Copy of Ethics Committee's Approvals

Hetal Shah

L M College of Pharmacy, Ahmedabad, India
Dr. Keyur Parikh,
Principal Investigator,
45, World Business House,
Nr. Parimal Garden,
Ahmedabad.

Sub: Neovasc Reducer Pilot Study : Clinical Trial Protocol :
Protocol No : NPSE002 Rev 03

With reference to your letter dt. 11/01/05 on the above subject, we are pleased to inform you that the Ethics Committee in its meeting held on 15th January, 2005 has approved the study at SAL Hospital subject to the following terms & conditions:

1. Adverse effect of the drug would immediately be brought to the notice of the Ethics committee.
2. Informed consent of the patient would be obtained if required in the local language also.
3. Any change in the protocol would be brought to the notice of the Ethics Committee in writing and their approval sought.
4. You will have to ensure that adequate insurance is covered.
5. The study may be withheld in case of non compliance of the protocol or any adverse event to the patients.
6. A progress report will be submitted to the committee every 3 months.
7. Patients will not be induced to come forward for the trial by offering any kind of monetary temptation.
8. Before conducting of the trial you will seek the permission from the Medical Director and fulfill all the norms laid down by the Central Government / State Government or any other authority in this regard, in case of any breach the Principal Investigator will be personally liable & under no circumstances the hospital will be liable.
Names of the members present in the above meeting.

1. Dr. R.L. VADI
2. Dr. DIPESH SHAH
3. Dr. BHAVINI SHAH
4. Mr. RASESH OZA
5. Shri. S.L. AGRAWAL

* You are hereby permitted to conduct the study at SAL Hospital as per Neovasc Reducer Pilot Study: Clinical Trial Protocol; Protocol No: NPSE002 Rev 03 submitted by you with prior permission of the Hospital Authorities.

For, Ethics Committee

( S. L. Agrawal )
Member Secretary
Subject: Approval of Protocol No 210-14-009 PAPIRUS

This is to inform you that the Ethics Committee (EC) has taken into consideration your request for the above mentioned trial for approval, in its meeting held on 23rd June 2005 and approved the same, subject to the following terms & conditions:

1. Adverse effect of any severity whether minor/ major would immediately be brought to the notice of the Ethics Committee.
2. Any Change in Protocol would be brought to the notice of the Ethics Committee in writing with reasons for the same and their approval sought.
3. You will have to ensure for an equal Insurance Coverage for the Hospital alsoas the Principal Investigator
4. The study may be withhold till review by the committee in case of non compliance of the protocol or any serious adverse event to the patients.
5. A progress report will be submitted to the committee every month.
6. Patient will not be induced to come forward for the trial by offering any kind of monetary temptation
7. Before conducting of the Trial you will seek the permission from the Medical Director and If needed, fulfill any requirements of the Central Government/ State Government for devicesor any authority in this regard, in case of any breach, the Principal Investigator will be personally liable and under no circumstances the Hospital will be
8. Apollo Hospitals International Limited, Ahmedabad will not be liable for any adverse effect/event of the trial.

The committee has approved the following documents:

1. Protocol 210--14-009 version 02
2. Informed consent form in English, version 02
3. Informed consent form English to Hindi Translation, version 02
4. Informed consent form English to Gujarati Translation, version 02

The following members of the Ethics Committee were present in the meeting:

1. Dr. Chirag Desai – Neutral Chairperson
2. Dr. Pankaj Divatia – Director Medical Services
3. Dr. Sucheta Mudgerikar – Consultant Neurologist
4. Ms. Puja Pushkarna – Clinical Psychologist
5. Mr. Ramesh – HOD Apollo Pharmacy Unit
6. Mr. S. Rajarajan – Executive Operations

It is to be noted that neither you nor any of your proposed study member was present during the decisionmaking procedures for the Ethics Committee.

Dr. Chirag Desai  
Chair Person – EC

Dr. Pankaj Divatia  
Director Medical Services