NATIONAL INSTITUTE OF AYURVEDA

Institutional Research Review Board (IRRB)

Background

Institutional Research Review Board (IRRB) is an intermediary board of the institute which will act as a reviewing and advisory body to all the Departmental research committees (DRCs) and will guide the DRCs to conceive and execute various research projects of the department. IRRB will prioritize the broad research areas, Thrust areas, Research goals and formulate the research policies of NIA. On the basis of these policies, IRRB will guide the DRCs to formulate the departmental research goals. IRRB will focus on high impact research. It will also find the high impact areas for the research and will be responsible for the generation of high quality P.G. Doctorate and other research project. The IRRB will act as a bridge between the DRCs and the Institutional Ethics Committee (IEC).

Composition

The composition of IRRB will be-

1. Director - Chairman
2. Heads of all the departments - members
3. Dean (Research) - member
4. Statistician - member
5. Pharmacy manager - member
6. Special invitees (At the discretion of Director)
7. Dean (PG studies) - Member Secretary

Sub-boards

1. **Fundamental Research Review Board [Route 1]:**
    a. HOD, (Maulik Siddhanta)
    b. HOD, (Sharir Rachana)
    c. HOD, (Sharir Kriya)
    d. HOD, (Swastha Vritta)

    Chair: Prof. Kedar Lal Meena, HOD, (Maulik Siddhanta)

2. **Pharmacological Research Review Board [Route 2]:**
    a. HOD, (Dravya Guna)

b. HOD, (Rasa Shastra)
c. HOD, (Agada Tantra)

Chair: Dr. K Shankar Rao, HOD, (Rasa Shastra)

3. **Clinical Research Review Board (A) [Route 3]:**
    a. HOD, (Kaya Chikitsa)
    b. HOD, (Pancha Karma)
    c. HOD, (Bala Roga)
    d. HOD, (Roga Nidana)

    Chair: Prof. Ram Kishor Joshi, HOD, (Kaya Chikitsa)

4. **Clinical Research Review Board (B) [Route 4]:**
    a. HOD, (Prasuti Tantra & stree Roga)
    b. HOD, (Shalya tantra)
    c. HOD, (Shalakya tantra)

    Chair: Prof. P Hemantha Kumar, HOD, (Shalya tantra)

The chairs of the respective Sub-boards may invite other faculty members for advice/ assistance in reviewing the projects as per the need. The chair may nominate a faculty member as member secretary of the sub-board.

Term of Reference

For three years

SOPs

1. The Director will notify the IRRB of the Institute for three years.
2. Every research project (including Projects of Teachers and P.G., Ph.D. scholars) will be forwarded by the DRC to the IRRB for review.
3. The Director of the Institute will be the ex-officio chairman of the IRRB.
4. IRRB will be responsible for the correctness of all the Research Projects and Programs of the Institute.
5. IRRB will ensure that
    a) The project submitted is according to the research goals established by the Institute.
    b) The research projects are according to the available resources of the institute and existing MOUs.

c) There is no violation of the research ethics and existing national and international operational laws.

6. Procedures for seeking approval to proceed with research

6.1 Research at National Institute of Ayurveda is conducted according to the principles set out in the AYUSH GCP . The policy applies to all staff and students of the Institute (including those with visiting or honorary contracts) and to third parties (e.g. staff from other institutions) who propose to undertake research with NIA. The policy states that all research must be conducted according to appropriate ethical, legal and professional frameworks, obligations and standards, and as a guide for staff and students, it specifies that the following types of research must undergo Technical and Pre-Ethical scrutiny by the appropriate IRRB or Sub-Board and obtain formal approval before it is submitted to the Institutional Ethics Committee (IEC):

a. Research involving living human participants, their tissue or their data;
b. Research with the potential for adverse environmental impact;
c. Research involving NIA patients, staff or resources;
d. Research involving animals;

6.1 Each cognate area has an established Institutional Research Review Board, to which individuals should apply to obtain approval for research.

6.1.1 The Four Sub-Boards support research in (i) Basics (ii) Pharmacological (iii) Clinical (A) and (iv) Clinical (B).

6.1.2 All staff research and post-graduate research student projects of the type listed above must be considered and approved by the relevant Sub-Boards supporting the cognate area before data collection can begin.

6.1.3 Ethical approval may only be sought after the research has been subject to IRRB review.

6.1.4 In order to avoid any potential conflict of interest, it is not permissible for an individual staff member to provide approval for their own research. Nor is it permissible for post-graduate research student supervisors to grant approval for their own students' research.

6.2 The process of ethical scrutiny and approval may follow any one of Four possible routes.

6.2.1 **Route One**: Identification that ethical approval is **not** required.

6.2.2 If the research is not of the type described above (6.1), does not appear to raise ethical issues as indicated by answering "no" to all of the screening questions, an application for ethical approval is not required. If in doubt, please consult the Chair/Secretary of the IRRB supporting the relevant cognate area.

