

Asian Institute of Gastroenterology

6-3-661, Somajiguda, Hyderabad - 500 082, INDIA.
Ph : 91-40-23378888 (10 lines), Fax : 91-40-23324255
Email: aigindiainfo@yahoo.co.in

ETHICS COMMITTEE

Chairman

Dr C S Bhaskaran

Retd. Director, A.P. Medical &
Health Sciences & Former VC of NTR
University of Health Sciences (A.P)

Convenor

Dr Manu Tandan

Gastroenterologist (A.I.G.)

Members

Dr D Bhaskara Reddy

Chairman, Division of Research and
Experimental Medicine

Dr D Nageshwar Reddy

Director, A.I.G.

Dr G V Rao

Director, A.I.G.

Dr P N Rao

Chief of Hepatology & Nutrition

Dr Jayanthi

J J Hospital, Hyderabad.

Dr K Anjanappa

Director - General (MGNIRSA)

Mr S A Daniel

President - Gospel Mission of India

Dr Dinesh Kumar

Asst. Director, Pharmacology
N.I.N., Hyderabad.

Mr K Suresh Reddy

Advocate, Hyderabad.

APPROVAL LETTER

Date: 29th September, 2010

Ref : Study Title : Efficacy and Safety of PEG- Interferon (Peg-
interferon Alpha 2b) for the Treatment of Chronic Hepatitis C-
An Open label, Multi Center Study in India.

Protocol No: VB021/2008

To,

Dr. P. N. Rao

Principal Investigator

Asian Institute of Gastroenterology

Hyderabad.

Dear Dr. P. N. Rao

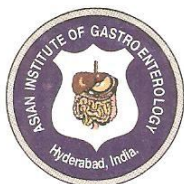
Ref : Your Letter 25/Sep/2010 Seeking Approval of IEC.

Sub : IEC Approval for the Conduct of the referenced Study
under your direction at Asian Institute of Gastroenterology

The Institutional Ethics Committee met on 25th September 2010
at 4: 00 pm in the Board room of Asian Institute of
Gastroenterology, Somajiguda, Hyderabad.

The following Members of Committee were Present during the
meeting.

1. Dr.C.S.Bhaskaran –Chairman
2. Dr.Manu Tandan- Convener
3. Dr. Jayanthi – Member
4. Mr.S.A.Daniel – Member
5. Mr.K.Suresh Reddy –Member
6. Dr.Anjanappa- Member
7. Dr.B.Dinesh Kumar –Member
8. Dr. G.V.Rao – Member
9. Dr.D.Bhaskar Reddy- Member
10. Dr.D.N.Reddy –Member



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Dr Dinesh Kumar

Asst. Director, Pharmacology
N.I.N., Hyderabad.

Mr K Suresh Reddy

Advocate, Hyderabad.

The Committee has reviewed and discussed Your Proposal to conduct the following clinical trial Protocol

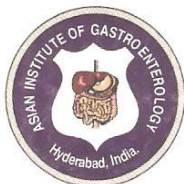
Title of the Project: Efficacy and Safety of PEG- Intron (Peg interferon Alpha 2b) for the Treatment of Chronic Hepatitis C- an Open label, Multi Center Study in India.

Protocol No: VB021/2008

Study to be Conducted at Asian Institute of Gastroenterology by Dr.P.N.Rao as a Principal Investigator and Dr. Rajesh Gupta as Co-Investigator

The Following Documents were reviewed:

S.No	Documents	Version no& Dated
1	Principal Investigator	-----
2	Clinical Trail Protocol	Version No .2 dated 15 th April 2009
3	Investigator Boucher	Version No. 1 Dated 01 November 2008
4	Informed Consent Form – English	Version No. 2, Dated 15 th April 2009
5	Informed Consent Form – Telugu	Version No. 2, Dated 15 th April 2009
6	Informed Consent Form – Hindi	Version No. 2, Dated 15 th April 2009
7	Informed Consent Form – Urdu	Version No. 2, Dated 15 th April 2009
8	Informed Consent Form _ Back Translation _ Hindi to English	Version 2, 15 th April 2009
9	Informed Consent Form _ Back Translation _ Urdu to English	Version 2, 15 th April 2009
10	Case Report Form	Version 2 Dated 15 th April 2009
11	DCGI Approval Letter	-----
12	Draft Clinical Trail Agreement	-----
13	Insurance Certificate	-----
14	Principla Investigator CV	-----



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Gastroenterologist (A.I.G.)

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Director, A.I.G.

Dr G V Rao

Director, A.I.G.

Dr P N Rao

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Director - General (MGNIRSA)

Mr S A Daniel

President - Gospel Mission of India

Dr Dinesh Kumar

Asst. Director, Pharmacology
N.I.N., Hyderabad.

Mr K Suresh Reddy

Advocate, Hyderabad.

Resolution:

The Committee after critical review and discussion of the documents approved the above clinical trial with suggestion to closely monitor the subjects especially for adverse events.

Further the Board made the following Observations:

1. The Investigator is further requested to follow the ethical Aspects of the clinical trial as described in the booklet "Ethical Guidelines for Biochemical Research on Human Subjects" Published by Indian Council of Medical Research New Delhi".
2. No Biological Sample collected from the Subject in the study shall be sent overseas for any purpose without the necessary permission from the appropriate authorities of Govt. of India. The Investigator shall ensure that this Condition is fulfilled and when required and the same to be informed to the IEC by the investigator.
3. The investigator shall communicate any Adverse events occurring at his/her investigational site or other SAE's brought to his/her notice by the sponsor during the course of the study to the IEC immediately.
4. The IEC shall review the Progress of the Study after 3 months and the completion report at the end of the Clinical trial.

