



INCUBATION POLICY
April 2022

9th Floor, NCA Building, All India Institute of Medical Sciences, New Delhi





Centre for Medical Innovations & Entrepreneurship (CMIE) is flagship bioincubator at All India Institute of Medical Sciences, New Delhi supported by BIRAC, Gol and AIIMS, New Delhi.

CMIE is 60th Bio-Incubator supported by BIRAC.

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ABBREVIATION

All India Institute of Medical Sciences **AIIMS** Centre for medical Innovation and Entrepreneurship **CMIE** Biotechnology Industry Research Assistance Council **BIRAC** BioIncubators Nurturing Entrepreneurship for scaling **BioNEST Technologies** Central Core Research Facility **CCRF** Centre of Excellences CoEs Sophisticated Analytical Instrumentation Facility SAIF **SCF** Stem Cell Facility Central Animal Facility **CAF** Intellectual Property Rights **IPR** TT **Technology Transfer** Limited Liability Partnership LLP IΡ Intellectual Property Small and Mid-size Enterprises SME Memorandum of Understanding MoU Collaborative Research Agreement CRA Non- Disclosure Agreement **NDA** CCO **Chief Coordinating Officer DST** Department of Science and Technology Department of Biotechnology **DBT** Ministry of Electronic and Information Technology MeitY Ministry of Micro, Small and Medium Enterprises **MSME** Department for International Development **DFID Technology Development Board TDB Business Development Officer BDO** Conflict of Interest COI National Cancer Institute NCI **Charactered Accountant** CA



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INTRODUCTION

All India Institute of Medical Sciences, New Delhi, a premier medical institution in India with excellent track record in Education, Research and Health Care aims to create an unparalleled ecosystem of Incubation of Innovations for Entrepreneurship and Inclusive Development of Indian Health Care utilising its huge clinical and biological (sample) resources.

AIIMS has established "Centre for Medical Innovation & Entrepreneurship", the 60th Bio-Incubator under the BioNEST program of Biotechnology Industry Research Assistance Council, Govt. of India.

CMIE encourages innovations in all wakes of health care with a preference to the cutting edge emerging technologies such as precision/molecular medicine, nanomedicine, regenerative medicine, biologics, robotics, AI-enabled medical devices, imaging and application of data science in medicine including digital health. The CMIE can utilize the advanced research infrastructure in AIIMS which includes the Central Core Research Facility, Sophisticated Analytical Instrumentation Facility, Central Animal Facility, the Centre of Excellences (COEs) and research laboratories of the departments. The existing facilities of the preclinical and clinical trial will be a great opportunity for the incubates for seamless translation of their innovations from bench to bedside. With nine super specialty centers and fifty departments in AIIMS, CMIE can access a large number of experts from diverse domains of health care and biomedical research as mentors guiding the innovators to develop interventions/products validating their Quality, Safety, Efficacy & Performance status, empowering indigenisation and "Make in India" program with global recognition.

The Bio-incubator "CMIE" at AIIMS, Delhi plans to work at the enabling phase of innovation to translate the proof of the concept studies to commercially viable products. It will incubate the start-up companies supported by Govt. of non-Govt funding on the basis of their goal for health care product development.

To build a robust ecosystem of need-based innovation for commercially viable health care products, training workshops/ boot camps in different areas of medical practice with Academia-Industry Regulatory interaction.

A network is being developed with other leading Indian Institutions, Incubators and Industries for the development of emerging technology-based products according to the critical need of the country and global requirements. The entrepreneurial business development activity will be led by management expert and business development expert who will be associated with the incubator. Thus the CMIE can work to a develop seamlessly integrated incubation facility with the provision of the preclinical and clinical trials.

