



**Apollo Institute of  
Medical Sciences & Research  
Chittoor**

**Institutional Ethics Committee  
Apollo Institute of Medical Sciences and Research Chittoor**

SOP No 06 / Version 01  
Confidentiality Maintenance  
Effective Date: 01-09-2024

**Title: IEC - AIMS R Chittoor**

**Confidentiality Maintenance - SOP Code: SOP No 06 /v1**

**Prepared by:**

Dr Sachidananda Adiga MN Member, SOP Sub-committee	Signature with date: <i>mnsadiga 28/08/2024</i>
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**Verified by:**

Dr Jayapriya T Member, SOP Sub-committee	Signature with date: <i>JPT 01/09/2024</i>
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**Approved by:**

Dr Ravi Prabhu G Chairperson, IEC, AIMS R, Chittoor	Signature with date: <i>Ravi Prabhu 01-09-2024</i>
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**Notified by:**

Dr Alfred Joseph Augustine Dean AIMS R, Chittoor	Signature with date: <i>Alfred's Augustine DEAN 01/09/2024</i>
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**Details of Current SOP No: 01 / Version 01**

SOP subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr Sachidananda Adiga MN	Version 01	01-09-2024	Prepared the SOP for Confidentiality Maintenance of IEC, AIMS R Chittoor including Purpose, Scope, Responsibility, Detailed instructions, References Flowchart and Glossary on of members

Apollo Institute of Medical Sciences and Research  
Murukambattu, Chittoor-517127 A.P.

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<b>1.Purpose:</b> The purpose of this SOP is to explain the process of confidentiality maintaining of documents and information pertaining to the functioning of IEC -AIMSR Chittoor.
<b>2.Scope:</b> This SOP include the policy related to the maintenance of confidentiality of documents and information and is applicable to all IEC -AIMSR Chittoor members, IEC - AIMS R Chittoor secretariat, independent consultants and guest/observer/invitee to the IEC - AIMS R Chittoor.
<b>3. Definition</b>
<b>3.1. Confidentiality:</b> Confidentiality, for the purpose of this SOP, is defined as the state of securely keeping information gathered from research-related documents and data without sharing or disclosing with unconcerned and unauthorized third parties
<b>4. Responsibility:</b>
<b>4.1. The Chairperson will:</b>
4.1.1. Ensure that the confidentiality of the IEC - AIMS R Chittoor functioning and its related data is maintained at all times.
4.1.2. Ensure that the IEC - AIMS R Chittoor documents are accessed only by authorized persons under strict confidentiality agreement at all times.
4.1.3. Reinforce that the IEC - AIMS R Chittoor members and any other person visiting the IEC AIMS R Chittoor office or attending the IEC - AIMS R Chittoor meeting should adhere to the confidentiality agreement pertaining to all the business activities of the IEC -AIMSR Chittoor.
4.1.4. Ensure that no identifying data pertaining to the protocols or IEC -AIMSR Chittoor members is divulged during the conduct of research or IEC - AIMS R Chittoor functioning.
<b>4.2. The Member-Secretary will:</b>
4.2.1. Prepare the core minutes of the meeting for the purpose of sharing with the Dean and C.O.O. AIMS R Chittoor, and the authorized persons (auditors/inspectors) without divulging names and other sensitive data.
4.2.2. Ensure that appropriately redacted versions of the protocol and protocol-related documents are prepared for sending to Independent Consultants for review.
4.2.3. Ensure that appropriately redacted version of protocol or related documents are used for academic purposes during research ethics training programs.
<b>4.3. The Secretariat will:</b>
4.3.1. Send confidentiality agreement forms to members, ICs, guest/ observer/ invitees.

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4.3.3. Prepare appropriately redacted versions of protocols and protocol-related documents for IC review and case study.

