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SOP No.-
RC 06Standard Operating Procedure for processing of Memorandum of
Understanding (MoU) Files

- A. Purpose: This SOP is framed to provide guidance and instructions to various departments/ units/ individuals at AIIMS, Rajkot concerning the preparation, review, institutional mechanism of approval, etc. of Memoranda of Understanding (MoU) done at AIIMS, Rajkot
- **B.** Background & Justification: MOUs are formal, written agreement between two or more parties that establishes a partnership. Each active MOU serves a specific purpose, ranging from academic cooperation, research collaboration, service delivery or resource sharing, IPR and conflict management. This policy sets basic standards for the various MOU that AIIMS Rajkot will enter into with other institutes/parties. The policy will also describe the institutional mechanism of approval, mechanism of electronic storage and disbursal of information to individuals at AIIMS Rajkot.

C. Definitions:

- 1. Joint Statements: A Joint statement is a common statement agreed upon by the parties regarding the object, statement and purpose to be achieved through the execution of the MOU. It shall be issued jointly by the authorized signatory of the parties involved mentioning the details of the MOU.
- 2. Letter/Expression of Intent (LOI/EOI): A letter/expression of intent is a non-binding document that acknowledges the parties' intent to explore the possibility of collaboration and cooperation in the relevant areas contained therein. Letters of intent are appropriate when a new project/undertaking is being initiated, and the specific areas of formal cooperation between parties are yet to be identified and negotiated.

In the context of research, sometimes it simply helps the funding agency/sponsor determine how many applications can be expected as a result of the solicitation or announcement of

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research proposals. They merely serve as an expression of interest as a pre-proposal and mere submission of the same doesn't in itself lead to research funding. They need not be routed through the administrative mechanism unless the funding agency/sponsor specifically asks for approval. An intimation regarding the submission of the same shall be forwarded by the PI or Co-PI/Co-I of the institute to the Research cell for information.

- **3.** Memorandum of Agreement (MOA): It is a formal and legally binding document written between parties to cooperatively work together on an agreed-upon project or meet pre-defined objectives. The purpose of an MOA is to have a written formal understanding of the agreement between parties. An MOA details the obligations and commitments of the parties and allocates and minimizes each party's risks. It can also be referred to as a contract and is legally binding. Individual project-specific agreements or pertaining to service delivery, shall be treated as MOA and they should be signed by the respective collaborating Principal Investigator (PI). However, such agreements will be reviewed by the AIIMS, Rajkot in a manner analogous to the MOUs.
- 4. Memorandum of Cooperation (MOC) or Association: A less formal agreement, usually of an administrative or technical nature of limited duration. MOCs could be concluded under the umbrella of a certain framework agreement. It is synonymous of MOU.
- 5. Memorandum of Understanding (MOU): It is a document of mutual consensus describing a bilateral or multilateral agreement between parties which expresses a convergence of will between the parties, indicating an intended common line of action. It is more formal than a verbal or "hand-shake" agreement but generally lacks the binding power of a contract. MOUs do not require any party to commit funds or other resources. It does not create duties or legally enforceable liabilities or obligations for any party nor does it establish a standard of care attributable to the activities associated with the subject of the agreement.
- 6. Party: The parties to the MOU shall be defined under this clause between whom the MOU/MOA shall be executed. Whereby it is specified that the first party will be the initiator

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of the MOU/MOA and the second or more party/parties shall be the party with whom the MOU/MOA shall be executed.

- **D. Parameters of MOU:** Every MOU/MOA that AIIMS, Rajkot will enter into shall mandatorily have the following parameters as listed below:
- 1. **Preamble:** The preamble should clearly name the institutes/ parties entering into the MOU/MOA. The preamble should broadly describe the mandate and work undertaken by the Institutes/ parties. As a reference, the description of AIIMS, Rajkot in the preamble can be:

AIIMS Rajkot is an autonomous Institute of National Importance (INI) functioning under the PMSSY Division of the Ministry of Health and Family Welfare (MoHFW) with the objectives of a) correcting regional imbalances in the availability of affordable and reliable tertiary healthcare services b) augmenting facilities for quality medical education to create a critical mass of healthcare professionals, and c) conducting research in the country relevant to the area. The institute is expected to absorb talent, provide highly trained medical professionals for the country and conduct research on national and regional health problems.

WHEREAS

Description of Other PARTY: It will vary as per the Other Party

- 2. Purpose/Objective of MOU: It should be explicitly stated mentioning the broad area(s) of co-operation
- **3.** Scope of Co-operation: The scope of cooperation should be explicitly stated and should be more objective in nature. There can be multiple areas for the scope of cooperation.
- 4. Modalities of Cooperation/Funding arrangements: The MOU should clearly mention the modalities and mechanisms for the mutual topics for collaboration. This section should also state the funding arrangements for various objectives and the mechanism for arranging the funds, if applicable.