Yours Sincerely

Manu Tandan
Dr. Manu Tandan
Convener

Ethics Committee

Asian Institute of Gastroenterology
Somajiguda, Hyderabad- 500082

ETHICS COMMITTEE

AADHYA INDEPENDENT ETHICS COMMITTEE
First Floor, Alka Hospital, 14- A, Vasant Vihar Society,
Opp. Helmet House, Nr. Mithakhali Six Roads, Navrangpura,
Ahmedabad, Gujarat -380009, India
Tel: 079- 26425065

Date: 04 June 2011

To,
Dr. Hasmukh B. Vora
Alka Hospital, 14/A, Vasant Vihar Society,
Opp Helmet House, Nr. Mithakhali Six Road,
Navrangpura, Ahmedabad- 380009.
Gujarat, India

Study Code: VB021/2008

REF: Efficacy and safety of PEG-Inferon (peg interferon alpha-2b) for the treatment of chronic hepatitis C- An open-label study in India.

Subject: Approval of Protocol VB021/2008

Dear Dr. Hasmukh Vora,

On, 4th Jun 2011, the Aadhya Independent Ethics Committee met, reviewed and discussed your application to conduct the clinical trials entitled

"Efficacy and safety of PEG-Inferon (peg interferon alpha-2b) for the treatment of chronic hepatitis C- An open-label study in India.

The following documents were reviewed during the meeting:

S. No	Document	Version No. & date
1	Protocol Synopsis	Version Number: 2; dated 15 th April, 2009
2	Protocol	Version Number: 2; dated 15 th April, 2009
3	Investigator Brochure	Version Number:1 ; dated 1 st November ,2008
4	Information to Patients, Patient Consent Form(English, Hindi, Gujarati)	Version Number: 2; dated 15 th April, 2009
5	Case Report Form	Version no.2; dated 15 th April, 2009
6	Insurance Certificate	Expiry on 13-04-2012
7	DCGI Approval Letter	Dated 11 th Feb 2010


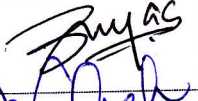
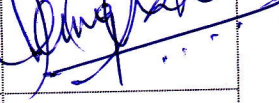
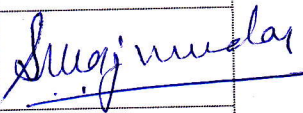
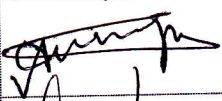
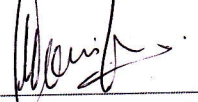

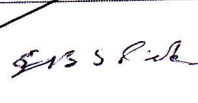
During meeting, the EC decided to approve the conduct of the above trial in its presented form.

AADHYA INDEPENDENT ETHICS COMMITTEE
First Floor, Alka Hospital, 14- A, Vasant Vihar Society,
Opp. Helmet House, Nr. Mithakhali Six Roads, Navrangpura,
Ahmedabad, Gujarat -380009, India
Tel: 079- 26425065

Venue: Alka Hospital, Ahmedabad

Time: 15: 30

The following members of the Ethics Committee who have signed were present and voted in the meeting and were involved in the approval process:

Member name	Degree (Qualification)	Sex	Designation in the committee	Signature
Dr. Mukulkumar Oza	M.D. (Medicine)	M	Chairperson	
Dr. Bhavesh Vyas	M.D. Pharmacology	M	Member Secretary	
Dr. Devang Shah	M.D. (Medicine)	M	Clinicians from various Institutes	
Dr. Paresh D Shah	MS (Ortho)	M	Clinicians from various Institutes	
Prof Sumant K Majmudar	MSW, MS	M	Philosopher	
Mr. Mayursinh Thakore	B.com., LLB	M	Advocate	
Ms. Monica Tariyal	MSc	F	Social Scientist	
Mr. Farshubhai Kakkad	B.Com	M	Lay person/Non scientific person from the community	
Mr. Shivabhai B Solanki	B.Sc. (Agri)	M	Lay person/Non scientific person from the community	

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First Floor, Alka Hospital, 14- A, Vasant Vihar Society,
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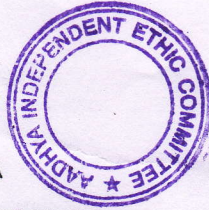
It is also confirmed that neither you nor any of the study team members participated in the voting procedures.

You are requested to report to the Ethics committee during the study:

- All deviations from, or changes of, the protocol to eliminate immediate hazards to the study subjects
- Changes that increase the risk to participating subjects and/or those that significantly affect the conduct of the studies.
- All serious adverse events.
- New information that may affect adversely the safety of the subjects or the conduct of the studies
- Any changes in the study documents

Yours sincerely,

Smayas
10/6/11



Member Secretary/ Chairperson,
Aadhya Independent Ethics Committee
First floor, 14/A, Alka Hospital,
Vasant Vihar Society. Opp Helmet House,
Nr. Mithakhali Six Roads, Navrangpura,
Ahmedabad-380009.
Gujarat, India

**AADHYA INDEPENDENT
ETHIC COMMITTEE**
1st Floor, Alka Hospital,
14-A, Vasant Vihar Society,
Opp. Helmet House,
Nr. Mithakhali Six Roads,
Navrangpura, Ahmedabad-380009,
Tel. : 079-26425065



