**APPLICATION FOR PERMISSION FOR HUMAN EXPERIMENTS**

1. Place where the experiment is to be performed :

Rajah Muthiah Medical College and Hospital,

Annamalai University, Annamalai Nagar,

Chidambaram – 608 002.

2. Date on which the experiment is to commence and duration of the experiment:

Date of commencement - Immediately after approval from IHEC

Duration of study - **1 year**

**Address for Communication :**

|  |  |
| --- | --- |
| Dr.G.Aarthipriyanka  I year Post Graduate  M.D. (PHARMACOLOGY)  Dept.of.Pharmacology  Rajah Muthiah Medical College  Chidambaram | **Permanent Address**  1/134,SKM Post Office street,  Sathiyavadi(P.O),  Virudhachalam (T.K),  Cuddalore-606110 |
|  |  |

Date :

Place :

Signature of Guide,

**Dr. SWADHIN RANJAN BEHARA. M.D.,**

**Associate** **Professor**

Department of Pharmacology,

RMMC.

Signature of Guide,

**Dr. SWADHIN RANJAN BEHARA. M.D.,**

**Associate** **Professor**

Department of Pharmacology,

RMMC.

Signature of Chief Investigator,

**Dr.G.AARTHIPRIYANKA**

I year Post Graduate

M.D (Pharmacology)

RMMC

Signature of Co-Guide,

**Dr. B. GOVINDARAJAN M.D,D.M,**

Department of Cardiology,

RMMC

Signature of HOD,

**Dr. VANITHA M.D,**

**Professor & HOD**

Department of Pharmacology,

RMMC

**Form – B**

Protocol form for research proposals to be submitted to the Institutional Human Ethical Committee for new experiments or extensions of ongoing experiments using human subjects.

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | Project title | : | AN OBSERVATIONAL STUDY ON DRUG UTILIZATION PATTERN IN CORONARY ARTERY DISEASE PATIENTS |
| 2. | Type of study | : | Observational Study |
|  | a. Drug Trails | : | Not applicable |
|  | b. Vaccine Trial | : | Not applicable |
|  | c. Surgical Procedure/ Medical Device | : | Not applicable |
|  | d Diagnostic agents - with special reference to use of radio active materials/X-rays | : | Not applicable |
|  | e. Trials with herbal remedies | : | Not applicable |
| **3. Investigator’s Curriculum Vitae** | | | |
|  | Chief Investigator: |  |  |
|  | a. Name | : | Dr.G.Aarthipriyanka |
|  | b. Designation | : | Post Graduate Student  Division of pharmacology,RMMC. |
|  | c. Qualification | : | MBBS |
|  |  |  |  |
|  | Guide | : | **Dr.SWADHIN RANJAN BEHARA., M.D.,**  Associate Professor  Department of Pharmacology,  RMMC, Annamalai University |
|  | Co-Guide | : | **Dr.B.GOVINDHARAJAN.M.D,D.M**  Department of Cardiology,RMMCH.  . |

4. Place where the experiment is to be performed :

Dermatology department, RMMCH, Annamalai University

5. Does the place of the experiment come under the jurisdiction of the IHEC?

Yes

6. Research Objectives:

1. To analyse the drug utilization pattern of coronary artery disease patients in cardiology department,RMMC.
2. To find out defined daily dose of the drug used

7. Rationale in undertaking the investigation in human subjects.

1) coronary artery disease leads to various complications,

which can be cured when diagnosed and treated with

appropriate drug dosages.

2)Drug utilization helps in analysing the drugs used in treatment of such

disorders and patient compliance to these

medications.

8. Subjects Recruitment Procedure:

Both male and female patients attending cardiology department for

treatment of coronary artery disease are included in the study.

9. Inclusion and Exclusion criteria for entry of subjects in the study:

Inclusion criteria:

1. Patients with the established diagnosis of CAD, attending outpatient department or admitted in the ward or Intensive Care Unit of Cardiology unit, RMMCH.

2. >18 years of age, of either gender

3. Patients with/without co morbidities, such as Diabetes Mellitus, Bronchial Asthma, Hypertension, Rheumatoid Arthritis or any other disease.