6.2.3 **Route Two:** Request that the IRRB supporting the relevant cognate area grant ethical approval by means of **expedited review**.

6.2.4 If the research is of the type described above (6.1) (i.e involves human participants etc), ***but does not appear to raise significant ethical issues*** as indicated by answering "no" to all of the screening questions, the applicant should submit an application for ethical approval to the IRRB supporting the relevant cognate area. The application should contain an outline of the project, a completed screening checklist, and all relevant appendices (e.g. informed consent, survey instruments, interview schedules etc). In the description of the project, the applicant should identify the ethical issues that have been considered, state that the ethical issues pose no more than minimal risk, and request that the project is considered for ethical approval by means of expedited review. The IRRB supporting the relevant cognate area will then consider the submission and provide a decision for the applicant. No research should be conducted until the IRRB supporting the relevant cognate area has granted approval in writing.

6.2.5 **Route Three:** Request that the IRRB supporting the relevant cognate area grant ethical approval **without the need for a full ethical review**.

6.2.6 If the research is of the type described above (i.e. involves human participants etc.) and does appear to raise some significant ethical issues as indicated by answering "yes" to some of the screening questions (and these are coloured blue), the applicant should then complete the questions on the decision tree. If all responses to the questions on the decision tree are "**no**", then the applicant should submit an application for ethical approval to the IRRB supporting the

relevant cognate area along with a completed research ethical considerations mitigation form.

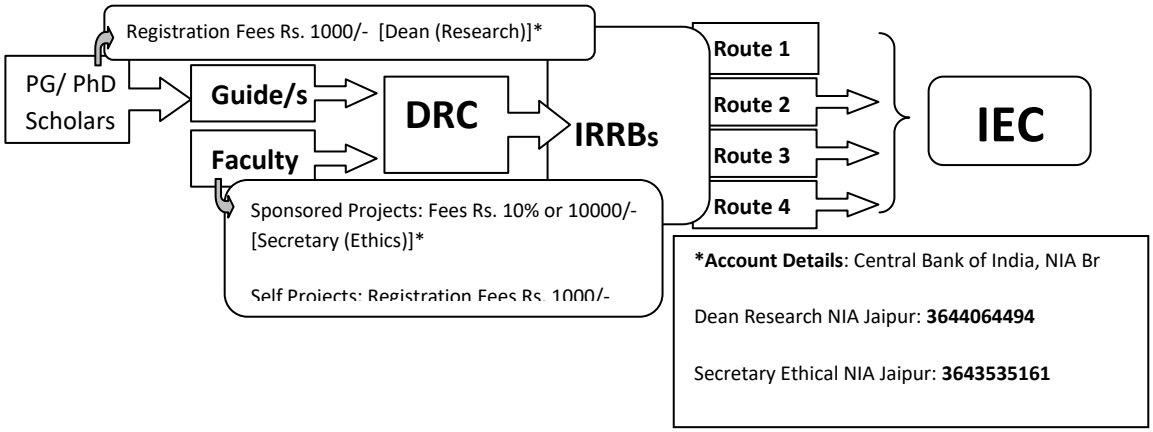
6.2.7 The application should contain an outline of the project, a completed screening checklist, the completed research ethical considerations mitigation form and all relevant appendices (e.g. informed consent, survey instruments, interview schedules etc). In the description of the project the applicant should identify the ethical issues that have been considered. On the mitigation form the applicant should detail how each of the identified ethical issues are to be mitigated and request that the project is considered for ethical approval without the need for a full ethical review. The IRRB supporting the relevant cognate area will then consider the submission and provide a decision for the applicant. No research should be conducted until the IRRB supporting the relevant cognate area has granted written approval.

6.2.8 **Route Four:** Request that the Research Ethics Committee supporting the relevant cognate area grant ethical approval following a **full** ethical review.

6.2.9 If the research is of the type described above (i.e involves human participants etc) and does appear to raise some significant ethical issues as indicated by answering "yes" to some of the screening questions (and these are coloured **Blue** or **Red**), the applicant should then complete the questions on the decision tree. If any of the responses to the questions on the decision tree are "yes" (**and these are coloured Red**) , then the applicant should submit an application for full ethical review to the IRRB supporting the relevant cognate area.

6.2.10 The application should contain a full research ethics proposal, and a request that the project is considered for approval by means of a full ethical review. The IRRB supporting the relevant cognate area will then consider the submission and provide a decision for the applicant. No research should be conducted until the IRRB supporting the relevant cognate area approval has granted written approval.

6.3 The procedure for obtaining ethical approval involves a number of steps as outlined below and in the procedures flowchart.



6.3.1 IRRB will review all the projects submitted and if some corrections/amendments are required then the project/s will be returned back to the respective DRCs along with suggestions.

6.3.2 DRCs/ Investigators should determine with the IRRB, the categories of research for which each type of ethics review requirement would apply. Every proposed project shall undergo the type of Technical and Ethics review corresponding to its risk of harm to research subjects. Where uncertain of the required extent of review, the research project should be subjected to a higher level of review.

