
	<b>Mochtar Riady Institute for Nanotechnology Ethics Committee (MRIN EC)</b>	<b>SOP /021/2020/01.6</b> <b>Effective date:</b> <b>2 January 2020</b>
	<b><u>Title:</u></b> <b>021. Agenda Preparation, Meeting Procedures and Minutes</b>	<b>Page 1 of 31</b>

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## **1. Purpose**

The purpose of this procedure is to identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of MRIN EC meetings.

## **2. Scope**


This SOP applies to administrative processes concerning the preparation of the agenda for all regular MRIN EC meetings, divided into three stages: before, during and after the meeting.

## **3. Responsibility**

It is the responsibility of the Secretariat to prepare the agenda for the EC meeting and to ensure the quality and validity of the minutes of the meeting. The Chairperson/ Secretary should review and approve the agenda and the minutes sent to him/her.

## **4. Flow chart**

<b><u>No.</u></b>	<b><u>Activity</u></b>	<b><u>Responsibility</u></b>
1	Before each Board Meeting	MRIN EC Secretariat
	↓	
2	During the Meeting	MRIN EC Secretariat, Members and Chairperson
	↓	
3	Consensus /Voting	MRIN EC Members without conflict of interest / Chairperson
	↓	
4	Prepare the Minutes and Decision Forms	MRIN EC Secretariat/ Secretary/ / Chairperson
	↓	
5	After the Board Meeting	Secretariat /Secretary/Chairperson

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## **5. Detailed instructions**

### **5.1 Before each Board meeting**

#### **5.1.1 Check for filled up forms for completeness.**

- Secretariat:
  - Reviews the new study application for completeness.
  - Documents the review by completing the appropriate checklist. If incomplete, Secretariat attempts to obtain the information from the person who submitted the application package.

#### **5.1.2 Consider the appropriate review channel of each protocol**


- Use the criteria and the procedures as described in the corresponding SOPs when deciding the review channel.
  - SOP /009/2020/01.4 for Expedited Review
  - SOP /010/2020/01.4 for Initial Review of Submitted Protocols
  - SOP/012/2020/01.5 for Review of Resubmitted Protocols
  - SOP/013/2020/01.6 for Review of Protocol Amendments
  - SOP/014/2020/01.6 for Continuing Review of Study Protocols
  - SOP/015/2020/01.5 for Review of Final Reports
  - SOP/018/2020/01.5 for Review of Protocol Terminations

#### **5.1.3 Assign protocol reviewers**

- Assign at least two reviewers (for technical and ethical reviews) for initial review of each submitted protocol by the EC Secretary.
  - The technical reviewer prepare the summary of the protocol reviewed
  - Complete and return the form to Secretariat within 7 (seven) working days
  - The assignment should be based on the information provided in SOP/005/2020/01.3 and SOP/006/2020/01.3.

#### **5.1.4 Prepare meeting agenda**

- Schedule the review as soon as possible after submission, either at the time of the next scheduled meeting or *within 4 weeks after submission*.
- Prepare the meeting agenda, according to the format shown in Annex 1 (AF/01-021/2020/01.6).
  - Schedule protocols in the agenda on a first-come first-serve basis.
  - Include “request to appeal” items in the agenda, upon receipt of the correspondence, preferably during the next convened Board meeting.

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- Prepare invitation letters to the reviewers and the members.
  - Allow at least **1 (one)** week for the review process.
  - EC members should inform the Secretariat for their availability/ inavailability for the meeting
- Specify the due date for the return of comments within 7(seven) days
- Include a protocol assessment form (AF/01-010/2020/01.4) with the protocol package along with the invitation letter, a response form and the meeting agenda.
- Prepare the package for delivery.
- Record the name of the assigned reviewers in the appropriate database or the review assignment file.

#### **5.1.5 Distribution of Protocol Packages to the MRIN EC Members**


- Comply with Procedure for Maintaining Confidentiality of MRIN EC documents (SOP/026/2017/01.2) when preparing and distributing documents.
- Distribute copies of the protocol submission packages to the assigned reviewers and EC members by either electronic mail (if electronic submission protocols) *two weeks in advance of the scheduled meeting.*
- Specify the due date for the return of comments within 7 (seven) working days
- Keep copies of “sent” e-mail, and/or letters accompanying posted materials in the Correspondence section of the respective protocol file.
- Verify (verbally, by e-mail, or by mail) with the members whether the protocol packages are received.