Independent Ethics Committee-Aditya

ACEASTM Clinical Research

001, Aradhya Apartments, Behind Hero-Honda Show Room, Under New Shreyas Fly Over, Ambawadi, Ahmedabad 380 015. India.
Telephones : +91 79 26460930, Mobile : +91 93280 18777 / 9327924927, Email : aceas@rediffmail.com • www.aceas.co.in

Dr. Manoj Kumar Agarwal
Belle Vue Clinic
9, Dr. U.N. Brahmachari Street, (Formerly Loudon Street)
KOLKATA 700 017

01-November-2010

Dear Dr. Agarwal,

Subject: Review and approval of clinical study No. : VB021/2008, Protocol Version 2, Dated 15-April-2009, titled "Efficacy and safety of PEG-Inferon (Peginterferon alpha-2b) for the treatment of chronic hepatitis C – An open label study in India"

This has reference to your letter for approval of the protocol and other related documents of the above clinical study, being sponsored and organized by M/s. Virchow Biotech Private Limited, Plot No. 4, S.V. Co-operative Industrial Estate, IDA, Jeedimetla, HYDERABAD 500 055.

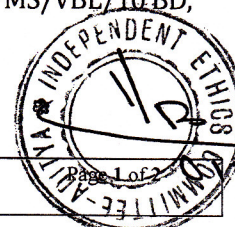
Independent Ethics Committee-Aditya (IEC-Aditya) has reviewed the protocol and other necessary documents of the above clinical study in its meeting held on Monday, 01-November-2010, in which the following members were present :

1	Dr. A.K. Batham
2	Dr. Jayesh V. Trivedi
3	Dr. V.M. Khandhar
4	Mrs. Sanchita Mitra

5	Dr. J.P. Joshipura
6	Dr. S.D. Biswas
7	Mr. Rajendra D. Rajput

Following documents have been reviewed :

- Protocol for the study Code : VB021/2008, Version No. 2, dated 15-April-2009
- Case Report Form, Version No. 2, dated 15-April-2010
- Information to Patients and Patient's Consent Form in English, Version No. 2, Dated 15-April-2009
- Investigator's Brochure, Version Number 1, Dated 01-November-2008
- Investigator's Undertaking, dated 19-August-2010
- Investigator's CV, dated 19-August-2010
- Copy of regulatory permission/no-objection from the office of the Drugs Controller General (India), New Delhi, to conduct the study, letter no. F.No. 2/PMS/VBL/10 BD, dated 11-February-2010



Nov. 10



Independent Ethics Committee-Aditya

ACEASTM Clinical Research

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Telephones : +91 79 26460930, Mobile : +91 93280 18777 / 9327924927, Email : aceas@rediffmail.com • www.aceas.co.in

- viii. Liability Insurance Certificate No. 612200/36/10/61/00000009 for the Period 14/04/2010 to 13/04/2011

Copy of the votes of the members of the IEC-Aditya who participated in the meeting are attached herewith for confirmation and record. Based on the favorable opinion given by all the 7 out of 7 members who participated in the meeting, Independent Ethics Committee – Aditya is pleased to grant approval to the conduct of the reviewed clinical study by you at Belle Vue Clinic, 9, Dr. U.N. Brahmachari Street, (Formerly Loudon Street), KOLKATA B700 017, subject to the following conditions:

- i. you will conduct the clinical study in full compliance to the regulatory and ethical requirements adhering to the Good Clinical Practice guidelines
- ii. the IEC-Aditya shall do a continuing review of the progress of the trial for which you shall provide periodic clinical updates on the progress of the study,
- iii. the IEC-Aditya shall provide, according to the applicable regulatory requirements, expedited review and approval/favorable opinion on minor change(s) in the trial during the course of its conduct, if required,
- iv. that no deviations from, or changes of, the protocol would be initiated without prior written IEC-Aditya approval/favorable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of monitor(s), telephone number(s))
- v. that you would promptly report to the IEC-Aditya: (a) deviations from, or changes made in, the protocol to eliminate immediate hazards to the trial subjects, (b) changes increasing the risk to subjects and/or affecting significantly the conduct of the trial, (c) all adverse events including, serious and unexpected, and (d) new information that may adversely affect the safety of the subjects or the conduct of the trial, and
- vi. that the IEC-Aditya would promptly notify in writing the investigator/institution concerning: (a) its trial-related decisions/opinions, (b) the reasons for its decisions/opinions, and (c) procedures for appeal on its decisions/opinions.

Best regards,

A. K. Batham, M.D.,
Chairman,
Independent Ethics Committee-Aditya

001, Aradhya Apartments,
Behind Hero-Honda Show Room,
Under New Shreyas Fly Over,
Ambawadi, Ahmedabad-380015. India



Independent Ethics Committee-Aditya

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VOTING SHEET

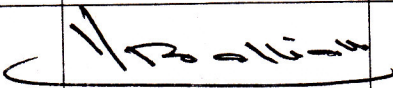

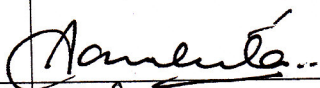
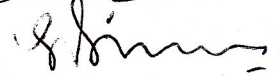
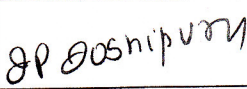
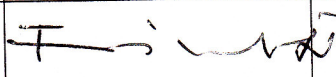

