


<b>TAGORE MEDICAL COLLEGE &amp; HOSPITAL</b> 	<b>Maintenance of Active Project Files</b>		<b>Institutional Ethics Committee</b>
			<b>TMCH/IEC/SOP/18</b>
<b>Amendment No: 00</b>	<b>Issue No: 01</b>	<b>Issue Date: 02/11/2020</b>	<b>PAGE 1 OF 4</b>

## Maintenance of Active Project Files

For Institutional Ethics Committee




Tagore Medical College & Hospital




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## 1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by the Institutional Ethics Committee (IEC).

## 2. Scope

This SOP applies to all active study files and their related documents that are maintained in the IEC office.

## 3. Responsibility

It is the responsibility of IEC Secretariat to ensure that all study files are prepared, maintained, circulated and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.




## 4. Flow chart


No.	Activity	Responsibility
1	Organize the contents of the active study files	IEC Secretariat
2	Maintain the active study files	IEC Secretariat

## 5. Detailed instructions

### 5.1 Organize the contents of the active study files

The Secretariat will:

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- Submission will be received in the IEC office. Preserve soft copy and one original set (hard copy for regulatory studies and if needed non regulatory studies) of the entire package called as master file. A Study Master File is the file comprising all essential documents and correspondence related to the study/protocol. Study master files should be established at the time of initial submission.
- The study files are assigned unique identifiers.
- All documents related to the study file are gathered, classified and combined together appropriately.
- The Administrative Officer will save the submissions which will be stored on e-EC software cloud based, on Google drive and on external hard disk.
- The submitted hard copy protocols and the related documents will be labeled and stored in cupboard with lock and key in separate cupboard of IEC.

### ***5.2 Maintain the active study files***

The Administrative Officer will:

- Combine related documents of the approved study files appropriately.
- Attach an identity Label to the package.
- Keep all active and potential study packages in a secure place.
- Maintain the study files in an easily accessible, but secure place until the final report is received, reviewed and accepted by the IEC or the matter will be discussed at Full Board by IEC.
- The soft active study files will be password protected and will be accessible only to the IEC secretariat.
- The cupboard where hard copies of the active study files are kept will be kept in a lock and key and will have controlled access only to the secretariat.
- The active study files will be password protected and will be accessible only to the IEC secretariat.
- If any IEC member/non-members (auditor or other authorized person) of IEC wants to have

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access, they can access the project file with the help of secretariat after the permission of chairperson.

- Annual subscription of appropriate anti-virus and malware protector will be availed for the soft copy submissions.
- Annual maintenance of fire proof service provider and paste control provider will be availed for the protection of hard copies.
- Send all closed study files to the archive.

## 6. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)-  
<https://www.who.int/tdr/publications/documents/ethics.pdf> (last accessed 22<sup>nd</sup> October 2020).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-<http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 22<sup>nd</sup> October 2020).
3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017

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