#### **5.1.6. Prepare for the meeting**

- Make a room reservation on the schedule meeting date and time.
- Make sure that the room, equipment and facilities are available in good running condition and cleaned for the meeting day.

### **5.2 During the meeting**


- The MRIN EC may allow investigators, project managers, sponsors, etc., to attend the portion of the Board meeting related to their studies.
- At the discretion of the Chairperson/Vice chairperson/Secretary, guests may be allowed to observe the Board meetings.
- These guests may include a potential client, students, etc.
- Guests are required to sign a confidentiality agreement (AF/02-004/2020/01.4, see ANNEX 2 of SOP/004/2020/01.4).

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- The Secretary/Designated member presents the agenda for discussion, and reports on the minutes of the previous meeting for approval
- The Secretary/Designated member records the discussions and the decisions made during the meeting.
- The Chairperson/Vice chair person/Secretary may inform members and attendees of the rules being followed during meetings.
- The Chairperson/Vice chair person/Secretary/designated members determine quorum and conflict of interest before the meeting
- The meeting proceeds in the order organized in the agenda; however, the Chairperson/Vice chair person/Secretary may allow some switching depending on the situation.
- The approval process starts when one of the reviewers gives a brief about the study and presents his/her observations and comments.
- In case the reviewer cannot be present during the meeting, a member of MRIN EC may give the briefing about the study by reading the comments and evaluation of the reviewers.
- In the case the reviewer cannot be present during the meeting, he/she may present about the study by video call, teleconference or other kind of communication
- The other members give their comments right after the presentation and the discussion about the study takes place.
- Investigators may be allowed to present their projects in brief and clarify any questions the MRIN EC members may have.

### **5.3 Consensus/Voting**

- If consensus is not achieved by the Board meeting, voting may be held on the recommendation of the Chairperson/ Vice chairperson/Secretary.
- In order to avoid conflict of interest, only those Board members who are independent of both the investigator and the sponsor of the trial, will vote on the research-related matters.
- All voting will take place after the observers / presenters / board members with a conflict of interest leave the meeting room.
- The Chairperson/Vice chairperson/Secretary determines if the number of voting Board members is sufficient to constitute a quorum and proceeds accordingly.
- A Board member makes a motion to recommend action on a protocol or issue being discussed.
- The motion is seconded and subsequently voting takes place.
- A motion is carried out if two third (2/3) members present vote in favor of the motion.

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#### **5.4. Preparing the Minutes and Decision Forms**

##### **5.4.1 Assembling the meeting minutes and the decision form**

- Use the format as shown in ANNEX 2 (Form AF/02-021/2020/01.5) to write a minute.
- Compose the summary of each meeting discussion and decision in a concise and easy-to-read style.
- Make sure to cover all contents in each particular category.
- Check spelling, grammar and context of the written minutes.
- Finish the minutes within one week after the meeting.

##### **5.4.2 Contents of the MRIN EC Meeting Minutes**

- The official minutes of the Board meeting consist of, but are not limited to, the following:
  - Name of person preparing the minutes
  - Location where the meeting was held (city, state)
  - Meeting date
  - Attending board members and guests
  - Agenda items
  - Individual serving as Chairperson of the meeting
  - Determination of a duly constituted quorum by the Chairperson to proceed with the meeting
- Requirements for each study or activity requesting Approval:
  - Sponsor's name;
  - Protocol number/date/version of protocol, when available;
  - Investigator's name;
  - Advertisements;
  - Name of board member presenting study materials;
  - Discussion as deemed appropriate by the Chairperson
  - Number of members voting 'yes' or 'no'
  - Reference to the investigator approval letter that lists all changes requested by the board;
  - Determination of the next requested continuing review.
- Requirements for each study or activity requesting Expedited Review:
  - Sponsor's name;
  - Protocol number, if applicable;
  - Investigator's name;
  - Lists of expedited approval requests and outcomes.
- Required for each Continuing Review Report:
  - Sponsor's name;
  - Protocol number, if applicable;
  - Investigator's name;

