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**Yenepoya Ethics Committee-1**

**Declaration of Conflict of interest (CoI) by researchers**

**Version 2 effective date 03-12-2020**

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| --- |
| This is for researchers investigating any of the following products: 1. Investigational drug/vaccine/remedy/herbal/any other
2. Medical device
3. Surgical instruments/ method
4. Equipment/device -diagnostic/ therapeutic
5. Supportive medical/ surgical device/ equipment

*Instructions for researchers:* 1. *In order to maintain the highest standard of ethical research and retain the trust of society in science, it is important that researchers declare any form of CoI at the time of submission of the protocol to Yenepoya Ethics Committee - 1 for review, during the conduct of the study and at the time of dissemination or reporting*
2. *Conflict of interest is defined as the influence of a secondary interest on a primary interest. In the context of research, it refers to any condition (causing a direct or indirect benefit to the researcher) that is likely to affect the impartiality of the research design, conduct, data collection, analysis and/or reporting.*
3. *CoI could be financial or non-financial or both.*
4. *CoI could be real or potential*
5. *In the context of research-related non-financial (or personal) conflict of interest, YEC-1 defines immediate relative as parent, parent of a spouse, spouse, sibling or sibling of a spouse, son, daughter. For details please refer YEC-1 SOP3A/v3 effective date 03/10/2019.*
6. *Please read the statements in the next section carefully and mark your response as Yes/ No in the response column*
7. *All members of the research team must fill individual CoI forms, duly signed*
8. *Please do not leave any statements unanswered.*
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**Protocol details**

|  |  |  |
| --- | --- | --- |
|  | Name of the researcher  |  |
|  | Affiliation |  |
|  | Protocol No.  |   |
|  | Title of the protocol  |  |
|  | Role of the researcher in the research team | Specify: (Principal investigator/ Co-PI/ Co-investigator/ Research coordinator/Guide/ Co-guide/ Mentor/other) |
|  | Source of funding (if any) for the study |  |

**Part A: Financial CoI**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No** | **Statement of CoI** | **Yes/ No**  | **For the researcher** **If yes**1. **Provide details**
2. **Attach relevant documents**
 | **For Reviewers (for official purpose only)****If the answer is Yes, Do you think this will affect recruitment/ data collection/analysis/ outcome of the study** |
| 1.
 | Is the study receiving a grant from any of the following agencies?GovernmentNon-governmental agencyCommercial sponsorInstitution (including YU)Any other |  |  |  |
|  | Are you receiving personal benefits from the sponsoring agency?* Salary/honorarium/ royalties/consultation fees
* Affiliation/employment
* Travel/writing/any other assistance/fellowship for the study or publication
 |  |  |  |
|  | Is the material/drug/device/ equipment used for the purpose of this research supplied by a company?  |  |  |  |
|  | Do you hold any of the following positions in any company/industry/startups which manufactures or markets any product that is related to this research or the outcome of this research (directly or indirectly)? 1. Owner
2. Advisor
3. Shareholder/ Investor
4. Beneficiary
5. Employee
6. Consultant
7. Any other position in the functioning of the company
 |  |  |  |
| 1.
 | Are you beneficiary of a surgical manufacturing company/distributing agency involved in the development of the investigational product of this research outcome (Medical device company/start-up/other manufacturing company)? |  |  |  |
|  | Are you a beneficiary of a company/agency involved in the marketing of the product (including post-approval marketing) of the investigational product related to the research outcome of this project (Pharma company/start-up/other manufacturing company)? |  |  |  |

**Part B: Non-Financial CoI**

Non-financial conflict of interest is a situation where a non-financial element such as the presence of an immediate relative, institutional affiliation, career advancement, competitiveness/rivalry or personal belief can cause a conflict of interest. If such an element exists all research team members are strongly encouraged to list it here.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No** | **Details of non-financial CoI** | **Yes/ No** | **If yes**1. **Provide details**
2. **Attach relevant documents**
 | **Reviewer’s comments (For YEC-1 office use only)** |
|  | Are any of your immediate relatives (see instructions to researchers above), an employee or stakeholder in the company that is sponsoring the product that is being researched? |  |  |  |
|  | Are you affiliated in some way with the institution funding the development of the product that is being researched? |  |  |  |
|  | Is the research outcome directly linked to your career advancement?  |  |  |  |
|  | Is the research an outcome of competitiveness/ rivalry with another company producing or marketing a similar product?  |  |  |  |

If the responses to any of the above questions in parts A or B is YES, then kindly fill the next segment (Part C). If not, then skip to Part D.

**PART C: Management of Conflict of interest**

|  |  |  |  |
| --- | --- | --- | --- |
|  | What is your plan (and please make this plan clear in the protocol) to ensure that the CoI will not affect the following: | Description of the plan and the person in charge | Reviewer’s comments |
|  | 1. Scientific design
 |  |  |
|  | 1. Participant inclusion
 |  |  |
|  | 1. Risk-benefit ratio
 |  |  |
|  | 1. Informed consent process
 |  |  |
|  | 1. Data collection and analysis
 |  |  |
|  | 1. Data analysis
 |  |  |
|  | 1. Data safety monitoring plan
 |  |  |
|  | 1. Preparing the report and publishing the results
 |  |  |
|  | In the participant information sheet, have you included that you or any of the researchers conducting this research have (or do not have) a conflict of interest? |  | Reference to the document with (Page no, line no) |

**PART D: Declaration**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of the research team member), working as \_\_\_\_\_\_\_\_\_\_\_\_\_ (role in the research team), for the protocol titled “\_\_\_\_\_\_\_\_\_\_\_\_\_ (title of the protocol)” do hereby declare that the above information furnished by me is factually correct, as on the time of submission. I hereby also declare that should any conflict of interest (financial or non-financial) arise in future, during the approval process, during the conduct of the research study, during data analysis and/or during the report-writing/dissemination/publication of this work, I shall declare the same to YEC-1. I further declare that I am aware of the policy of Yenepoya deemed to be University and Yenepoya Ethics Committee - 1 towards non-declaration of research-related conflict of interest and understand that should such a situation arise with respect to this study, I am liable (as also all my research work) to suitable action as decided by Yenepoya deemed to be University.

Signature of the Researcher (with name and date):

Signature of the PI for the protocol (with name and date):