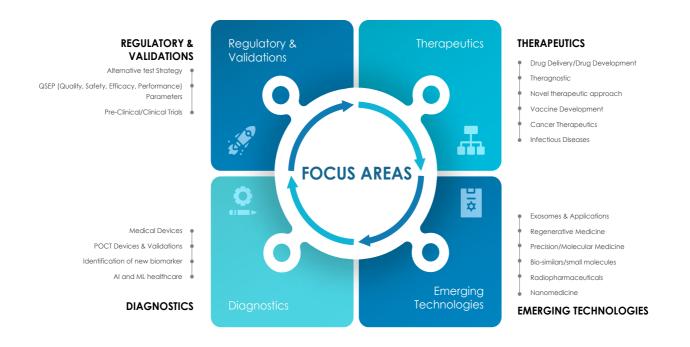


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Thrust Areas:



AIM



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CMIE is set up under BioNEST program at AIIMS with an aim to create an ecosystem of Incubation of Medical Innovations for Entrepreneurship and Inclusive Development of Indian Health Care.

OBJECTIVES:

- 1. To establish a platform for the start-ups and innovators to incubate innovative ideas for translation in Health Care Sector
- 2. To facilitate the incubatee with mentoring support from medical experts from diverse disciplines for optimising diagnostic, therapeutic and other health care interventions
- 3. To create a streamlined access for incubatee to preclinical and clinical trials/research through advanced institutional facilities like CAF, CCRF, SCF, SAIF and other advanced laboratories.

ELIGIBILITY

CMIE is open to:

- Start-ups (Ideation to mature stage)
- Students, Faculties, Researchers, and Individual Innovators having S&T background.

Applicants must fulfil the below mentioned criteria for making an admission to the CMIE, for making an application for virtual incubation programme, pre-incubation programme or acceleration programme.

The primary criteria of admission of the incubatees (innovator group or a start-up) shall be based on a valid business plan around a technology idea organizations and companies possessing synergies with the research and development programs at AIIMS, New Delhi.

The proposals for business incubation should meet the following parameters:

- a) Proposals with Innovation and IP component
- b) Proposals which will have social and strategic impacts,
- c) Proposals with the core team having a good background and credentials to execute the project. Majority of Founders/ core team should be Indian citizens.
- d) Proposals having good technical and commercial viability.
- e) Proposals with potential for large resource generation, impact value and visibility to incubation activities.

Applications for admission to CMIE will be made in the name of registered unlisted companies within the meaning of the Companies Act, 1956 or Limited Liability Partnership Act, 2008. If a company has not been registered, an application may be made in the names of all promoters/founders; however, the promoters/founders must ensure that the company is registered within a period of three months from the date of approval of the application for admission in CMIE.



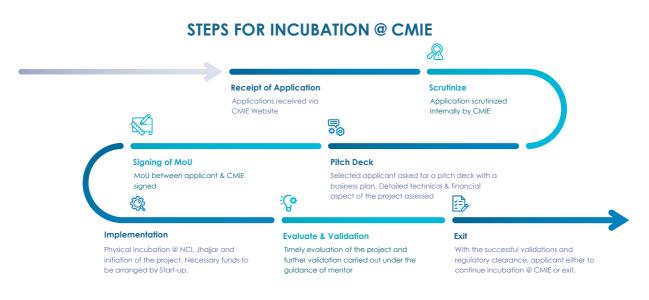
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ADMISSION AND INCUBATION PROCESS

At the opening level, applicants for admission in CMIE will be required to submit an online application form available on the CMIE website. The application will be scrutinized by the screening committee of CMIE. While submitting application, applicants will also disclose information on the executive involvement of the promoters/ founders in other companies or commercial entities.

Based on the initial scrutiny of incubation application and affirmative assessment, applicants will be asked to give a presentation via physical or virtual mode to explain their project in detail. A detailed process is as below:



Some representative criteria to be applied for evaluation (not limited to these)

- Strength of the product idea in terms of its technology content, innovation, timelines and market potential
- IP already generated or the potential of the idea for IP creation and scope for technology transfer to the Industry/SMEs/Clusters
- Extent of involvement of CMIE facility, resources, and support
- Credentials of the core team
- Funds requirement and viability of raising finance

CMIE will have a sole discretion whether to admit or reject a proposal for incubation and the decision of CMIE in this regard shall be final. CMIE is not bound to give any reason in case a proposal is rejected.



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DETAILED PROCESS FOR INCUBATION AT CMIE, AIIMS

A. Receipt of Application:

As a first step in the admission process, the prospective start-up should submit an Incubation application containing all the details of the start-up applicant like team members, the stage of development with a business plan and relevant documents. An important detail to be furnished is the financial supports.