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- Indication of the Board’s determination to continue, terminate, or amend the study;
- Lists of recommendations or actions to be taken up with the investigator, if applicable.
- Required for each Adverse Event notification and Final Report:
  - Sponsor’s name;
  - Protocol number, if applicable;
  - Investigator’s name;
  - Actions deemed appropriate by the Board’s review.
- Required for Termination of Approval:
  - Sponsor name’s;
  - Protocol number, if applicable;
  - Investigator’s name; reason for termination

#### **5.4.3 Approval of the minutes and the decision**

- Check the correctness and completeness of the minutes.
- Get the Chairperson/ Secretary of the MRIN EC to sign and date the relevant sections of the minutes of the EC meeting and the decision form.

#### **5.4.4 Filing the minutes**


- Place the original version of the minutes and the signed decision form in the MRIN EC files for the specific protocol.
- Place all correspondence in the appropriate file.
- Place a copy of the approval letter in the “minutes” file to inform the Board Members of the Expedited approval.
- Document the appeal requests in the meeting minutes.

#### **5.4.5 Distributing the minutes and the decision**

- Send summary of the relevant section of the minutes using form SOP 8(Notification of Decision) and Result of Review

### **5.5 After the Board meeting**

The Secretariat draft Minutes of Meeting to be signed by the Chairperson/Vice chairperson/Secretary.

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## **6. Glossary**

Agenda	A list of things to be done; a program of business at a meeting
Minutes	An official record of the business discussed and transacted at a meeting, conference, etc.
Quorum	One half and plus one of MRIN EC members required to act on any motion presented to the Board for action.
Majority vote	A motion is carried out if two third (2/3) of the members of the required quorum vote in its favor.
Consensus	A decision generally agreed among MRIN EC Members


## **7. Annex**

Annex 1	AF/01-021/2020/01.5 Agenda format
Annex 2	AF/02-021/2020/01.5 Form of MRIN EC Meeting Minutes
Annex 3	AF/03-021/2020/01.5 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](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.



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- Associated SOP/004/2020/01.3, -SOP/006/2020/01.3, SOP/007/2020/01.4, SOP/009/2020/01.4, SOP/015/2020/01.5, SOP/011/17/01.3, and SOP/026/2017/01.2.



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**Annex 1**

Form AF/01-021/2020/01.6

**Format of an Agenda**


**Agenda of the MRIN EC Meeting**

Agenda Number : ..... Meeting Room : .....

Meeting Date : ..... Time of Meeting : .....

The meeting will proceed in the following sequences:


1. Identify the Quorum
2. Addressing of Conflict of Interest by the Members
3. Approval of the last Meeting Minutes
4. Report of Expedited / Exempted Reviewers

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No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
					1. 2. 3.	<input type="checkbox"/> Minor Revision <input type="checkbox"/> Major Revision <input type="checkbox"/> Approved <input type="checkbox"/> Not Approved

6. New Protocol /Full board review :

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
					1. 2. 3.	<input type="checkbox"/> Minor Revision <input type="checkbox"/> Major Revision <input type="checkbox"/> Approved <input type="checkbox"/> Not Approved


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7. Resubmission : -

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
					1. 2. 3.	( ) Minor Revision ( ) Major Revision ( ) Approved ( ) Not Approved

8. Protocol Amendment for full review :

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
					1. 2. 3.	( ) Minor Revision ( ) Major Revision ( ) Approved ( ) Not Approved


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9. Continuing Review :-

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
					1. 2. 3.	<input type="checkbox"/> Minor Revision <input type="checkbox"/> Major Revision <input type="checkbox"/> Approved <input type="checkbox"/> Not Approved

10. SAE Report: -

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers/SAE Reviewers
.					1. 2. 3.
	Finding		Decision <input type="checkbox"/> Request an amendment to the protocol or the consent form <input type="checkbox"/> Request further information <input type="checkbox"/> Suspend or terminate study		
Conclusion :					


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11. Protocol Deviation / Violation

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
						<input type="checkbox"/> Noted <input type="checkbox"/> Corrective action required <input type="checkbox"/> Site visit needed
Action taken :						