Virchow Biotech Private Limited, Hyderabad 500 055

30-October-2010, Time: 06:30 pm

Study Code : VB021/2008, Protocol Version 2, Dated 15-April-2009

Clinical Study : Efficacy and safety of PEG-Inferon (Peginterferon alpha-2b) for the treatment of chronic hepatitis C – An open label study in India

Clinical Investigator : Dr. Manoj Kumar Agarwal, Belle Vue Clinic, 9, Dr. U.N. Brahmachari Street, (Formerly Loudon Street), KOLKATA 700 017

No.	Member	Approvable	Non-approvable	Modifications required for approval
1	Dr. A.K. Batham		-	-
2	Dr. Vinod M. Khandhar		-	-
3	Mrs. Sanchita Mitra		-	-
4	Dr. Swapna D.Biswas		-	-
5	Dr. Jagdish. P. Joshipura		-	-
6	Dr. Jayesh V. Trivedi		-	-
7	Mr. Rajendra D. Rajput		-	-



COSMOPOLITAN HOSPITALS (P) Ltd.

PATTOM, THIRUVANANTHAPURAM - 695 004
Phone : 91-471-2521252 (20 lines), Fax : 91-471-2449188

RESOLUTION PASSED BY HOSPITAL ETHICAL COMMITTEE

The Institutional Ethical Committee of Cosmopolitan Hospitals Pvt Ltd held at 4 p.m. on 11th September 2010 in the Board Room of Cosmopolitan Hospitals Pvt. Limited, Thiruvananthapuram resolved as follows: (the list of members present in the meeting is attached)

1. After the presentation of Dr. Jacob Philip on the Phase IV Clinical Trial, Protocol entitled "Efficacy and safety of PEG Inferon (peg interferon alpha-2b), it was decided to approve the study.
2. The Protocol of the study was also approved.
3. The informed consent form was approved; it was suggested to have Malayalam and Tamil translation of the consent form.
4. Dr. Jacob Philip was requested to apprise the member Secretary of the Committee the progress of the project once in 3 months. If it becomes necessary, the Ethical Committee will be reconvened to decide further course of action.
5. The member Secretary is authorized to communicate the decision to the Sponsors M/s.Virchow Biotech Private Ltd., Hyderabad (ii) to Dr.Jacob Philip and (3) to the Administrator, Cosmopolitan Hospitals Pvt Ltd.

Dr. P Ravindran
Member Secretary
Hospital Ethical Committee

13th September 2010

ATTENDANCE SHEET.

Mr.. Mohankumar

Dr. P. Ravindran

Mr. B. Raghunathan

Fr. George John

Mr. Prasanth

Mr. Abdul Salam

Dr. P.P.Joseph

Dr.Retnavally

Dr. Vijayakrishnan

INVITTEES.

Dr. Jacob Philip

Mr. N.K. Subash

Mr. S. Reghunathan Nair

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No: 04425305301

Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. Narayanasamy, MD. DM.,
Professor & HOD
Department of Hepatology
Madras Medical College /GGH , Chennai -3

Dear Dr. Narayanasamy, MD. DM.,

The Institutional Ethics Committee of Madras Medical College reviewed and discussed your application for approval of the clinical trial entitled " Efficacy and Safety of PEG Interferon (peg interferon alpha 2b) for the treatment of Chronic Hepatitis C- an Open label, Multicentre Study in India" No. 25022011.

The following members of Ethics Committee were present in the meeting held on 17.02.2011 conducted at Madras Medical College, Chennai -3.

- | | |
|---|--------------------|
| 1. Prof. S.K. Rajan, MD | - Chairperson |
| 2. Prof. A. Sundaram, MD
Dean i/c , Madras Medical College, Chennai -3 | - Member Secretary |
| 3. Prof R. Sathianathan
Director , Institute of Psychiatry, MMC,Ch-3 | - Member |
| 4. Prof R. Nandhini, MD
Director, Institute of Pharmacology, MMC, Ch-3 | - Member |
| 5. Prof. Pregna B. Dolia MD
Director , Institute of Biochemistry, MMC, Ch-3 | - Member |
| 6. Prof. C. Rajendiran .MD
Director , Institute of Internal Medicine, MMC, Ch-3 | - Member |
| 7. Prof. Geetha Subramanian, MD,DM
Prof. & Head , Dept. of Cardiology, MMC, Ch-3 | - Member |
| 8. Thiru. A. Ulaganathan
Administrative Officer, MMC, Chennai -3 | - Layperson |
| 9. Thiru. S. Govindasamy . BA.BL | - Lawyer |
| 10. Tmt. Arnold Soulina | - Social Scientist |

We approve the trial to be conducted in its presented form subject to approval from the Director of Medical Education and on payment of 5% of actual cost involved.

Sd / . Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report


Member Secretary, Ethics Committee



INSTITUTIONAL ETHICS COMMITTEE (IEC)

GLOBAL HOSPITALS AND HEALTH CITY

Ref: CR/Drug/007-01

13 January 2011

To

Dr. Joy Varghese
Principal Investigator
Senior Consultant - Hepatology & Transplantation
Global Hospitals and Health City
Chennai 600 100

Ref: Clinical trial protocol Peginterferon alpha-2b, Study code: VB021/2008, Efficacy and safety of PEG-Inferon (Peginterferon alpha-2b) for treatment of chronic hepatitis C – An open lable, multicentre study in India”

Sub: Institutional Ethics Committee Approval

Dear Dr. Joy Varghese

The Institutional Ethics Committee, Global Hospitals and Health City, Chennai, reviewed and discussed your application dated 03rd January 2011 to conduct the clinical trial entitled “Clinical trial protocol Peginterferon alpha-2b, Study code: VB021/2008, Efficacy and safety of PEG-Inferon (Peginterferon alpha-2b) for treatment of chronic hepatitis C – An open lable, multicentre study in India” on 13th January 2011.