**4.4. IEC -AIMSR Chittoor Members will:**

4.4.1. Understand the definition and need for confidentiality

4.4.2. Adhere to the confidentiality of documents sent to them for review

4.4.3. Adhere to the confidentiality of information on the review, decision making in the IEC -AIMSR Chittoor meetings and all other activities of the IEC -AIMSR Chittoor functioning

**4.4.4. Adhere to the confidentiality of post-approval activities of the protocols**

**4.5. The Independent Consultant (IC) will:**

4.5.1. Understand the definition and need for confidentiality

4.5.2. Adhere to the confidentiality of documents sent to them for review

4.5.3. Adhere to the confidentiality of information on review and decision-making

**4.6. The guest/observer/invitee will:**

4.6.1. Understand the definition and need for confidentiality

4.6.2. Adhere to the confidentiality of documents accessed by them

4.6.3. Adhere to the confidentiality of information on the review and decision-making.

**5. Detailed Instructions:**

**5.1. IEC -AIMSR Chittoor Members:**

5.1.1. **At the time joining IEC -AIMSR Chittoor:** IEC - AIMS Chittoor members (including the Chairperson and Member-Secretary) and staff of IEC -AIMSR Chittoor secretariat shall sign a declaration – at the time of joining the service of the ethics committee – that they will maintain confidentiality of the research-related documents and other information for their entire tenure and beyond (if necessary).

5.1.2. **At the time of review:** Maintain confidentiality of the documents and the assessment forms sent to them at the time of review

5.1.3. **IEC -AIMSR Chittoor meetings:** Maintain confidentiality of the agenda, proceedings and the minutes of the IEC - AIMS Chittoor meeting. The members will not divulge any details of the protocols discussed, the proceedings and decisions on the protocols to anyone outside the IEC -AIMSR Chittoor by any means.

5.1.3 **In the post-approval activities:** Maintain confidentiality of protocol related post-approval activities like site monitoring/audits/deviations/ violations/continuing review

**5.2. Independent consultants:**

5.2.1. **At the time of joining IEC - AIMS Chittoor:** All ICs shall sign a declaration – at the

time of joining the service of ethics committee – that they will maintain confidentiality of the documents and other information for their entire tenure as ICs and beyond.
<b>5.2.2. At the time of review:</b> Maintain confidentiality of the documents and the assessment forms sent to them at the time of review.
<b>5.2.3. During IEC - AIMS Chittoor meetings:</b> Maintain confidentiality of the agenda, proceedings and the minutes of the IEC - AIMS Chittoor meeting, if invited to attend the meeting.
<b>5.3. Guest/observer/invitee:</b>
<b>5.3.1. At the time of being permitted as a guest/observer/invitee:</b> Any individual who is permitted by the Chairperson to visit the IEC - AIMS Chittoor office and/or attend the IEC -AIMS Chittoor meeting shall sign a declaration that they will maintain confidentiality of the documents and other information during their visit and beyond.
<b>5.4. Confidentiality form:</b>
5.4.1 The confidentiality form will be prepared as per the format (Ann01/SOP6A/v01
5.4.2. The confidentiality form will encompass Documents sent by email for review, Agenda and minutes of the meeting sent by email, Proceedings of the minutes, Research files and data accessed during the post-approval activities and Any other documents/data/information that needs to be confidential.
<b>5.5. Recording of the confidentiality agreement:</b>
5.5.1. The confidentiality agreement will be countersigned by the Chairperson
5.5.2. The IEC - AIMS Chittoor Secretariat will scan a copy and give it to the concerned individual. The original will be kept in the member's file/ IC file/ guest/observer/invitee's file.
5.5.3. The Secretariat will file the Confidentiality Agreement forms signed by the IEC AIMS Chittoor members, ICs or guest/observer/invitees in the respective files
<b>5.6. Maintenance of confidentiality at the IEC -AIMS Chittoor office:</b>
5.6.1. Access to the archival room, computer, hard disc and IEC -AIMS Chittoor documents will be restricted only to authorized personnel.
5.6.4. Protocols used for academic purposes during research ethics training will be redacted so that the researcher or /institution will not be identified.
5.6.5. The detailed minutes of the meeting will be filed in the IEC -AIMS Chittoor office. Only core minutes of the meetings will be forwarded to the Dean, C.O.O of AIMS Chittoor or any other authority (auditors/accreditors/inspectors) to which it needs to be sent. (SOP05/v1)
5.6.6. The core minutes of the meetings will <b>not</b> include
5.6.6.1. The detailed discussion
5.6.6.2. Names of the IEC -AIMS Chittoor members who raised the issues during discussion
5.6.6.3. The names of the IEC -AIMS Chittoor members who dissented during voting.
5.6.6.4. The names and affiliations of the investigators