12. Site Visit/Monitoring Reports:

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers/Monitors
1					1. 2. 3.
	Finding :				
	Conclusion :				

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13. Final Reports -

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
					1. 2. 3.	( ) Accepted ( ) Accepted with remark

Assessment of Final Reported:
Conclusion

14. Other Issues ;



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Annex 2  
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**MRIN EC Meeting Minutes**

Minutes Number : Meeting room :  
Meeting Date : Time of Meeting :  
Full board/Emergency :


List of Attendees			
	Total of Members (ToM) :		No. of Members attendance (NMa):

**1. Approval of Last Meeting Minutes :**




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		Sponsor			
					<input type="checkbox"/> Minor Revision <input type="checkbox"/> Major Revision <input type="checkbox"/> Approved <input type="checkbox"/> Not Approved
	Topics	Discussion		Conclusion	
<b>A</b>	<b>Methodology :</b>				
	Study Design				
	Sample Size				
	How to Acquire Samples				
	Inclusion Criteria				
	Exclusion Criteria				
	Site				
	Time of Research				
<b>B</b>	<b>Ethical Issues :</b>				
	Vulnerable Subjects				
	Voluntariness				
	Risks				
	Benefits				
	Confidentiality				

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	Compensation		
	Withdrawal Criteria		
	Emergency Care		
<b>C</b>	<b>Informed Consent :</b>		
	Complete Information		
	Language and Comprehension		
	Voluntariness		
<b>D</b>	<b>Other Issues :</b>		
	Team		
	Protocol format		
	Compliance with Regulations		
	Budget		

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**4. Resubmission for full review**


No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
						<input type="checkbox"/> Minor Revision <input type="checkbox"/> Major Revision <input type="checkbox"/> Approved <input type="checkbox"/> Not Approved

<b>Elements of Improvement</b>	
Topic of Recommendations	Comment
<b>Methodology</b>	
<b>Ethical Issue</b>	
<b>Informed Consent</b>	
<b>Others</b>	
Conclusion :	

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**5. Protocol Amendment: for full review**

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
						<input type="checkbox"/> Minor Revision <input type="checkbox"/> Major Revision <input type="checkbox"/> Approved <input type="checkbox"/> Not Approved
<b>Element of Changes</b>						
Old version		New version		Comment		
Conclusion :						

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**6. Progress Report :**

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decisions
					1. 2. 3.	( ) Minor Revision ( ) Major Revision ( ) Approved ( ) Not Approved
<b>Assessment on Progress report</b>						
	Topic			Comment		
a	No of participants enrolled to the date and since the time of the last review					
b	Changes of the methodology /study design since the last review					
c	Changes in the informed consent or documentation since the last review					
d	Amendment since the last review					
e	Protocol Deviation/Violation					
f	Others					
Conclusion :						

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**7. SAE Report: -**

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers/SAE Reviewers
	Finding		Decision <input type="checkbox"/> Request an amendment to the protocol or the consent form <input type="checkbox"/> Request further information <input type="checkbox"/> Suspend or terminate study		
Conclusion :					

**8. Protocol Deviation/Violation**

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
						<input type="checkbox"/> Noted <input type="checkbox"/> Corrective action required <input type="checkbox"/> Site visit needed



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Action taken :

**9. Site Visit/Monitoring Reports:**

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers/Monitors
	Finding :				
	Conclusion :				

**10. Final Reports for full review :**

No	Protocol No.	Protocol Title	Proposing Institution/ Sponsor	Principal Investigator	Primary Reviewers	Decision
1					1. 2. 3.	( ) Accepted ( ) Accepted with remarks


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Assessment of Final Reported:
Conclusion

**11. Other Issues ;**

Written by :  
Date :

Approved by :  
Date :


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**Annex 3**


Form AF/03-021/2020/01.6

Document History


Author	Version	Date	Description
EC Members	01.0	2 January 2013	<b>Final version</b>
Ivet, Lia, Mona	01.1	11 October 2014	<ol style="list-style-type: none"> <li>1. Synchronize the topic number and SOP number</li> <li>2. Format Document History : Author, Version, Date and Description of the main change</li> <li>3. Section 5.1.3. timeline for protocol reviewers to submit the completed assessment form</li> <li>4. Designate a member of the EC to write the minutes on a regular basis Annex 1 &amp; Annex 2 : Template for Agenda and Meeting Minutes</li> <li>5. Section 5.2. : Secretary/Designated</li> </ol>

