

Form AF/02-010/2020/01.4

11	Has this protocol been submitted to other Ethics Committee	☐ Yes; ☐ accepted ☐ rejected ☐ No		
12	Research Description			
1	a. Research Type and Design	☐ Explorative/Descriptive		
		☐ Quantitative/Deductive		
		☐ Cross Sectional	☐ Case Control	☐ Cohort
		☐ Community Experiment	☐ Public/population Experiment	
		☐ Qualitative ☐ Mix Method		
	b. Type of Samples	☐ Individual	☐ Population	☐ Institutional, specify .....
	c. Number of Samples	1). Based on problem	☐ Yes	☐ No
		2). Based on minimum requirement for function: - participant observation	☐ Yes	☐ No

		- indepth interview		
		3). Based on population number (representative ness of the samples)	☐ Yes	☐ No
	d. Sample Collection	1). Probability :	☐ Simple Random ☐ Progressive Random ☐ Point Prevalence Survey ☐ Cluster	
		2). Non Probability	☐ Purposive Samples ☐ Quota Samples ☐ Chunk Samples ☐ Volunteer Samples	
	e. Type of Data	☐ Primary	☐ Secondary	
	f. Data Collection	☐ Interview ☐ Physical Examination ☐ Laboratory and/or Radiology Examination ☐ Document Analysis ☐ OTHERS (explained) : ……..		
	g. Time estimate for interview / sample measurement of one subject: ..... (minute(s)/hour(s)/day(s)/week(s)/month(s)/year(s)*)			

	* delete as applicable
13	Will biological samples be sent abroad? ☐ Yes ☐ No If Yes, Please include Material Transfer Agreement

14	Ethical Issue that might be encountered by subject			
	a. Data Confidentiality		☐ Yes	☐ No
	b. Research Risk			
	b.1. Interference of routine healthcare service activities		☐ Yes	☐ No
	b.2. Causing adverse effects on subject		☐ Yes	☐ No
	b.3. In opposition to common cultural values		☐ Yes	☐ No
	b.4. Occurrence of economical loss and stigmatization of subject		☐ Yes	☐ No
	c. Benefit of Participation			
	c.1. Incrementing on new knowledge		☐ Yes	☐ No
	c.2. Provision of medical attention		☐ Yes	☐ No
	d1.Compensation	☐ Yes ☐ No	If yes, state form of compensation: ☐ Item(s) describe.....	☐ Cash (describe total amount :...) ☐ Insurance
	D2. Gift (*please state it.....*)			
	e. Factors affecting compensation (coercion)			
	e.1. Researcher-Subject Relationship		☐ Yes	☐ No
	e.2. If yes, state type of relationship:		☐ Physician-Patient	☐ Teacher-Student

		☐ Employer-Employee	☐ Others
15	Informed Consent		
	a. Informed Consent Grouping:	☐ Individual	☐ Public
	b. Please detail means to invite subjects in participating in research when using individual/public groups. By verbal consent or situations where no informed consent is available, please provide explanatory feedback.		
16	If the research involves healthy individuals, please state the method of examination		
	If the research involves affected individuals, please state the method of examination		
17	Please name type of intervention (Information session, mass treatment, training, etc.)		
18	Please details documentation procedure during research, including adverse effects and subsistent complications.		

C. Document Completeness (Tick on box when appropriate)	
	One copy of cover letter from referring institution
	One copy of original proposal as approved by advisor or institute director. (Attach approval from authorized parties. Outline of research proposal should refer to guideline for PI Item 3.3f.)
	Two copies of application form for initial review Protocol Submission Form For Health Related Research,Survey, Registry, Surveillance, Epidemiology, Humaniora, Stored Biological Specimen**,** Non-Clinical, including suppoting documents below
	Attachment 1. Information for Subject
	Attachment 2. Informed Consent Form & checklist
	Attachment 3. Memorandum of Understanding between Researcher, Sponsor and Research Institution (For Research Cooperation)
	Attachment 4. Ethical Approval from Other Institution (When Available)
	Attachment 5. Case Report Form/ Incidence Card
	Attachment 6. Forms: Questionnaire, Laboratory/Radiology Examination Request, Laboratory/Radiology Examination Results
	Attachment 7. Adverse Event Report Form
	Attachment 8. Investigator's Brochure (When Necessary)
	Attachment 9. Budgeting Details and Funding Resources
	Attachment 10. Others (e.g. Workflow)
Ethical Responsibility and COI Statement (please tick)	
	I hereby pledge to address all form of COI that I may have and perform my tasks objectively, protect the scientist integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator

Principal Investigator
Signature

_____ _____

Name Date

TYPE OF INITIAL REVIEW:*	ASSIGNED REVIEWERS:*
☐ Expedited Review ☐ Full Board Review	1. 2. 3.
SIGNATURE*: _____ Date:…… *to be filled by Chairperson/Vice Chairperson/Secretary MRIN EC	

Annex 3
Form AF/03-010/2020/01.4

Informed Consent Form & checklist

Indicate if the ICF has the specified element	Page and paragraph where element is found (if it is not related , please state not applicable)
1. Statement that the study involves research	
2. Statement describing the purpose of the study	
3. Study-related treatments and probability for random assignment	
4. Study procedures including all invasive procedures	
5. Responsibilities of the participant	
6. Expected duration of participation in the study	
7. Approximate number of participants in the study	
8. Study aspects that are experimental	
9. Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; and integrating risks as detailed in the investigator's brochure	
10. Risks from allowable use of placebo (as applicable)	
11. Reasonably expected benefits; or absence of	

direct benefit to participants, as applicable	
12. Expected benefits to the community or to society, or contributions to scientific knowledge	
13. Description of post-study access to the study product or intervention that have been proven safe and effective	
14. Alternative procedures or treatment available to participant	
15. Compensation or insurance or treatment entitlements of the participant in case of study-related injury	
16. Anticipated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount	
17. Compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries	
18. Anticipated expenses, if any, to the participant in the course of the study	
19. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled	
20. Statement that the study monitor(s), auditor(s), the MRIN EC and regulatory authorities will be granted direct access to participant's medical records for purposes	