5.6.6.5. No identifying data pertaining to protocols/researchers or IEC -AIMSR Chittoor members will be divulged during the conduct of research on IEC -AIMSR Chittoor functioning

6. Annexures:

- 1.1. **Ann01/SOP 06/v1:** Confidentiality Agreement Form for IEC -AIMSR Chittoor member
- 1.2. **Ann02/SOP 06/v1:** Confidentiality Agreement Form for Independent Consultant
- 1.3. **Ann03/SOP06/v1:** Confidentiality Agreement Form for Guest/Observer/Invitee
- 1.4. **Ann04/SOP06/v1:** Confidentiality Agreement Form for Staff of the Secretariat

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**Ann01/SOP6/v1  
Confidentiality Agreement Form for IEC -AIMSR Chittoor member**

I, Dr/Mr/Ms \_\_\_\_\_ (Member's name, his/her position on IEC -AIMSR Chittoor and affiliation) have been appointed as a member of IEC -AIMSR Chittoor.

- 1 (IEC -AIMSR Chittoor). I have read and understand the confidentiality policy of the IEC -AIMSR Chittoor. I agree that:

1. All confidential information (and copies/notes thereof) shall remain the sole property of IEC -AIMSR Chittoor
2. All the confidential information is shared with me in trust or confidence as a IEC -AIMSR Chittoor member
3. I shall use the documents/ information shared with me, only for the authorized purposes
4. I shall not share any documents with the PI or sponsor or any third unconcerned person/party
5. I shall not photocopy/ photograph any of the documents accessed by me from the archival
6. I shall delete all the IEC -AIMSR Chittoor documents from my email/computer/ mobile/ electronic storage/cloud/prints after the research study is completed.
7. I shall ensure that all soft copies are deleted annually or at the end of my term in IEC -AIMSR Chittoor, whichever is earlier.
8. This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as a member of IEC -AIMSR Chittoor and may include:
  - a. The protocol/ protocol-related documents sent to me for review by email:
  - b. The agenda and minutes of the meeting sent to me by email
  - c. Proceedings of the IEC -AIMSR Chittoor meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the IEC -AIMSR Chittoor meeting:
  - d. The protocol/ protocol-related documents/ IEC -AIMSR Chittoor files accessed from the archival room:
  - e. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review:
  - f. Any other, if applicable

I, Dr/Mr/Ms \_\_\_\_\_ (Member name, IEC -AIMSR Chittoor designation) have read and accept the aforementioned conditions as explained in this agreement. I am liable to be removed from IEC -AIMSR Chittoor and/or liable to legal actions from AIMS Chittoor, if confidentiality is willfully breached by me.

Signature

Date

Chairperson's Signature

Date

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*[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat IEC -AIMSR Chittoor. A copy will be given to the Undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the IEC -AIMSR Chittoor Chairperson and me Signature Date:

**Ann02/SOP6/v1**

**Confidentiality Agreement Form for IEC -AIMSR Chittoor Independent Consultant**

I, Dr/Mr/Ms \_\_\_\_\_ (IC's  
 name and affiliation)

have been appointed as an Independent Consultant of IEC -AIMSR Chittoor (IEC -AIMSR Chittoor). I have read and understand the confidentiality policy of the IEC -AIMSR Chittoor. I agree that:

1. All confidential information (and copies/notes thereof) shall remain the sole property of IEC -AIMSR Chittoor
2. All the confidential information is shared with me in trust or confidence as a IEC -AIMSR Chittoor member
3. I shall use the documents/ information shared with me, only for the authorized purposes
4. I shall not share any documents with the PI or sponsor or any third unconcerned person/party
5. I shall not photocopy/ photograph any of the documents accessed by me from the archival
6. I shall delete all the IEC -AIMSR Chittoor documents from my email/computer/ mobile/ electronic storage/cloud/prints after the research study is completed.
7. I shall ensure that all soft copies are deleted annually or at the end of my term in IEC -AIMSR Chittoor, whichever is earlier.
8. This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as a member of IEC -AIMSR Chittoor and may include:
  - a. The protocol/ protocol-related documents sent to me for review by email:
  - b. The agenda and minutes of the meeting sent to me by email
  - c. Proceedings of the IEC -AIMSR Chittoor meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the IEC -AIMSR Chittoor meeting:

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- d. The protocol/ protocol-related documents/ IEC -AIMSR Chittoor files accessed from the archival room:
- e. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review:
- f. Any other, if applicable

I, Dr/Mr/Ms \_\_\_\_\_ (IC's name, affiliation) have read and accept the aforementioned conditions as explained in this agreement. I am liable to be removed from IEC -AIMSR Chittoor and/or liable to legal actions from Apollo Institute of Medical Sciences and Research Chittoor, if confidentiality is willfully breached by me.