CMIE can play a major role in being the advanced incubator facility for facilitating the startup with validations, refinements and improvisation of the working principle of the innovations.

B. Scrutinize:

The submitted application will be assessed initially by CMIE's Pre-screening committee followed by the CMIE's screening committee and other invited internal/external experts for comments on the technical and business feasibility of the idea. According to the area of innovation, mentor/(s) will be assigned for accelerating further development of the product. Evaluation of the proposal will be based on several criteria including the following:

- Strength of the product idea in terms of its novelty, technology content, innovation, timeliness and market potential.
- Profile of the core team/promoters
- Intellectual property generated and potential of the idea for IP generation, or potential thereof
- Stage of the product/start-up and time to market.
- Commercialisation prospect, potential demand and break-even period.
- Scalability
- Financial/Commercial viability
- Funds available and viability of raising funds
- A brief note mentioning the expected assistance required from faculty/experts from AIIMS in product development path.

Notification on selection or rejection would be provided to the applicant within 3 to 5 weeks.

C. Pitch Deck:

The applicant selected after affirmative assessment will be asked to give a pitch deck via physical or virtual mode in front of the screening committee and perspective mentor/(s) from AIIMS, New Delhi.



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Throughout the application process, on an as-needed basis, CMIE will perform research and due diligence of the applicant, the management team, the current and future competitive elements involved in the business.

D. Signing of MoU

The selected applicant would have to sign an MoU with CMIE. The MoU comprises of the:

- incubation period,
- acceptance to pay towards incubation charges and charges for instrumentation facilities
- acceptance to abide by the rules and regulations of CMIE.
- acceptance to sign the Collaborative Research Agreement (CRA, Annexure I), Non-Disclosure Agreement (NDA, Annexure II)
- acceptance to acknowledge the assistance of CMIE and respective supporting Government agencies i.e. DST/BIRAC-DBT/MeitY/MSME/DFID/TDB etc. while publishing or presenting in any manner, its progress or its success as applicable.

E. Implementation:

Incubatee would be provided physical incubation space at AIIMS-NCI, Jhajjar. The incubation space varies from a 5 X 2.5ft wet laboratory table with office desk and chair to a 6 membered dedicated cubicle. Apart from this, the incubatee would be having an access to landing laboratory and landing office at 9th Floor, National Centre for Aging, AIIMS, New Delhi.

As a part of the incubation, incubatee would be working with a mentor (faculty/scientists on regular appointment at AIIMS). It is mandatory to get appropriate ethical clearance before the initiation of work under CMIE. Mentors will apply for the appropriate ethical clearance. Various committee functioning at AIIMS are as follows:

- a. Institutional Ethics Committee
- b. Institutional Animal Ethics Committee
- c. Biosafety Committee
- d. Institutional Committee for Stem Cell Research
- e. Serious Adverse Events Committee

Work conducted by the incubatee with a mentor or vice versa should be limited to the objectives as approved in the agreement. New agreement will have to be signed by the incubatee for the initiation of a new project/work/collaboration with the mentor.

The incubatee shall treat the CMIE premise with the utmost care, and not do anything unprofessional, illegal or immoral that may disrupt the working culture, reduce or



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adversely affect the productivity of the said office or otherwise bring CMIE to disrepute in any manner.

The Company shall not be permitted to use the CMIE/AIIMS premises or the address of CMIE/AIIMS for the registration of the Company

F. Evaluate and Validate:

Incubatee's progress and performance while at CMIE would be evaluated every month. Incubatee will have to submit a report to CMIE in a prescribed format after every 6 months. The evaluating committee would consist of Chief Coordinating Officer, Bio-Incubation Manager, 2 experts from the screening committee. The companies may also be subject to an annual assessment by a committee comprising of external experts. The involvement of the mentor will be monitored.

The evaluation also involves the presentation of any new development made in the project while being incubated at CMIE.