The following documents were reviewed and approved:

1. DCGI Approval Letter; Dated 11-Feb-2010
2. Insurance Certificate; Expiry on 13-Apr-2011
3. Investigator Brochure; Version Number: 1 dated 01-Nov-2008
4. Protocol; Version Number: 2; Dated 15-Apr-2009
5. Case Report Form; Version Number: 2; Dated 15-Apr-2009

Institutional Ethics Committee – Global Hospitals and Health City, Chennai
Tel: +91 44 2277 7000, Extn: 3033

Page 1 of 3

Global Hospitals & Health City, #439, Cheran Nagar, Off OMR,
Sholinganallur-Medavakkam Road, Perumbakkam, Chennai - 600 100
Ph.: +91 44 2277 7000 / 2277 2234 / 2277 7777 / 4477 7000 Fax: +91 44 2277 7100
A Unit of Ravindranath GE Medical Associates Pvt. Ltd.
Email: info@globalhealthcity.net www.globalhospitalsindia.com

Chennai | Bangalore | Hyderabad | Mumbai | Kolkata | Bhubaneshwar

Emergency ☎ : 24 24 24 24



6. Information to Patients, Patient Consent Form (English); Version Number: 2, Dated 15-Apr-2009

The following members of the Institutional Ethics Committee were present at the meeting held on 08th October 2010.

S.NO.	NAME OF THE MEMBER	ROLE IN IEC
1	Mr. M. Leon Raymont	Chairperson
2	Dr. C. Emmanuel	Member Secretary
3	Dr. V. Kanagaraj	Clinician
4	Dr. I. A. Ranjit Kumar	BioMedical Scientist
5	Dr. P. P. Vijaya	BioMedical Scientist
6	Rev. Dr. Ignacimuthu	Philosopher
7	Mrs. Latha A. Kumaraswami	Lay Person
8	Mr. P. Kandasamy	Lay Person
9	Dr. J.K.B.C. Parthiban	Medical Expert
10	Dr. S. Dinesh Nayak	Medical Expert

The study was unanimously approved by all the members, who were present.

We confirm that principal investigator and his study team members did not participate in the deliberations of the ethics committee for this study and did not vote on the proposal for this study.

Please note that you should follow the requirements given below for this study:

- Do not implement any deviation from, or change to, the protocol approved by the IEC without the prior written approval of this Institutional Ethics Committee. Deviations/ changes to the approved protocol may be implemented without prior approval of this Institutional Ethics Committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone number(s)]

Institutional Ethics Committee – Global Hospitals and Health City, Chennai
Tel: +91 44 2277 7000, Extn: 3033

Page 2 of 3

**Global Hospitals & Health City, #439, Cheran Nagar, Off OMR,
Sholinganallur-Medavakkam Road, Perumbakkam, Chennai - 600 100**
Ph.: +91 44 2277 7000 / 2277 2234 / 2277 7777 / 4477 7000 Fax: +91 44 2277 7100
A Unit of Ravindranath GE Medical Associates Pvt. Ltd.
Email: info@globalhealthcity.net www.globalhospitalsindia.com
Chennai | Bangalore | Hyderabad | Mumbai | Kolkata | Bhubaneswar

Emergency ☎ : 24 24 24 24



Promptly report to the Institutional Ethics Committee:

- Any changes to or deviations to the protocol approved by this ethics committee that you may implement to eliminate hazards to the trial subjects
- All serious adverse events
- New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit to the IEC, the status report of the study at every 3 months interval. Please provide a close out report to the Institutional Ethics Committee on the completion of the study.

The IEC is organized and operates according to the requirements of ICH – GCP and requirements of the Indian Council of medical Research (ICMR) and Schedule Y.

Thank you for your time and efforts.

Cordially

Mr. M. Leon Raymont
Chairperson
Institutional Ethics Committee
Global Hospitals and Health City
Chennai 600 100



Dr. C. Emmanuel
Member Secretary
Institutional Ethics Committee
Global Hospitals and Health City
Chennai 600 100

Institutional Ethics Committee – Global Hospitals and Health City, Chennai
Tel: +91 44 2277 7000, Extn: 3033

Page 3 of 3

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Emergency ☎ : 24 24 24 24

Institute of Post Graduate Medical Education & Research
244, Acharya J. C. Bose Road, Kolkata – 700020
IPGME&R Research Oversight Committee

Memo No. Inst/IEC/ 1136

Date: 11.04.2011

Prof. Abhijit Chowdhury
Head – School of Digestive & Liver Diseases
Institute of Post Graduate Medical
Education & Research (IPGME&R)
Kolkata – 700020

A meeting of the Institutional Ethics Committee of IPGME&R, Kolkata was held on April 2, 2011 at 12:00 noon. In this meeting the members reviewed the protocol of your project (Protocol No. VB021/2008 (Study Code) dated Nil.) titled:

Efficacy and safety of PEG-INFERON (peg-interferon alpha-2b) for the treatment of chronic hepatitis C – an open-label study in India.