Signature

Date

Chairperson's Signature

Date

*[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat IEC -AIMSR Chittoor. A copy will be given to the Undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the IEC -AIMSR Chittoor Chairperson and me Signature. Date:

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**Ann03/SOP6/v1**

**Confidentiality Agreement Form for IEC -AIMSR Chittoor Guest/Observer/Invitee**

I, Dr/Mr/Ms \_\_\_\_\_ (*Member's name and affiliation*) herein referred to as the "undersigned" has been appointed permitted to visit the IEC -AIMSR Chittoor office/ attend a IEC -AIMSR Chittoor meeting as a Guest observer.

I understand the Confidentiality policy of the IEC -AIMSR Chittoor and I agree that

1. All the confidential information (and any copies and notes thereof) shall remain the sole property of IEC -AIMSR Chittoor
2. All the confidential information is shared with me in trust or confidence as a guest observer to IEC -AIMSR Chittoor office/meeting
3. I shall use the documents/ information shared with only for the contemplated purposes
4. I shall not share the documents with the PI or sponsor or any third unconcerned person/party
5. I shall delete all the documents from my email/computer/ mobile/ electronic storage/cloud/prints after the purpose of the visit is completed, if shared with me.
6. This agreement encompasses any information deemed confidential, provided to me in conjunction with my visit to IEC -AIMSR Chittoor and may include:
  1. The protocol/ protocol-related documents:
  2. Proceedings of the IEC -AIMSR Chittoor meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the IEC -AIMSR Chittoor meeting, when applicable
  3. The protocol/ protocol-related documents/ IEC -AIMSR Chittoor files accessed from the archival room, if applicable:
  4. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review, if accessed by me/shared with me
  5. Any other, if applicable

I, Dr/Mr/Ms \_\_\_\_\_ (Guest observer name) have read and accept the aforementioned conditions as explained in this agreement. I am liable to legal actions from the AIMSR Chittoor, if confidentiality is/ will fully breached by me.

Signature

Date

Chairperson's Signature

Date

[The original will be kept on file in the custody of Secretariat IEC -AIMSR Chittoor, with a copy to the Undersigned] I acknowledge that I have received a copy of this Agreement signed by the IEC -AIMSR Chittoor Chairperson and me

Signature

Date

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**Ann04/SOP6/v1**

**Confidentiality Agreement Form for Staff of the Secretariat**

I, \_\_\_\_\_, Secretarial Staff, IEC -AIMSR Chittoor (Staff name & designation) herein referred to as the “undersigned”, have been appointed as a staff of the IEC -AIMSR Chittoor Secretariat. This agreement encompasses any information deemed confidential provided to the undersigned in conjunction with the duties as a staff of the IEC -AIMSR Chittoor. All confidential information (and any copies and notes thereof) shall remain the sole property of the IEC -AIMSR Chittoor.

The undersigned hereby agrees not to disclose or utilize, directly or indirectly all confidential information known to him/her during the tenure of his/her service and beyond if necessary.

I, \_\_\_\_\_, Secretarial Staff, IEC -AIMSR Chittoor (Staff name & designation) have read and accept the conditions as explained in this agreement.

Signature

Date

Chairperson’s signature

Date

*[Original (signed/ dated agreement) will be kept on file in the custody of IEC -AIMSR Chittoor. A copy will be given to the undersigned.]*

