

ALL INDIA INSTITUTE OF MEDICAL SCIENCES

RESEARCH SECTION

Ansari Nagar, New Delhi – 110029

F. NO. 5-59/Intramural/2010/RS

Dated: 22.01.2014

CIRCULAR

Subject:- Grant of Institute Research Project for the financial year 2014 – 2015.

Dear Colleagues,

The Annual Research Grant for the AIIMS faculty and scientists will be sanctioned for a period of 1 year which can be extended for another year. In this connection, the Research Section invites novel project proposals for consideration during the financial year 2014-2015. The projects would be funded on competitive basis along with the usual terms and conditions (attached).

Only one project per investigator is permissible in a financial year. Those investigators who have been funded any Intramural Project earlier can only apply if their previous project has been completed & its final report submitted to the Research Section.

The funding is for consumables only upto a maximum of Rs. 5.0 lacs/year. Staff and items included in the learning resource allowance are not covered in this grant.

The prescribed format for submission is enclosed. Please indicate on the application form the category (Basic or Clinical) under which the project should be considered. Three copies of the project need to be submitted to the Assistant Administrative Officer, Research Section by 28th Feb., 2014 along with a soft copy on a CD and a copy of the Ethical Clearance if already obtained.

The investigators will be called for presentation to the respective Project Review Committee (Basic/Clinical) in the month of March, 2014.

The application form can be downloaded from the AIIMS website (www.aiims.edu, www.aiims.ac.in).

Guidelines for preparing the protocol:

1. The research hypothesis should be clearly stated.
2. The research question should be specific and focused only on one particular aspect.
3. The background should be brief and not more than one page.
4. The objective should be clear and the methodology should be well written.
5. The budget should clearly specify the requirements for consumables only. Please do not tailor the budget to make it around Rs. 5.0 lacs.
6. In general, please refrain from submitting 'Clinical Trial' proposals as they require DCGI clearance and also compensation to be paid in the event of serious adverse reaction. The budget allocation will have no provision for providing compensation. 'Annexure-1' provides details about a 'Clinical Trial' and the mandatory requirements that a principal investigator should adhere to for conducting a 'Clinical Trial'.
7. Please obtain ethical clearance preferably before submitting the proposal for funding. In any case, funds will be allocated for approved projects only after ethical clearance is obtained.
8. Please avoid submitting duplicate projects which have already been submitted elsewhere.
9. Please submit a check list along with the proposal to ensure adherence to these guidelines.

Check List

- | | |
|---------------------------------------|-----------------------|
| 1. Already having Intramural Project. | Yes/No |
| 2. If Yes, final report submitted. | Yes/No/Not Applicable |
| 3. Ethical Clearance. | Yes/No/Applied for |

(Dr. Pramod Garg)
Sub-Dean (Research)

‘ANNEXURE-I’

What is a Clinical Trial? Although any study that aims to evaluate the effectiveness and safety of any drug/device/procedure can be labelled as a clinical trial, the Drug & Cosmetic Act 1940 (amended 2005, 2008) and Drug & Cosmetic Rules 1945 (amended 2005), GOI has defined a clinical trial as follows:

Definition of Clinical trial (Rule 122DAA): For the purpose of this part, “Clinical trial” means a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effects with the objective of determining safety and/or efficacy of the new drug.

Definition of ‘new drug’ (Rule 122E): For the purpose of this Part, ‘new drug’ shall mean and include:

(a) A drug, as defined in the Act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority mentioned under rule 21 for the proposed claims:

Provided that the limited use, if any, has been with the permission of the licensing authority.

(b) A drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.

(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage, dosage form (including sustained release dosage form) and route of administration. (See items (b) and (c) of [Appendix VI] to Schedule Y.)

Explanation: For the purpose of this rule–

(i) all vaccines shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;

(ii) a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.

Major Changes in Rules/Regulations/Guidelines: Recently, major changes have been introduced for conducting ‘clinical trials’. It has become mandatory for all ‘clinical trials’ investigators in India to follow these rules/regulations/guidelines regarding the following issues:

- (i) Obtaining permission to start a clinical trial from Technical Review Committee, Ministry of Health.
- (ii) Registration of trial at www.ctri.in .
- (iii) Obtaining audio-visual consent of a trial participant
- (iv) Monitoring of a clinical trial by Institute Ethics Committee.
- (v) Reporting of Serious Adverse Reaction (SAE) within 24 hours
- (vi) Compensation to be paid in case of SAE