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- **5.** Governance and management: This section should mention the modalities for governing or managing the scope of cooperation which may be either through individuals or through the formulation of a joint working group (JWG). This section should also mention the frequency of reviewing or supervising the progress or work done with respect to the objectives of the MoU. It is highly desirable to state the modalities of meeting and/or the bearing party for the expenses occurring for such meetings. The expenses may be related to travel, accommodation, local transportation, boarding etc. of such personnel if any need arises. It is also desirable to objectively state the terms of references (TOR) of such individuals or JWG.
- 6. Intellectual property rights (IPR), commercialization and Publications including authorship (if any): Ownership issues and responsibilities need to be carefully worked out well before data are collected and researchers should ensure clarity about data ownership, publication rights and obligations following data collection. They should also be explicitly mentioned in the MOU. In MOUs seeking research collaboration, the parties entering into an agreement shall ensure the appropriate IPR protection of each other on IPRs generated through activities arising out of mutual cooperation. Both parties should apply as Co-applicants for the protection of IPRs of each other. The grant of IPRs will be sought and jointly owned by both parties in case research results are obtained through joint activities. This section should also explicitly mention that the parties will not assign any rights or obligations to any third party without the consent of the other Party. If any Party doesn't agree to this, it should also be clearly stated in the MOU.

The MOU shall also state any policy about the research publications/ documents and /or any other paper arising out of the joint activities. The use of the name, logo and/or any official emblem of the Parties on any publication/document and/or paper shall require prior permission of both the Parties and they should not be used/misused for any commercial activity or marketing of any kind.

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- 7. Confidentiality: The MOU should explicitly state that the confidentiality of each Party shall be honoured and no Party, their employees or affiliates should disclose the confidential information of the other Party. It should be stated that no Party shall make any public announcement related to the scientific research outcome, or commercialization for work which has arisen out of the joint activities, without the other Party's prior consent. Additionally, such information should not be transmitted or shared with any Third Party, unless agreed by both or all Parties.
- 8. Ethical issues/ transfer of biological material/data sharing (if any): Both Parties should mutually agree on the ethical issues related to the protection of human and animal subjects. For this, the agreement must be by each country's applicable laws, regulations and policies, in case of Parties belonging to different nations. Both Parties should agree to obtain necessary approvals from the local Ethics Committee before initiating the work on jointly agreed research proposals. Parties may also mention any policy of utilising the relevant Ethics Committee of the other Party to expedite the work on research proposals. The Parties should also mention about any Material transfer agreement (MTA) done about the transfer of biological materials, including but not limited to human and animal subjects by any applicable local or national laws. Similarly, the Parties should state and agree with each other on the data-sharing policy, by any applicable local or national laws.
- **9. Disputes resolution mechanism:** The MOU shall mention the modalities related to the settlement of any disputes which may arise. It may be done through mutual consultations/ negotiations by the governing individuals/ JWG or through arbitration. In MOUs, the settlement of disputes shall be done by mutual consultations. In case they fail, the MOUs can be terminated with the consent of both parties. In case of MOAs, both parties shall mutually decide the procedure for the appointment of an arbitrator for dispute resolution and the same shall be binding to all the parties. The place of arbitration preferably shall be Rajkot (Gujarat) and is subjected to the territorial jurisdiction of District Court Rajkot. If any other

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place of arbitration is mentioned in the MOA, only the PI shall bear the cost of any travel or related legal expense.

- **10. Exclusivity:** The MOU shall state that this relationship is not exclusive and will not prevent either Party or its members from associating/collaborating with any other Party to conduct/undertake similar programmes/ research/academic activities.
- **11. Obligations on each party:** The MOU shall explicitly state the obligations of each party on another and shall modify other clauses in light of these obligations.
- **12. Duration of validity of MOU:** The MOU shall mention the duration of the scope of cooperation which usually is mot more than 05 years after which MoU needs to be renewed.
- **13. Policy of amendment:** The MOU should clearly state any terms and conditions for the MOU's amendments, revisions or modifications. The amendments shall be effective from the date of the written agreement signed by both parties.
- 14. Conditions of termination: They should be well defined in the MOU including mention of any notice period. The termination conditions shall not be unilateral and shall not affect the implementation of initiated or ongoing activities and projects.
- **15. Authorised Signatories:** The MOU, in duplicate or multiple copies depending on the number of Parties, should be signed by the duly authorised representatives of either Party. The language of the MOU can be either English or Hindi, as agreed upon by the Parties and should mention the date of execution of the MOU. The validity of the MOU shall be counted from the date of execution of the MOU. It is proposed that the authorised signatory for MOUs which have academic or research cooperation shall be signed by the Executive Director or his/her nominee.

16. Other General Conditions:

a) All MOUs shall mandatorily have the above listed 15 clauses except for Clause no. 6

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and 8. These should be listed in the MOU but shall be explicitly mentioned as "Not Applicable" if they are not applicable per the MOU's nature.