G. Exit:

MoU gets terminated automatically after a period of 18 months. Any further extension can be granted for 12 months at sole discretion of CMIE. The MoU may also terminate forthwith on or prior to the term of the agreement as follows:

i. By CMIE

- If any default in payment of incubation service charges or any financial fraud is played by the incubatee, by giving advance notice of 7 working days.
- Any violation of any statue, rules and regulations of CMIE/AIIMS/AIIMS-NCI, by giving advance notice of 15 working days. On severity of the case, CMIE may/may not consider to hear the justification from the incubatee.
- Underperformance or unviability of the business proposition: criteria for the same will be decided and applied by CMIE on the case to case basis.
- Irresolvable disputes between promoters/ founders. CMIE will decide the position or point when disputes are deemed to be irresolvable.
- Change in promoters'/ founders' team without concurrence of CMIE.
- Any other reasons for which CMIE may find it necessary for the incubatee to leave, by giving a notice of one month.

ii. By both parties

By mutual written consent of the incubatee and CMIE, by giving a notice of one month.



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iii. By the Incubatee

By giving an advance of one month to CMIE in writing, and clearing all the dues as part of closing of agreement.

However, any IP generated within the incubation period at CMIE will stay valid.

iv. By graduation

Conditions for graduation

- Completion of 18 months from the date of execution of the MoU if no extension is provided by CMIE.
- Incubatee's team operating at CMIE crosses headcount of 15 persons
- Raising substantial investment from angel investor/venture capital/any other investor INR 2 crores or more.
- When the annual revenues of the company exceeds Rs. 2 crores or when a company achieves a Profit Before Tax of Rs. 50 Lakhs.
- When the company enters in an acquisition, merger or amalgamation deal or reorganisation deal resulting substantially a change in the profile of the company, its promoters, directors, shareholders, products or business plans, or when a company plans for a public issue.

Notwithstanding anything written elsewhere, CMIE's decision in connection with the exit of an incubatee company shall be final and shall not be disputed by any incubatee company.

NON-DISCLOSURE

CMIE adheres to strict confidentiality throughout the application process. However, CMIE will not sign any 'non-disclosure' agreement with the Start-up during the evaluation. However, external& screening committee members sign the NDA for evaluating the proposal.

INTELLECTUAL PROPERTY (IP)

IP are of 2 kinds:

a. Background IP:

All rights, title and interest in or to any information, data, reports, documents, procedures, forecasts, technology, know-how, and inventions, including any patent, designs, copyrights, trademarks and any application for patent, designs, copyrights or trademarks, in India and anywhere else in the world, that are owned by or vest by incubatee before execution of MoU with CMIE shall remain the property of such incubatee.

b. Project IP:

IP that arises during the incubation period at CMIE post the execution of the MoU with CMIE. Unless otherwise agreed, the incubatee and CMIE will jointly own and seek protection for Project IP.



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The project IP will stay valid even after the completion of the incubation term at CMIE. Both incubatee and CMIE shall mutually agree the concerning the cost of filing, maintenance and commercial exploitation of project IP.

The detailed document (CRA) to be signed by Incubatee and CMIE during the execution of the MoU.

OFFERINGS BY CMIE

Upon admission to CMIE, the following infrastructural facilities will be offered to the incubatee companies on an individual basis, apart from a set of shared/ common infrastructure mentioned hereinafter:

- Office space: Company specific
- Internet connection
- Common use printer and reception service
- Audio/Video Conference Rooms
- Common Lab services
- Advanced research infrastructure in AIIMS which includes
 - Central Core Research Facility (CCRF) ,
 - Sophisticated Analytical Instrumentation Facility (SAIF), the Centre of Excellences (COEs) and
 - Research laboratories of the departments.
 - The existing facilities for preclinical and clinical trials will be a great opportunity for the incubates for seamless translation of their innovations from bench to bedside.
- Support of AIIMS Faculty (Mentor)

Our AIIMS incubator CMIE would be the world-class incubator for validations, improvisations, and refinement of the innovations in healthcare. The faculty of AIIMS can bring social and economic impact for start-ups/technologies.