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			<p>Members reports on the minutes of the previous meeting and presents the agenda for discussion and records the discussions and the decisions made during the meeting</p> <ol style="list-style-type: none"> <li>6. Annex 1 : Format Agenda</li> <li>7. Annex 2 : Format Minutes of Meeting</li> </ol>
Ivet, Lia, Mona	01.2	15 November 2014	<ol style="list-style-type: none"> <li>1. Annex 1 &amp; 2 : Addition Sponsor information in the protocol information in the agenda</li> <li>2. Section 5.1.4 &amp; 5.1.5 : Remove two days before the meeting</li> </ol>
Liliana Kurniawan, Lia Siti Halimah, Monalisa	01.3	1 April 2017	<ol style="list-style-type: none"> <li>1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header</li> <li>2. Item 5.1.3.: Time line review to return protocol to Secretariat from 7 days to 7 (seven) working days.</li> <li>3. Item 5.1.4.: Delete the sentence “arrange extra MRIN EC meeting to accommodate protocol reviews” Delete the sentence “consult the Chair person to schedule meeting”</li> <li>4. Item 5.1.5: To add time line to specify the due date for return of comments</li> </ol>

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			<p>within 7 working days</p> <ol style="list-style-type: none"> <li>5. Item 5.4: Delete the sentence “a motion is carried out if 2/3 members present vote in favor of the motion”</li> <li>6. Annex 1: To add report of “exempted review” in point 4, and delete point 9 (progress report)</li> <li>7. Annex 2: To add report of “exempted review” and “total number of expedited and exempted protocol” in point 2</li> </ol>
LSH, MW, IS	01.4	1 January 2018	<ol style="list-style-type: none"> <li>1. Item 5.2 Box 8 : To add “The Chairperson/Secretary/designated members determine quorum and conflict of interest before the meeting”</li> <li>2. Annex 2 : Revise Template Minutes of Meeting</li> </ol>
MW	01.5	2 January 2019	<ol style="list-style-type: none"> <li>1. Item 3, 4.1 , 5. 2- 5.4 : to add vice person</li> <li>2. Annex 2 : to include numbering of affiliated/non affiliated, medical person etc in order to indentify the quorum</li> </ol>
IS,MW,LSH,	01.6	02 January 2020	<ol style="list-style-type: none"> <li>1. Flowchart : Delete the statement “Preparing the Minutes Meeting”</li> </ol>

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GE			<ol style="list-style-type: none"> <li>2. Flowchart, No.5 : include the decisions form”</li> <li>3. 5.1.4 : Delete the statement of “ write down the running number of the protocol.....the form ... and sign the second page of.... The form”</li> <li>4. 5.2, box 5 : revised with “ approval previous minutes of meeting”</li> <li>5. 5.3 : add the word of “consensus”</li> <li>6. 5.4 becomes 5.5</li> <li>7. 5.4.5, box 1 : include the notifications, decisions and result of review</li> <li>8. 5.4.5, box 2 &amp; 3 : DELETE</li> <li>9. 5.5 becomes 5.4</li> <li>10. 5.5, box 2.2 : delete If the Committee modification to any of the documents, the Secretariat either generates the revision to the documents, or sends a written request of the specific changes to investigator to make the necessary changes and resubmit the</li> </ol>
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			<p>documents to the MRIN EC</p> <p>11. 5.5 : replace “the secretariat prepare” with “ the secretariat draft”</p> <p>12. 5.2, during the meeting : In the case the reviewer cannot be present during the meeting, he/she may present about the study by video call, teleconference or other kind of communication</p> <p>13. Annex : add item of “ Protocol Deviation”</p> <p>14. Annex 2 , template of minutes meeting : to include decisions in the Progress Report</p> <p>15. References :</p> <ul style="list-style-type: none"> <li>• Delete link WHO</li> <li>• Delete FERCAP SOP</li> <li>• Add ICH 2016</li> </ul>
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