- b) Individual research project-specific MOUs with the funding agencies/ other research collaborators shall be categorized as Memorandum of Agreement (MOA) and are usually signed by the individual faculty members in the capacity of PI/Co-PI/CO-I, as may be applicable. These MOAs will be scrutinized by the MOU & Innovation Committee in a manner analogous to that of the MOUs.
- c) A joint Letter/Expression of intent involving other or multiple institutes/universities/ entities need not be forwarded to the MOU & Innovation Committee unless approved by the funding agency, at which time, a full proposal may be submitted to the Research cell for consideration.
- d) If an MOU is to be executed with a Private entity or Non-Governmental Organisation (NGO), the following details (Checklist in Annexure III) are required at the time of submission of the proposal:
 - i Company registration certificate under the Company Registration Act for Private entities and Society Registration certificate under Society Registration act of the NGO mentioning the date and place of registration.
 - ii Memorandum of association and bye-laws.
 - iii If the NGO is empanelled with the Niti Aayog, then Unique ID allotted to the NGO by Niti Ayog or details of empanelment with any Ministry of Government of India or State Government
 - iv Work Experience of last 5 years in the field with government department/Organisation.
 - v Details of the annual financial statements of the last 5 years maintained by the Private entity/NGO.
 - vi Details regarding the source of funding.

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vii Any other document as the Competent Authority may deem fit.

e) The decision regarding the execution of the MOU with a Private entity/ NGO shall be finalized by the Competent Authority, AIIMS Rajkot

E. MOUs with Foreign Agencies/Organizations/Institutes:

- 1. International collaboration can include all or any of the following elements:
 - a) funding by international agencies, such as UN Agencies, NIH, WHO, Wellcome Trust, World Bank and others;
 - b) academic collaborations with foreign institutions, universities, organizations, foundations with or without external funding; and
 - c) formal government inter-country bilateral/multilateral collaborative arrangements between Indian research bodies/institutions and similar bodies/institutions of other countries.
- 2. The other Party should agree to understand and follow the relevant ethical guidelines and regulatory requirements which govern foreign funding in India.
- 3. The International Party must understand and agree that AIIMS Rajkot will function as partners with the collaborator(s) and sponsor(s) in terms of ownership of samples and data, analysis, dissemination, publication and IPR related to research in India, as may be considered appropriate.
- 4. Any research specific MOUs in whom such research is proposed, which cannot be conducted in the country of origin shall not be honoured. Hence, ethical approval of the proposed research in the Institute of the Collaborating international Party is essential for research specific MOUs with international collaboration.
- 5. It is highly desirable in the International MOUs seeking research collaboration that such collaborating researchers should be trained to understand and recognize ethical perspectives that reflect India's best interests.

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- 6. The proposer of the MOU shall ensure protection against imposition of moral or ethical standards of the sponsoring country (ethical imperialism) which may not be in agreement with India's ethnical, ethical and regulatory requirements.
- All biomedical and health research proposals involving foreign assistance and/or collaboration should be submitted to the Health Ministry's Screening Committee (HMSC), ICMR Headquarters, New Delhi, for consideration and approval before initiation.

F. Institutional Mechanism for Approval of MOU:

- 1. The MOU can be initiated only by any regular faculty at AIIMS, Rajkot, who will be the Proposer of the MOU.
- 2. The MOU can be initiated by a proposer with a covering note sheet along with a draft MOU and mark it to the Dean (Research), AIIMS Rajkot, through its respective Head of the Department . Parallelly, a soft copy of the editable version of the draft MOU and a scanned copy of the accompanying note sheet along with any annexures should be sent to the email id: researchcell@aiimsrajkot.edu.in
- 3. The initially marked entity shall forward it to the Research Cell AIIMS Rajkot for technical review and vetting of the draft MOU.
- 4. Research Cell shall review the proposed MOU and shall communicate any modifications/ incorporations to the proposer.
- 5. After getting the modifications by the proposer, the Research Cell shall vet the proposal and subsequently, the file shall be marked to the Executive Director (ED) for final approval.
- 6. After final approval by the ED, the file will be marked to the Research Cell AIIMS Rajkot, which will notify the proposer regarding the modifications if required.
- 7. The MOU shall be printed on Rupee 500/- Non-judicial Stamp. It will be the responsibility of the proposer to get the MOU/MOA printed on the appropriate paper and communicate a

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mutually agreeable modality to obtain the signatures of all Parties and the witnesses. The proposer shall provide a copy of the MOU/MOA to the Research Cell after it is signed by all Parties.

8. The Research Cell shall maintain a copy of the final signed document for its record keeping and database management.

G. Institutional Mechanism for Approval of MOA:

- 1. Individual research project specific proposals involving funding will be considered as memorandum of agreement (MOA)
- 2. The MOA can be initiated by a proposer/Principal Investigator with a covering note sheet along with a draft MOA and mark it to the Dean (Research), AIIMS Rajkot through its respective Head of the Department.
- The format for the contents of the MOA shall be as described in Clause D "Parameters of MOU) of this Policy however, the obligations on each party of the MOA should be explicitly stated.
- 4. The remaining steps will be as per the clause E Institutional mechanism for approval of MOUs.
- 5. It is the responsibility of the Proposer/ Principal Investigator to provide a copy of the final signed MOA to the Research Cell for its recordkeeping and database management.

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