- Technical mentorship
- Intellectual Property
- Regulatory compliances
- Product development
- o Product user need analysis
- Validation/Preclinical/Clinical Trials

Other Services

Apart from physical infrastructure and expert mentorship as stated above, CMIE intends to create certain other supports and services which would include:

Pool of experts in technology, legal, financial, and related matters



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- Organising events to help companies in networking and showcasing their technologies,
- The Incubatees will be provided mentorship and handholding for activities related to:
 - IP Management,
 - Business Development mentoring
 - Pitch deck preparation and guidance
 - Legal services
 - Technical mentoring
 - Company incorporation support
 - Networking events



INFORMATION SUBMISSION

Incubatee companies will submit information to CMIE about all material changes or developments taking place in their companies from time to time. Such information could be (but is not limited to) change in name of the company, change in business or product profile,

Networking Opportunities



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change in directors, promoters or shareholders, acquisition of a new office, additional equity or debt investments. CMIE may require incubatee companies to submit other information as it deems fit. Prior concurrence of CMIE should be obtained for effecting such changes.

CONFLICTS OF INTEREST AND CONFIDENTIALITY OF INFORMATION

When a person plays two separate roles in two different positions and he/ she uses one position for his/ her personal benefit in the other role, a situation leading to conflict of interest arises.

CMIE, AIIMS endeavours to draw a line between appropriate and inappropriate interactions among its board members, employees, mentors, consultants, affiliates, incubatee companies, their employees, persons connected to them or their promoters, employees and staff, various service providers and suppliers.

Conflicts between private interests and official responsibilities of all stakeholders must be handled in a transparent manner, and CMIE, AIIMS considers the full voluntary disclosure as the best mechanism for managing conflicts of interest.

Since situations leading to conflicts of interests are inevitable, a transparent policy, based on full disclosure of relevant information by the concerned parties, and discouraging their influence on decisions and activities to avoid personal benefit to them. The policy is not exhaustive, and hence situations having potential for conflicts of interest though not covered in the policy will nonetheless be subject to the policy. The policy makes all stakeholders related to CMIE, AIIMS and incubatee companies aware that no one should use his/ her position in one role for the personal gains in the other role, and when necessary, explicit permission from relevant stakeholders may be obtained. Appropriate judgment should be applied by all concerned parties while assessing the genuineness of conflicting interests.

This policy also deals with the maintenance of confidentiality of proprietary information.

A committee may be set up by CMIE, AIIMS to resolve any dispute over such a situation causing conflicts of interests.

ACKNOWLEDGEMENT

The incubatee company shall acknowledge the assistance of CMIE, AIIMS, and respective supporting Government agencies i.e. DST/BIRAC-DBT/MeitY/MSME/DFID/TDB, etc. while publishing or presenting in any manner, its progress or its success.

DISCLAIMER

The incubatee company will understand and acknowledge that CMIE, AIIMS intends to provide support and services to the start-ups in good faith to pursue its objective to promote



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entrepreneurship by converting innovative technologies developed in the Institute and commercializing alongside incubating and supporting new enterprises. It is understood that by agreeing to provide various supports and services, CMIE, AIIMS does not undertake responsibility for:

- Ensuring the success of an incubatee company, its products/ process/ services or marketability.
- Ensuring quality of support and services provided by CMIE, AIIMS to the complete satisfaction of the incubatee companies or their promoters/ founders.
- Ensuring quality of services of the consultants engaged by the incubatee companies through CMIE, AIIMS/its network. Incubatee companies will have to apply their judgments before getting into a relationship with them.

The incubatee agrees that CMIE, AIIMS or their employees shall not be held liable for any reason on account of the above.

AGREEMENTS

The following agreements are required to be signed by the companies to the extent applicable:

A. Incubation Agreement (MoU) (Annexure I)

Between CMIE and incubatee company for admission of the company in CMIE, AIIMS.

B. Collaborative Research Agreement (CRA) (Annexure II)

Between CMIE, Mentor and incubate to initiate the project at CMIE. The document covers the mutual consent for collaboration while being incubated at CMIE.

C. Non-Disclosure agreement (NDA) (Annexure III)

Between CMIE & incubatee company/Client for availing incubation at CMIE

APPENDIX A:

Policy on Conflicts of Interests and Confidentiality

A. Policy objective:

The intent of this document is not to eliminate all possible situations leading to conflict of interests, an obvious impossibility. Rather, it is to enable an interested person to recognise situations that may be subject to question, to take steps to minimise such conflicts and to ensure that such situations are properly reviewed and, if necessary, corrected. All potential conflict of interest situations should be handled in a manner and all relevant activities are conducted in a manner consistent with the values of CMIE, AIIMS and AIIMS-NCI and public values and interests. This policy makes all stakeholders related to CMIE, AIIMS and AIIMS - NCI aware that no one should use his/her position in one role for personal gains in



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the other role, and when necessary, explicit permission of relevant stakeholder may be obtained.