The following additional documents were reviewed (applicable ones are checked):

- ☒ Informed consent document and form in English.
- ☒ Informed consent document and form in Hindi.
- ☒ Informed consent document and form in local language (Bengali).
- ☒ Case report form.
- ☒ Investigator's brochure.
- ☒ Letter of approval from Drugs Controller General of India.
- ☐ Others _____

After deliberations and review the committee unanimously took the following decision regarding your project:

☒ Approved ☐ Disapproved ☐ Resubmit after modification ☐ Decision pending

The list of members present are appended to this page.

Additional points, if any, mentioned on Page 2 are to be noted.

Arjit Hazra

Member-Secretary
IPGME&R Research Oversight Committee

Member - Secretary
INSTITUTIONAL ETHICS COMMITTEE
Institute of Post Graduate Medical Education
& Research, Kol-20

Continued on Page 2

Continued from Page 1

<input checked="" type="checkbox"/> Additional points to be noted	A brief project completion report is to be submitted to the IPGME&R Research Oversight Committee. If the duration of the project exceeds 1 year from commencement, a brief annual progress report should also be submitted.
<input type="checkbox"/> Reasons for disapproval	
<input type="checkbox"/> Modifications suggested	
<input type="checkbox"/> Reasons for decision pending	

List of institutional ethics committee members who attended the meeting on 02.04.2011

SN	Name	Gender	Designation
1	Prof. Subir Kumar Dutta [Chairperson]	Male	Ex-Dean of Faculty of Medicine, University of Calcutta & Retired Professor of Pathology
2	Dr. Nabanita Bhattacharya	Female	Ex-Associate Professor – Department of Community Medicine, IPGME&R
3	Prof. Jayanta Chatterjee	Male	HOD – Department of NEMS, IPGME&R
4	Prof. Bijoy Kumar Majumdar	Male	HOD – Department of Plastic Surgery, IPGME&R
5	Prof. Krishnendu Mukherjee	Male	HOD – Department of Pathology, IPGME&R
6	Prof. Amal Santra	Male	Scientist – Department of Gastroenterology, IPGME&R
7	Shri Kajal Kumar Das	Male	Advocate, Calcutta High Court
8	Dr. Avijit Hazra [Member Secretary]	Male	Associate Professor – Dept. of Pharmacology, IPGME&R

Avijit Hazra
11/04/2011

Member-Secretary

IPGME&R Research Oversight Committee

Member - Secretary
INSTITUTIONAL ETHICS COMMITTEE
Institute of Post Graduate Medical Education
& Research, Kol-20

Date: 14/09/2010

To,
Dr. Abraham Koshy
Lakeshore Hospital
NH-47 Bypass
Maradu, Metoor
Kochi-682304
Kerala- India

Ref: Protocol title: Protocol No- VB021/2008: Efficacy and safety of PEG-Inferon (peginterferon alpha-2B) for the treatment of chronic hepatitis C- An open-label, multicentric study in India

Subject: Approval of the study documents and the conduct of the referenced study at our institution.

Dear Dr. Koshy,
We have received from you 09 copies of the following study-related documents

1. Investigators Brochure Edition version 1.0 dated 01 Nov 2008
2. Clinical Protocol Version 2.0 dated 15 April 2009
3. Information to Patients, Patient consent form(English & Hindi) version 2.0 dated 15 april 2009
4. Case Report Form version 2.0 dated 15 April 2009
5. Insurance certificate Expiry on 13 April 2011
6. DCGI approval letter dated 11 February 2010

At the Ethics Committee meeting held on 14/Sep/2010, these document were examined and discussed. After due consideration, the Committee has decided to approve the conduct of the study and the submitted documents.

Any Serious Adverse Event that occurs during the conduct of the study at Lakeshore Hospital NH-47 Bypass, Maradu, Netoor, Kochi-682304, Kerala- India should be reported to the Ethics Committee.

We also require that a report of the study be sent to us, the Ethics Committee.

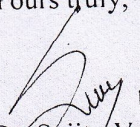


Lakeshore
Hospital & Research Centre Ltd.

NH-47 By-pass, Maradu, Nettoor P.O., Kochi - 682 040, Kerala, India. Tel : 91 - 484 - 2701032/33
Fax : 2701996 E-mail : info@lakeshorehospital.com Web : www.lakeshorehospital.com

It is hereby confirmed that neither you nor, any of the study team members have participated in the voting/decision making procedures of the committee.

Yours truly,


14/09/2010
Dr. Sujit Vasudevan
Chairman/ Ethics Committee



14/09/2010
Date: 13/09/2010

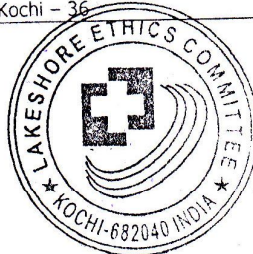


Lakeshore
Hospital & Research Centre Ltd.

NH-47 By-pass, Maradu, Nettoor P.O., Kochi - 682 040, Kerala, India. Tel : 91 - 484 - 2701032/33
Fax : 2701996 E-mail : info@lakeshorehospital.com Web : www.lakeshorehospital.com

The members who attended the meeting held on 14th September 2010
at 6:30 pm at the Lakeshore Hospital Board Room wherein
your proposal was discussed are listed below:

