PUSHPANJALI HOSPITAL ETHICS COMMITTEE

Registration No. : ECR/1235/Inst/UP/2019

Notification of Decision of IEC/IRB

Ref. No. ..... Dt. .....

To,

Date: 03 JUNE 2021

[redacted]

Pushpanjali Hospital & Research Centre Pvt. Ltd.
Pushpanjali Palace, Delhi Gate
Agra-282002
Uttar Pradesh, India

Subject: **Protocol No.:** ECTS/20/002

Title: An open label, multicentric, non-comparative clinical study to investigate the efficacy, safety and tolerability of Sucroferric Oxyhydroxide Chewable Tablet (Dynulta™) in patients with chronic kidney disease on dialysis.

[redacted]

The meeting of Pushpanjali Hospital Ethics Committee, Pushpanjali Palace, Delhi Gate, Agra, Uttar Pradesh-282002 was held on 31st May 2021 at 03:00 PM onwards at Meeting Room, 3rd Floor, Pushpanjali Hospital & Research Centre Pvt. Ltd., Agra to review and discuss on your application to conduct proposed Study Title - An open label, multicentric, non-comparative clinical study to investigate the efficacy, safety and tolerability of Sucroferric Oxyhydroxide Chewable Tablet (Dynulta™) in patients with chronic kidney disease on dialysis.

The following documents were reviewed:

Sr. No.	Documents	Version and Date
1.	Study Protocol	Version 01, 14 Dec 2020
2.	Amendment to Study protocol	Version 001, 12 Mar 2021
3.	Protocol Signature Page (Signed on 27 Mar 2021)	Version 001, 12 Mar 2021
4.	Investigator Brochure	Version 00, 04 MAY 2021
5.	Subject Information Sheet and Informed Consent Form – English	Version 02, 02 Apr 2021

[redacted]

6.	Subject Information Sheet and Informed Consent Form – Hindi (Translated from English to Hindi on 07 Apr 2021)	Version 02, 02 Apr 2021
7.	Back Translated Subject Information Sheet and Informed Consent Form - Hindi to English (Translated on 07 Apr 2021)	Version 02, 02 Apr 2021
8.	Subject Information Sheet and Informed Consent Form Translation and Back Translation Certificate - Translated from English to Hindi - Back Translated from Hindi to English	-
9.	Screening Case Report Form	Version 00, 28 Apr 2021
10.	Case Report Form	Version 00, 28 Apr 2021
11.	Unscheduled Visit Case Report Form	Version 00, 28 Apr 2021
12.	Subject Diary – English	Version 00,02 Apr 2021
13.	Subject Diary – Hindi (Translated from English to Hindi on 07 Apr 2021)	Version 00,02 Apr 2021
14.	Back Translated Subject Diary (Hindi to English) (Translated from Hindi to English on 07 Apr 2021)	Version 00,02 Apr 2021
15.	S. Diary Translation and Back Translation Certificate - Translated from English to Hindi - Back Translated from Hindi to English	-
16.	Regulatory Documents - Approval Letter - DCGI Notification of Amendment(Amendment Ver. 001 Dated 12 MAR 2021)	-
17.	CV and MRC of Principal Investigator (Signed on 22 Sep 2020)	-
18.	Investigator Undertaking (Signed on 27 Mar 2021)	Version 001, 12 Mar 2021
19.	Clinical Trial Insurance Policy	-
20.	Draft Clinical Trial Agreement	-

The following members of the Ethics Committee were present during meeting held on 31st MAY, 2021:

S. No.	Ethics Committee Member Name	Educational Qualification	Designation in the Committee	Affiliation
1	[redacted]	MA,MCOM,LLB/CMA	Chairperson	NO
2		MBBS, MS (Orthopaedics), PGDHA	Member Secretary	YES
3		MSC-Math, PhD	Social Worker	NO
4		B.Com, LLB	Legal Expert	NO
5		MBBS,MD (Pharmacology)	Basic Medical scientist	NO
6		10th	Lay person	NO
7		MBBS, MD (Obs & Gynae),DNB (Obs & Gynae), MRCOG (UK), FNB (Reproductive Medicine)	Clinician	YES
8		MBBS (MD-Pulmonary Medicine)	Clinician	NO