Conflict of interest policy and operating guidelines of CMIE if any, must be reviewed and followed by all incubatees of CMIE who aspire to set up a company to be incubated in the Business Incubator administered by CMIE. A key requirement for them is that care must be taken to separate clearly and cleanly the personal financial aspects of the entrepreneurial activities from their respective roles, duties and responsibilities in CMIE. On admission in the Incubator, such entrepreneurial activities should not be confused with assigned duties of CMIE. The use of CMIE facilities and equipment must be free from unauthorised or conflicting uses and must be compensated for as per the policies of CMIE. Appropriate judgement should be applied by all concerned parties while assessing the genuineness of conflicting interests.

Also, each party in receipt of confidential information should restrict the use of such information for the purpose for which it is disclosed. Concerned parties should safeguard and protect confidentiality of information by using the same degree of care as they would use to protect their own information of like nature to prevent unauthorised disclosure.

B. Conflict of interest

In this policy refers to a situation in which financial or other personal considerations compromise, or have an appearance of compromising an individual's professional judgement and ability to perform his/ her responsibilities to CMIE or Incubatee companies as the case may be.

This also includes certain grey situations or grey areas that might involve the appearance of conflict.

C. Situations leading to Conflict of Interests

Certain situations leading to conflict of interests are explained herein below. However, the list is not exhaustive, and hence situations having actual or potential for conflicts of interest though not covered in this document will nonetheless be subject to this policy.

- A CMIE member (employees of CMIE, members, associates and mentors from AIIMS)
 is in a position to influence a departmental decision for the acquisition of laboratory
 and other equipment which could benefit an incubatee company in which he/ she is an
 interested person.
- A CMIE member is in a position to circumvent prevailing policies for making use of CMIE's various facilities for the benefit of an incubatee company in which he/ she is an interested person.



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- A CMIE member is in a position to make use of the suppliers and service providers of CMIE for undue advantage of an incubatee company in which he/ she is an interested person.
- A CMIE member procures consultancy assignments or other business in name of CMIE and out sources them to the incubatee company in which he/ she is an interested person.
- When a CMIE member is in a position to influence policy decisions of CMIE with an intention to benefit an incubatee company in which he is an interested person.
- A person who is interested in one incubate
- Company and also involved in a decision-making process affecting other incubatee companies leads to situation of conflict of interest.
- When an incubatee company, its promoters, employees and staff or any interested person acts in manner to benefit the incubatee company at the disadvantage of CMIE or AIIMS or AIIMS – NCI.
- An incubatee company, its employees and its staff having access to CMIE resources are in position to exploit them by bypassing CMIE's policies.
- When CMIE members, and staff of incubatee companies are neglecting their respective commitments to CMIE or CMIE for their association with incubatee companies.

D. Confidentiality of information:

CMIE members may come in possession of proprietary information which may be of confidential or sensitive nature. Recipients of such information should make all efforts to preserve confidentiality of such information. They should not disclose or use it for their financial or personal benefits without explicit approval of the disclosing party.

E. Management of conflict of interest:

Since situations leading to conflict of interests are inevitable, it is expected that the interested persons follow transparency in their actions based on full disclosure of relevant information by them. Following guidelines are suggested for the management of actual or potential conflict of interests and to address disputes arising out of the conflict of interests and maintenance of confidentiality:

- Appropriate disclosure of the conflicting situations involved in a decision or transaction,
- Abstaining from participating in the decision-making process or transactions involving such situations,
- Obtaining appropriate approvals to avoid conflicts,
- Reporting of the breach of the policy without deliberate intention or knowledge.
- If any dispute arises in terms of this policy, the same should be reported to:
- If it pertains to CMIE or Incubatee company, it should be reported to the Chief Coordinating Officer.

NOTE: The policy is subject to change from time to time as needed.