Name	Title	Affiliation (Name of Institute/Organization or None)	Signature	Voting during this meeting	Member of the Study Team
Dr. Sujit Vasudevan	Chairman	Consultant Physician Ojus Clinic & Nursing Home Mullassery Canal Road Cochin - 35		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Dr. Thomas Thachil	Secretary	Medical Superintendent & Consultant Urologist & Andrologist Lakeshore Hospital Kochi		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Dr. Philip Augustine	Member	Managing Director & Medical Director Lakeshore Hospital Kochi		Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Dr. H Ramesh	Member	Chief Surgeon G I Surgery Department Lakeshore Hospital Kochi	Absent	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Dr. Abraham Koshy	Member	Director - Division of Hepatology, Digestive Diseases Centre & Director of Research Lakeshore Hospital, Kochi		Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Dr. V P Gangadharan	Member	Consultant Oncologist Lakeshore Hospital Kochi		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Rev. Fr. Cyriac Muricken	Member	Theologist St. Sebastian's Carmel House Kottarappilly, T.V. Puram P.O Vaikom - 686606		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Mrs. Sumathi Dhandapani	Member	Sr. Advocate, Kerala High Court Tripphi T D Road, North End Kochi - 682 035		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Mr. Sunder Rajagopal	Member	Lay Person Ceramic Designs, HIG 20, Panampilli Nagar, Kochi - 36		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>



● Mahalasa Independent Ethics Committee. ●

CHAIRMAN,

- Dr. N. Y. Kazi
- M. D.,
- Consulting Physician,
- Jehangir Nursing Home, Pune.

- SECRETARY,

- Mr. Rajendra Kotnis
- L. M. E.,

MIEC/04-11/157

19th April 2011

To,
Dr. Nitin V. Pai,
Pai Clinic & Diagnostic Center,
778/B-1, Abhinav Apts.,
Shivajinagar, Pune 411 005.

Dear Dr. Nitin Pai,

This has reference to the proposed clinical trial on "Efficacy and Safety of PEG-Inferon (peginterferon alpha-2b) for the treatment of chronic hepatitis C - An open-label study in India" (Virchow Biotech Pvt. Ltd.)

Project No.MIEC/Proj/02-11/038.

The Protocol was reviewed by the members at the meeting held on 19th March 2011 at 3.00pm.at the committee office.

The following study-related documents were reviewed:

Sr. no	Document	Version No. & date
1	Protocol Synopsis	Version Number:2; dated 15 th April, 2009
2	Protocol	Version Number:2; dated 15 th April, 2009
3	Investigator Brochure	Version Number:1; dated 1 st November, 2008
4	Information to patients, Patient Consent Form(English, Marathi & Hindi)	Version Number:2; dated 15 th April, 2009
5	Case Report Form	Version Number:2; dated 15 th April, 2009
6	Insurance Certificate	Expiry on 13-04-2011
7	DCGI approval letter	Dated 11 th Feb 2010
8	CTRI Registration Number	
9	CTAg Draft	

The following members were present in the meeting:

Names of members	Role in the EC	Designations	Gender
1. Dr. N.Y. Kazi	Clinician	Chairman	Male
2. Dr. V.S.Padbidri	Basic Scientist/Philosopher	Member	Male
3. Dr. D.D.Shetty	Cinician	Member	Male
4. Dr. Kalpana U. Shah	Pharmacologist	Member	Female
5. Mrs. Perveen Bharucha	Social Worker	Member	Female
6. Mrs. Anita S. Pawar	Legal Expert	Member	Female
7. Dr. Vikas G. Pai	Clinician	Member	Male
8. Mr. R.G.Kotnis	Lay Person	Member Secretary	Male

● Mahalasa Independent Ethics Committee. ●

- CHAIRMAN,

● **N. Y. Kazi**

- M. D.,
- Consulting Physician,
- Jehangir Nursing Home, Pune.

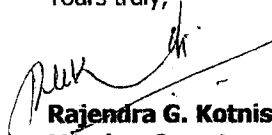
- SECRETARY,

● **Mr. Rajendra Kotnis**

- L. M. E.,

We have received the clarifications regarding the queries raised vide your letter dt. 6th April 2011. The Ethics Committee in view of the above grants a final approval for conducting the trial as per the documents submitted. The committee should be kept informed about any amendments in the protocol, receive periodical progress reports and be given a copy of the final report. Please note, one of the members, Dr. Vikas G. Pai being related to the PI did not participate in the process of decision making. It is compulsory to register the trial under "Clinical trial Registry of India"

Thanking you,
Yours truly,



Rajendra G. Kotnis
Member Secretary



Peerless Hospital & B. K. Roy Research Centre

(A Unit of Peerless Hospitex Hospital and Research Center Limited)

Date April 13, 2011

Dr. Ashokananda Konar
Sr. Gastroenterologist
Dept. of Gastroenterology,
Peerless Hospital & B K Roy Research Centre,
360, Panchasayar,
Kolkata – 700 094

Dear Dr. Konar,

Thank you very much for your presentation on clinical trial for “Efficacy and safety of PEG-Inferon (peginterferon alpha-2b) for the treatment of chronic hepatitis C – An open-label, multicentre study in India” which we have reviewed thoroughly in the institutional Ethical Committee of Peerless Hospital & B K Roy Research Centre in the meeting held at Peerless Hospital & B K Roy Research Centre on 5th January, 2011 and 11th April, 2011 respectively.

Members present in the said Ethical Committee meeting have unanimously agreed and suggested to reconsider the following points;

- The Ethical Committee discusses all the ethical issues of the project proposal of Dr. A. Konar (Safety and Efficacy of PEG-Interferon) and appreciating the urgency of the study (as presented by the Principal Investigator) has given their PROVISIONAL CLEARANCE for the study subject to approval of the Informed Consent by the Sponsorers containing the necessary criteriae as mentioned by Ethical Committee in the previous meeting, held on January 05, 2011.