4. Patients willing to give written informed consent

Exclusion criteria:

1. Patients who are not willing to participate in the study.

2. Patients who are in critical condition.

3. Patients who are diagnosed with other cardiac diseases.

10. Precise description of methodology of the proposed research including drug dosages...,

1)Hundred prescriptions with drugs for coronary artery disease

will be analyzed

11. A description of plans to withdraw or withhold standard therapies

in course of research

No plans to withhold the standard therapy.

12. Plans for statistical analysis of the study

Yes.

13. Procedure for obtaining informed consent forms in English and vernacular,

(a copy has to be enclosed)

Informed consent forms in English and vernacular is enclosed

14. Safety of proposed interventions or drug-vaccine to be tested

(please enclose results of relevant laboratory and animal research)

No drug,vaccine will be used

15. Does the study entails more than minimal risk?

(If so give the account of plans to provide medical therapy

for such risk or injury or toxicity due to over dosage)

No

16. Proposed compensation and reimbursement of incidental expenses

Not applicable

17. Storage and maintenance of all data collected during the study

The collected data will be stored and maintained in the

Department of Pharmacology,RMMC.

18. Plans for publication of results positive or negative - (Privacy and confidentiality of the study participants should be maintained)

After completion of the study, data will be published in a peer reviewed scientific journal. The privacy and confidentiality of the study participant will be maintained**.**

19. Statement of probable Ethical Issues and steps taken to tackle the same

Not applicable

20. Relevant documents related to the study protocol including regulating clearances (Copies to be enclosed)

Not applicable

21. Indicate if you agree to comply with national and international GCP protocols

Yes

22. Details of Funding Agency/sponsors and fund allocation for the proposed work

Self .

**INVESTIGATORS DECLARATION :**

1. I certify that I have determined that the research proposal herein is *not* unnecessarily duplicative of previously reported research.

2. I certify that individuals working on this proposal, and experimenting have been trained and qualified physicians in their system of medicine.

3. I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress.

4. I will obtain approval from the IHEC before initiating any significant changes in this study.

5. Certified that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body (Institutional Scientific Advisory Committee/Funding Agency /other body (to be named).

6. Institutional Biosafety Committee’s (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents of human pathogens).

7. I shall maintain all the records.

**Signature**

**Name of investigator**

Date : Dr.G.AARTHIPRIYANKA

**(for IHEC usage)**

Proposal Number :

Date first received :

Date received after modification (if any) :

Approval date :

Expiry date :

Name of IHEC :

**Signature**

**ANNEXURE - II**

**INFORMED CONSENT FORM**

I Mr/Ms…………………………………..........Residing at ……………... ………………………………………………………………………………………. in sound mind accept the following.

1. My age is ………………..
2. I have been explained in detail about the procedure .I understand the advantages and the prognosis of the procedure
3. I accept to undergo this procedure with consciousness. This decision was taken by me without any external influence.

Signature of the Patient

Place:

Date:

Time:

என் பெயர் திரு/ திருமதி : …………………………………………………………………………………………………………………...........

முகவரி: ………………………………………………………………………………………………………………………………………………………………………

தெளிவான மனதுடன் கீழ்கண்டவற்றிற்கு சம்மதிக்கிறேன்.

1. என் வயது
2. வைத்திய முறை பற்றி என்னிடம் விளக்கி உள்ளார்கள் அவற்றை நான் நன்றாக புரிந்துக்கொண்டேன்.

என் முழு சுய உணர்வோடு மருத்துவ முறைகளுக்கு சம்மதிக்கிறேன்.

இடம்: கையொப்பம்

தேதி:

நேரம்:

**ANNEXURE –I**

**PROJECT TITLE:**

The Drug utilization study of Coronary artery disease patients.

**PART A-INFORMATION SHEET**

This study is going to analyse the prescription pattern of drugs used in coronary artery disease

**Voluntary participation**

The following paragraphs will give you the details of the study and you can ask any information regarding the study.It is entirely your choice to participate in the study.

**Procedures**

The investigator will ask details of your prescription

**Potential Risk**

The study does not have any risk.

**Confidentiality of Records**

Your idendity and information will be kept confidential.

You can ask any question for further clarifications,doubts about the study.you can fully satisfy regarding the study before giving consent.

You can free to contact the following officials for any details.

Dr.G.AARTHIPRIYANKA

9688572808