6.3.3 For this purpose, Sub-boards will be constituted as above.

6.3.4 All HBR projects involving interventions that pose a more than "minimal risk" to research subjects shall be subjected to a full review. "Minimal risk" refers to the probability and magnitude of harm and discomfort anticipated in the research that are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination.

6.3.5 It may be ethically acceptable to abbreviate, or temporarily suspend, the usual ethics review procedures and requirements in some exceptional circumstances, provided that all other applicable legislative and regulatory requirements are satisfied. In situations where urgent research has to be carried out by the institution for the sake of national security or for the urgent protection or treatment of whole

populations at risk, the IRRB may give special exemption or expedited review of the specific research project.

7 MONITORING AND IMPROVEMENT PROGRAMME

7.1 A monitoring and improvement programme shall be put in place for the IRRB(s) to systematically review and evaluate the working processes involved in the ethics review of research projects. This will improve the overall standards of ethics review and human subject protection.

7.1.1 The functions of the monitoring and improvement programme may be performed by one or more sub-boards appointed by the institution.

7.1.2 The IRRB so appointed, it will take on the programme, which would focus on the following components:

7.1.3 Monitoring of feedback from research subjects.

7.1.3.1 The IRB will act as the key institutional agency that receives, acts upon, and reports to the relevant authorities on concerns and feedback expressed by the research subjects. The IRRB will formalise and make known arrangements that allow research subjects a one-stop direct access to the IRRB, or an appropriate senior officer of the institution. In this way, research subjects can have access to independent officers in order to give feedback on the research or to express their concerns. Feedback may be submitted verbally, or in writing, and be anonymous. IRRBs and will have systems in place to provide protection against the disclosure of the identity of the person providing the feedback.

7.1.4 Investigation of complaints about approved research projects

7.1.4.1 The IRRB may investigate complaints relating to research projects that it has approved. The findings of, and recommendations following, each investigation should be submitted to the institution. A complaint which cannot be resolved at the level of the IRRB should be escalated to the IEC. Where necessary, approval of the research project in question should be withheld, pending the outcome of investigations.

7.1.5 Compliance monitoring

7.1.5.1 The IRRB will put in place a robust system for monitoring the conduct of research projects for compliance with the IRB-approved protocols, institutional standards or regulatory requirements. Monitoring may be effected through site visits to selected clinical investigator sites, review of documentation, and/or interviews with relevant personnel. Aspects which may be monitored include: a. Consent document, including the

informed consent process; b. Subject enrolment, including recruitment criteria of subject; c. Data integrity; d. Documentation; e. Safety reporting.

7.2 There shall be at least one monitoring and improvement programme coordinator who has oversight of the various functions performed under the research programme of each DRC.

7.3 The operational procedures related to the functions of the monitoring and improvement programme, and the roles and responsibilities of its coordinator(s), shall be clearly stipulated by the IRRB.

8 IRRB will be convened within two weeks of the Last DRC of the academic year.

9 In case of the project proposals by faculty, IRRB may be convened as per the need.

10 As a general practice, the concerned Investigator, PG and Ph. D. Student/s shall make a brief presentation following which there will be discussion for clarification.

11 The IRRB may waive off the presentations if it deems fit.

12 After complete review of all the proposals, the chairman, with the help of the member secretary, will prepare a note of the reviewed projects and will submit the approved projects to the Institutional ethics Committee (IEC).

13 The unapproved projects will be returned to the PI/P.G. or Ph. D. Scholars with clear note of reasons for the rejection and suggestions as well. A limited time frame will be given to re-submit the project/s.

14 No research project will be submitted directly to the Institutional Ethics committee (IEC).

15 Member secretary will obtain the attendance of the members attending the meeting with their names and will write down the proceedings in the IRRB register.

16 Submission of the projects to the Institutional Ethics Committee (IEC):

16.1.1 Chairman will submit the projects to the IEC with following details:

16.1.1.1 Department

16.1.1.2 Name of the chairman

16.1.1.3 Project No.

16.1.1.4 Title of the project

16.1.1.5 Research scholar (If project is of PG/Ph.D. scholars)

16.1.1.6 Principal investigator/Supervisor/Guide

16.1.1.7 Co-principal investigator/co-supervisor/Co-guide

16.1.1.8 Date of submission of the synopsis

16.1.1.9 Date of DRC

16.1.1.10 Members of the DRC

16.1.1.11 Approved or not approved

16.1.1.12 Other Remarks

17 In case if project/s is/are rejected by IRRB or Ethics committee

17.1.1 In case if the projects are returned/rejected by IRRB or Ethics committee with some objections the chairman of respective DRC will ask the investigators to make suggested amendments and resubmit the project.

17.1.2 Then again the synopsis will be put before the DRC and same procedure will be followed as was followed the first time.