As soon as you get the modification of the above point, please let us know for further proceedings.

Thanking you,

Yours faithfully,

Dr. Amitava Sarkar
Chairman, Ethical Committee
Peerless Hospital & B K Roy Research Centre



Peerless Hospital & B. K. Roy Research Centre

(A Unit of Peerless Hospitex Hospital and Research Center Limited)

Dr. Ashokananda Konar
Sr. Gastroenterologist
Dept. of Gastroenterology,
Peerless Hospital & B K Roy Research Centre,
360, Panchasayar,
Kolkata - 700 094

Date : January 11, 2011

Dear Dr. Konar,

Thank you very much for your presentation on clinical trial for "Efficacy and safety of PEG-Inferon (peginterferon alpha-2b) for the treatment of chronic hepatitis C – An open-label, multicentre study in India" which we have reviewed thoroughly in the institutional Ethical Committee of Peerless Hospital & B K Roy Research Centre in the meeting held at Peerless Hospital & B K Roy Research Centre on 5th January, 2011.

Members present in the said Ethical Committee meeting have unanimously agreed and suggested to reconsider the following points;

- Reimbursement of travel expenses should be provided to all the patients with one attendant, if needed, for traveling to and from the hospital for the study, which will be borne by the sponsor company.
- The patients should be given further treatments and/or rehabilitation (if necessary) if any damage / complications / adverse effect ~~causes to~~ arises affecting the patients, due to the study.
- Consent form should also be printed in Bengali language along with English and Hindi.
- In the consent form there should be a clear indication that damage caused by this trial should be covered by the Insurance Company i.e. the New India Assurance company Limited.
- The patients taking part in the study should be clearly informed as to how they will get benefit in future course if they have to receive the same medication in future.
- Regarding compensations for any damage due to the study, the consent form should clearly mention that Peerless Hospital & B K Roy Research Centre shall not be held liable for any compensation if any question arises and it has no role in the study. The sponsor shall keep the patient indemnified against all damage, if any, caused to the patient through insurance coverage under The New India Assurance Company Limited as per their terms and conditions..
- Patient should be given sufficient and reasonable time to examine all the papers and other factors which he/she may consider necessary before giving consent to the study for the purpose and time should also be given to enable the patient to consult with others before giving consent.

As soon as you get the modification of the above points, please let us know for further proceedings.

Thanking you,

Yours faithfully,

Dr. Amitava Sarkar
Chairman, Ethical Committee
Peerless Hospital & B K Roy Research Centre



Sanjay Gandhi Postgraduate Institute of Medical Sciences

Raebareli Road, Lucknow – 226014, India

Dr. Subhash B. Yadav

Associate Professor (Endocrinology) and
Member Secretary, Institute Ethics Committee

PGI/BE/022/2011

Dated: 14.2.2011

To,
Prof. G. Chaudhury
P I, Department of Gastroenterology
SGPGIMS, Lko

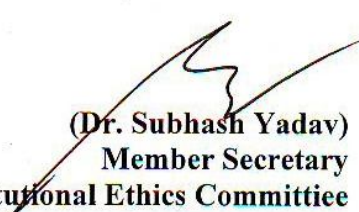
Sub: Research Protocol No.: A17: PGI/DT/IEC/52/19/11/2010

Dear Sir,

The clarifications submitted by you regarding the Research Protocol entitled "Efficacy & safety of PEG ----- Treatment of chronic hepatitis C: An open label study in India" were reviewed by the three member committee. After due deliberation committee decided that:

"The above Research Protocol presented in the 52nd Ethics Committee Meeting may be cleared from Ethical Point of view"

This is for your information and necessary action.


(Dr. Subhash Yadav)
Member Secretary
Institutional Ethics Committee



HUMAN ETHICAL COMMITTEE

MEDICAL COLLEGE, THIRUVANANTHAPURAM

(Constituted as per order No. G1/14540/06 MCT Dated 03-07-2006)

IEC. No.01/33/2011/MCT.

14/1/2011.

**Communication of Decision of the Institutional Ethics Committee (IEC)/
Institutional Review Board (IRB)**

Protocol Title: " Efficacy and Safety of Peg-Inferon (peginterferon Alpha-2b) for the Treatment of Chronic Hepatitis C "		
Principle Investigator : Dr. Premaletha. N		
Name & Address of Institution: Department of Gastroenterology, Medical college, Trivandrum.		
<input checked="" type="checkbox"/> New review	<input type="checkbox"/> Revised review	<input type="checkbox"/> Expedited review
Date of review (D/M/Y): 14/01/2011.		
Date of previous review, if revised application:		
Decision of the IEC/IRB:		
<input checked="" type="checkbox"/> Recommended	<input type="checkbox"/> Recommended with suggestions	
<input type="checkbox"/> Revision	<input type="checkbox"/> Rejected	
Suggestions/Reasons/Remarks:		
Recommended for a period of study : 1 Year.		

Please note*

- Inform IEC/IRB immediately in case of any Adverse events and Serious adverse events
- Inform IEC/IRB in case of any change of study procedure, site and Investigator
- This permission is only for period mentioned above. Annual report to be submitted to IEC/IRB.
- Members of IEC/IRB have right to monitor the trial with prior intimation.



Reneega

Signature of Member Secretary
IEC/IRB

Address for correspondence Member Secretary, Human Ethical Committee,
Department of Pharmacology, Medical College, Thiruvananthapuram - 695 011, India
Telephone : 91 - 471 - 2528378