3.3.1 The institution has a stated Code of Ethics to check malpractices and plagiarism in Research

Provide upload the URL having code of ethics	Whether Colleges have been provided access to plagiarism detecting software (Yes/No)	Mechanism for detecting plagiarism
http://www.cdsco.nic.in/writereaddata/IRwin212.pdf	Yes	liclibrary.du@analysis.urkund.com
http://www.cdsco.nic.in/forms/list.aspx?lid=1899&Id=1		

File No. ECR/1067/Irwin/Indt/DL/2013

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 17/10/2014

To,

The Chairman,
Ethics Committee,
Diretor's Office,
Lady Irwin College,
Sikandra Road, New Delhi-110001,
India.

SUB: - Ethics Committee Registration no. **ECR/212/Indt/DL/2014** issued under Rule 122DD of the Drugs & Cosmetics Rules1945.

Sir/Madam,

Please refer to your application **no.** Nil dated Nil submitted to this office for the Registration of Ethics Committee.

Based on the documents **submitted** by you, this office hereby registers the **ETHICS COMMITTEE, DIRETOR'S OFFICE, LADY IRWIN COLLEGE** situated at **SIKANDRA ROAD, NEW DELHI-110001, INDIA** with Registration number **ECR/212/Indt/DL/2014** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. **The Ethics Committee shall review and approve only the study protocols and related documents of Bioavailability/Bioequivalence studies of the approved drug molecules and also carry ongoing review of such studies.**
2. The Ethics Committee shall review and accord its approval to Bioavailability/Bioequivalence studies and also carry ongoing review of such studies at appropriate intervals, as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well being of the trial subjects.
3. In the case of any serious adverse event occurring during Bioavailability/Bioequivalence studies, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
4. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to Bioavailability/Bioequivalence studies and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of Bioavailability/Bioequivalence studies.

5. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.

6. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

7. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.

8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled.

9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non Medical and Non-scientific fields including lay public.

10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution besides; there should be appropriate gender representation on the Ethics Committee.

11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

12. Members should be conversant with the provisions under Schedule Y, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:

    i. Basic medical scientist (preferably one pharmacologist)
    ii. Clinician
    iii. Legal expert
    iv. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
    v. Lay person from community

14. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.

15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.

18. This certificate is issued to you on the basis of declaration/ submission by you and that registration is sought for Independent Ethics Committee.

19. Ethics Committee should review such number of protocols of Bioavailability/Bioequivalence studies of approved drug molecules which should be commensurate to the infrastructure and facilities available with them.

20. Status report of the functioning of the Ethics Committee should be submitted to the CDSCO headquarters and concerned zonal office on quarterly basis.

21. The details of funding support and amount of honorarium, if any, payable to the ethics committee members should be defined in the Standard Operating Procedure (SOP) of the committee and records to this extent shall be maintained.

22. Ethics committee should have dedicated office with required infrastructure and supporting staff.

However, it is informed that this Ethics Committee can carry out periodic review of ongoing clinical trials already approved by them prior to 30.01.2013

17/6/2014

(A. Visala)
Deputy Drugs Controller (I) & Licensing Authority

A. Visala
Deputy Drugs Controller (I)
Dte. General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi-110002

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L A D Y I R W I N C O L L E G E

(University of Delhi)
SIKANDRA ROAD, NEW DELHI-110 001

Dr. Anupa Siddhu
Director

No. LI//IEC/31/2017
27th December, 2017

The Drug Controller General of India
Central Drugs Standard Control Organization
FDA Bhawan,
Kotla Road,
New Delhi 110002

Sub: **Submission of the annual report (2016-2017) of the Institutional Ethics Committee of Lady Irwin College, University of Delhi.**

Sir,

Please find enclosed the Annual report (2016-2017) of the Institutional Ethics Committee (IEC) of Lady Irwin College, University of Delhi (registration No. ECR/212/INDT/DL/2014) as Annexure-I, 1 pg.

Thanking you,

Yours faithfully,

Dr Anupa Siddhu
Director

Encl.: Annual Report (2016-2017), 1 pg.

Institutional Ethics Committee

Lady Irwin College

Annual Report 2016-17

The Institutional Ethics Committee had registered with the DCGI (registration number ECR/212/Indt/DL/2014) and was permitted to review and approve study protocols and related documents of bioavailability/bioequivalence studies of the approved drug molecules and also conduct ongoing review of such studies.

The Committee inducted Dr. Bhanumathi Sharma, Institutional nominee, as Member Secretary. Dr. Pulkit Mathur was accorded appreciation for her efficient and valuable management of the affairs of the committee especially in having the committee registered with the DGCI in 2014. Dr.Ravinder Chadha,was inducted as the institutional member of the Department of Food and Nutriton, in place of Dr. Pulkit Mathur.

The Institutional Ethics Committee had a total of 5 meetings in the academic year, between September 2016 and April 2017. The details of these meetings are presented below:

- 27th September 2016: 19 MSc dissertation proposals of the Department of Food and Nutrition. PhD proposals: 3
- 26th October 2016: One PhD proposal; 22 MSc dissertation proposals of the Department of Human Development and Childhood Studies, and 22 MSc proposal of the Department of Fabric and Apparel Science.
- 9th November 2016: 16 MSc dissertation proposals of the Department of Resource Management and Design Application and 19 MSc proposals of the Department of Development Communication and Extension.
- 17th January 2017: 133 B.Tech project proposals of Food Technology.
- 6th April 2017: PhD proposals, 2

The IEC gave clearance to a total of 98 M.Sc. dissertation proposals, 5 PhD proposals and 133 projects B.Tech Food Technology during the academic year 2016-2017. None of the study proposals involved clinical trials.

Prof IS Marwah
Chairperson

Bhanumathi Sharma Ph.D
Member Secretary