



सत्यमेव जयते

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: 27/06/2012

To

The Chairman
HURIP Independent Bioethics Committee
Flat No. 2B, 2nd Floor, 76/D/Ibrahimpur Road
Kolkata- 700032, West Bengal
India

Sub: - Ethics Committee Re-registration No. ECR/103/Indt/WB/2013/RR-16 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945.

Sir/Madam,

Please refer to your application submitted to this Directorate for the Re-registration of Ethics Committee.

Based on the documents submitted by you, this office hereby re-registers the HURIP INDEPENDENT BIOETHICS COMMITTEE situated at FLAT NO. 2B, 2ND FLOOR, 76/D/IBRAHIMPUR ROAD, KOLKATA- 700032, WEST BANGAL, INDIA with Re-registration Number ECR/103/Indt/WB/2013/RR-16 as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

- The re-registration shall be in force from 16.08.2016 to 15.08.2019, unless it is sooner suspended or cancelled.
- 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.
- 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.
- 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.
- 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.
- 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.

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- 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 hard and soft copies).
- 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.
- This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled.
- 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.
- 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.
- The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.
- 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.
- For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:
 - Basic medical scientist (preferably one pharmacologist)
 - Clinician
 - Legal expert
 - Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
 - Lay person from community
- 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.
- 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.
- 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.
- Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.
- This certificate is issued to you on the basis of declaration/ submission by you and that registration is sought for Independent Ethics Committee.
- 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.
- Status report of the functioning of the Ethics Committee should be submitted to the CDSCO headquarters and concerned zonal office on quarterly basis.
- 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.

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- Ethics committee should have dedicated office with required infrastructure and supporting staff. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.
- Funding mechanisms for the Ethics Committee to support their operations should be designed to ensure that the committees and their members have no financial incentive to approve or reject particular studies.
- SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.
- The Chairman of Ethics Committee shall enter into MOU with institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained as long as required.
- Ethics Committee may undertake the review and monitoring of clinical trial protocols of other investigator(s) and site(s) who do not have their IEC, subject to the condition that the other sites are within the loco- regional and community settings similar to that of the registered Ethics committee. The approving ethics committee must be willing to accept their responsibilities for the study at such trial site(s) and the trial site(s) willing to accept such an arrangement.
- Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial. The ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts where required, for deciding relatedness and compensation, as per condition no (4) mentioned above.

(Dr. V. G. Somani)
Joint Drugs Controller (I) & Licensing Authority
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi-110002

F.No.4-14/2011/BA-BE/17 (TAAB)
Directorate General of Health Services
Office of Drug Controller General (India)
(Drugs Control Section)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated

To,

M/s Taab Biostudy Services,
77/2/18/1, Bade Raipur Road,
Jadavpur, Kolkatta- 700 032

19 JAN 2016

Sub:- Renewal for Approval of Bioavailability/Bioequivalence Study Centre of M/s. Taab Bio study Services, 77/2/18/1, Bade Raipur Road, Jadavpur, Kolkatta- 700 032- regarding.

Sir,

Please refer to your application no. Nil dated 06.05.2015 vide FTS no. 25666/15 dated 15.5.2015 on the above subject.

As per documentation submitted by you, this Directorate will accept the protocol and bioavailability/ bioequivalence study reports of New Drugs from your study centre having:

- Clinical facility of 24 beds at M/s. Taab Bio study Services, 77/2/18/1, Bade Raipur Road, Jadavpur, Kolkatta- 700 032.
- Bio analytical facility at 76/D, Ibrahimpur Road, Kolkata-700032.

Subject to the following conditions:-

- The study centre should ensure that the whole Informed Consent Process should be documented through Audio- Video means maintaining the principle of confidentiality as per GSR 611(E) dated 31.07.2015.
- Specific protocol for conducting BE/BA studies with new drug formulation should be cleared by Institutional Ethics Committee and then got approved from this office on case by case basis.
- After one year there will be assessment of performance of said study centre for continued acceptance of protocol and reports in this regard.

Yours faithfully,

(Dr. S. Eswara Reddy)
Joint Drugs Controller (India)

Copy to:-

The Deputy Drugs Controller (I), Central Drugs Standard Control Organisation, (East Zone), C.G.O. Building, Nizam Place, 2nd Floor, 234/4, A.J.C. Bose Road, Kolkata-700020.