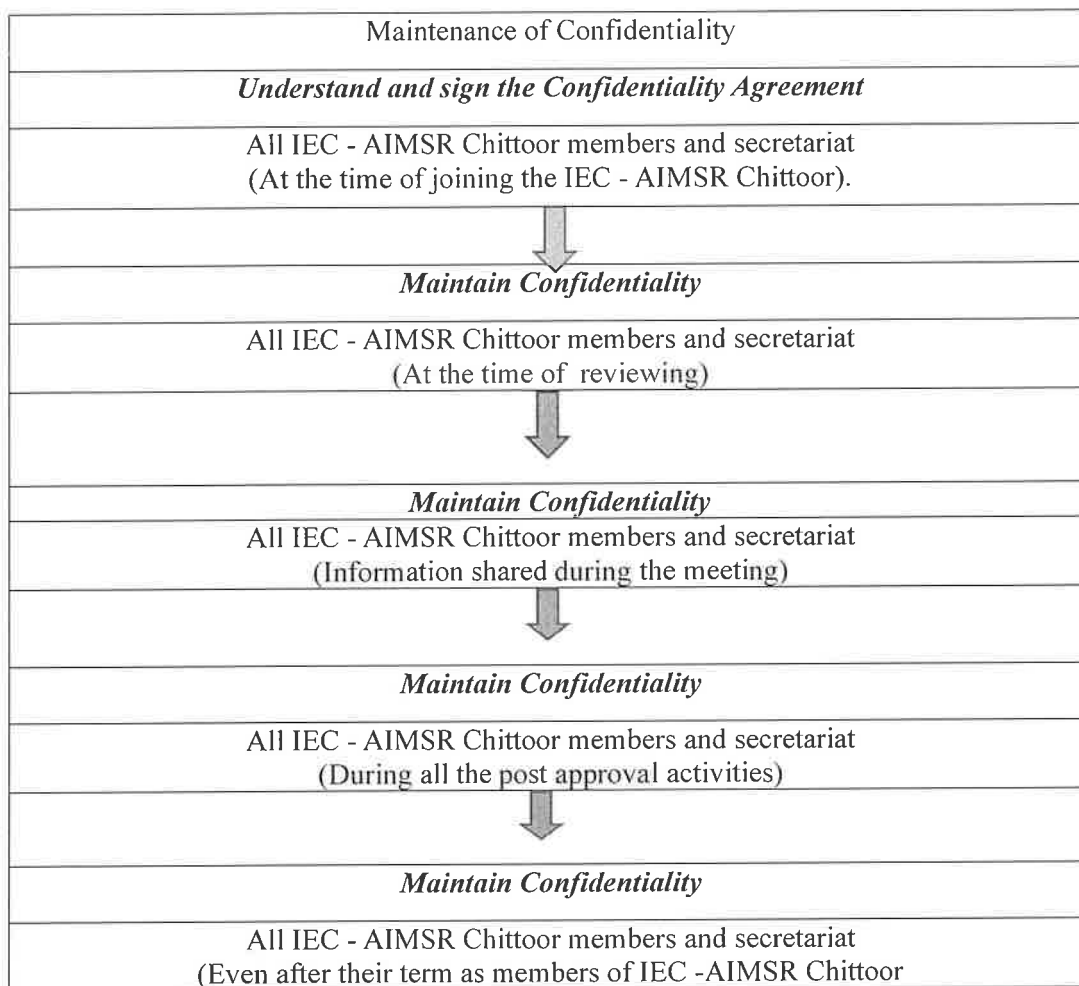
I acknowledge that I have received a copy of this Agreement signed by the IEC -AIMSR Chittoor Chairperson and me

Signature.

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7. Flow Chart:



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**8. Glossary:**

IC: Independent Consultant  
SOP: Standard Operating Procedure

**Title: IEC - AIMSRS Chittoor**

**Confidentiality Maintenance - SOP Code: SOP No 06 /v1**

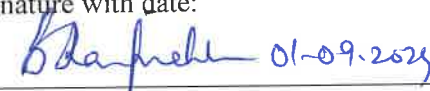
**Prepared by:**

Dr Sachidananda Adiga MN Member, SOP Sub-committee	Signature with date:  28/8/2024
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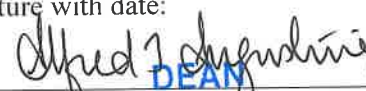
**Verified by:**

Dr Jayapriya T Member, SOP Sub-committee	Signature with date:  01/09/2024
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**Approved by:**

Dr Ravi Prabhu G Chairperson, IEC, AIMSRS, Chittoor	Signature with date:  01-09-2024
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**Notified by:**

Dr Alfred Joseph Augustine Dean AIMSRS, Chittoor	Signature with date:  01-09-2024 <b>DEAN</b>
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