ONLY of verification of clinical trial procedures and data	
21. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality	
22. Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant	
23. Possible direct or secondary use of participant's medical records and biological specimens taken in the course of clinical care or in the course of this study	
24. Plans to destroy collected biological specimen at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant's right to refuse future use, refuse storage, or have the materials destroyed	
25. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development	
26. Statement that the participant or participant's legally acceptable representative will be	

informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue participation	
27. Statement describing access of participant to the result of the study	
28. Statement describing extent of participant's right to access his/her records (or lack there of vis à vis pending request for approval of non or partial disclosure)	
29. Foreseeable circumstances and reasons under which participation in the study may be terminated	
30. Sponsor, institutional affiliation of the investigators, and nature and sources of funds	
31. Statement whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider	
32. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury	
33. Comprehensibility of language used	

Annex 4
Form AF/04-010/2020/01.4

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	**Final version**
Ivet, Lia, Mona	01.1	11 October 2014	1. Synchronize the topic number and SOP number 2. Format Document History : Author, Version, Date and Description of the main change 3. Synchronize Annexes 1, 2, 3 of SOP 10, and streamline the items required to avoid repetition of information submitted by the PI 4. Revise Annex 1 : Correction "continued and "modified" 5. Section 5.7.: Time line for communication decision 6. Section 5.5.2 : Time line for reviewers feedback to Secretariat.
Irawan Yusuf, Yan Nuryanto, Monalisa	01.2	1 April 2017	1. Delete Komisi Etik Penelitian Kesehatan (KEPK) on the header 2. Item 5.5.2, box 2 : Time line of reviewer from 7 days to 7 (seven) Working days 3. Item 5.7 : Time line of notification communication decision to PI from 7 days to 7 (seven) Working days. 4. Item 5.7: Delete box 4 5. Item 5.7, box 3 : delete the word of "Immediately" 6. Item 5.7 : Delete Box 5 7. Annex 3 & 4 : delete attachment 7 (Research Description) & 8 (Material and Methods) 8. Annex 5 : delete attachment 5 (Research Description) & 6 (Material and Methods). 9. Annex 3,4, and 5 point 11 : to change documents submission from 5 copies to 3 copies

LSH/MW/IS	01.3	2 January 2019	1. Item 5.6 Box 4.2 Require minor modifications to item(s) noted at the convened meeting and to be followed-up by the Primary Reviewers after receiving the requested modifications 2. Item 5.6 Box 4 : replace the wording "vote" with "decide" and delete the statement "The Chairperson or designee calls for a separate vote on each element in review". 3. Annex 2 : To add required field to describe in details (what, where, when and how) 4. Annex 3 Item 12 : to include GCP Training (Copy of Certificate) 5. Annex 5 : Delete 6. Annex 6 : Replace Annex 6 with Annex 5 7. Annex 3 no. 12 : Replace 3 copies with 1 set 8. Item 4 & 5.2 : to add Chairperson & Vice Chairperson 9. Item 5 Box 3 : to add Vice Chairperson 10. Annex 1 : to add COI Declaration 11. Annex 3 & 4 attachment 2 : to add check list 12. Annex 3 & 4 attachment 3 : to add job description 13. Annex 3 & 4 attachment 3 : to reduce multiply of document from 3 to 2 copies 14. Annex 5 : Informed Consent and Check list 15. Replace Annex 5 :"Document History" to Annex 6
IS,MW,LSH, GE	01.4	02 January 2020	1. Flow Chart : Revised two step become one step 2. Flow chart : mix No.4 & 5 included detailed instructions, delete the step No. 5 in the flowchart 3. Step 4 Flowchart : " include verify the content of the

			package" 4. 5.2 : to include assign reviewer by the chairperson/vice chairperson/secretary MRIN EC 5. 5.2, box 1 : Include the chairperson/vice chairperson decided…. Review 6. 5.4.3 : to add appeal procedures 7. 5.5.1, box 1 : delete the statement of "the protocol chairperson…. secretariat" 8. Delete 5.5.1,box 2 9. 5.6, box 1 : add the word of "primary" 10. 6. Glossary : add Glossary "Gift/Souvenir and Compensation" 11. Form Non Clinical Trial : • D1, box "item(s) : Add the word " describe….." 12. Annex 1 & 2 : to add statement " Ethical Responsibility and COI Statement (please tick)" 13. Annex 4 & 5 becomes Annex 2 & 3 14. Form Clinical Trial "Funding Resources : to add" : ☐ Investigator Initiated ☐ sponsor 15. FORM Study Type of Research, No.17 : replace the "measure" with "intervention" 16. Form Clinical Trial,No.18 : to add "Information about drugs" 17. Documents completeness : • To add attachment 11 & 12 • attachment 11, 12 becomes 13 & 14 18. References : • Delete link WHO • Delete FERCAP SOP

			• Add ICH 2016 • Add SOP UP Manila Research Ethics Board