Comments: Since the Ethics Committee gives the Conditional Approval, therefore, the site cannot be initiated or patients cannot be screened into the Study before submitting the following documents:

1. Signed CTA
2. CTRI registration certificate which reflects the site details.

Type of review

New Review √

Revised Review

Expedited Review

Review outcome:

Approval

Conditional Approval √

Request for modification or information

Disapproval

Termination/suspension of the research proposal/ongoing study

Remarks/ Suggestions:

The IEC/IEB hereby approves the research proposal to be conducted in its presented form only.

The IEC/IRB expects to be informed immediately (within 24 hours of knowledge of occurrence) in case of any Serious Adverse Events (SAE).

The IEC/IRB expects to be informed about study related information (new or changed or updated) that may affect safety of subjects and/or conduct of the study.

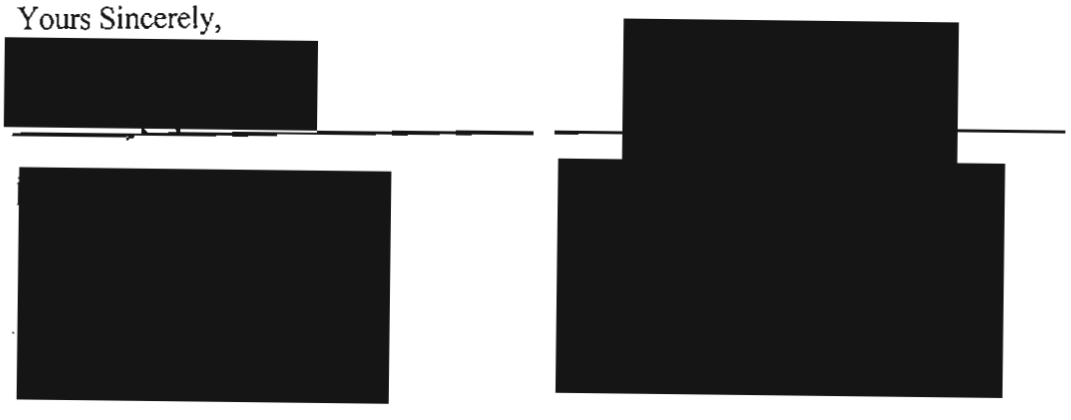
The IEC/IRB expects to be informed about the progress of the study at least six (06) months once from date of its first approval letter and/or case-by-case basis for pharmacodynamic study, pharmacokinetic study, epidemiological study, COHORT study etc.

Member of IEC/IRB will have right to monitor study site and conduct of study with prior intimation.

Notification letters regarding initiation, on-going and completion of study should be informed.

Our Ethics Committee operates in accordance with applicable ICH- GCP guidelines, Indian Council of Medical Research (ICMR) Guidelines and New Drugs and Clinical Trial Rules 2019.

Yours Sincerely,



Institutional Ethics Committee
Mysore Medical College & Research Institute
and Associated Hospitals, MYSORE-570001
EC REG:ECR/134/Inst/KA/2013/RR-19

[redacted]

[redacted]

Ref: MMCEC/116/21

Date: 20/8/21

To,

[redacted]
Assistant Professor
Department of Nephrology
K R Hospital, MMC &RI, Mysuru.

From,
Chairperson/Member Secretary
Institutional Ethics Committee,
Mysore Medical College & Research Institute & Associated Hospitals,
Mysore Medical College & Research Institute
Mysore-570001, Karnataka (India)

Protocol No: ECTS/20/002 (Version No. 01, Dated 14 DEC 2020)

Amendment to Protocol (Version 001, Dated 12 MAR 2021)

Study Title: "(An open label, multicentric, non-comparative clinical study to investigate the Efficacy, safety and tolerability of Sucroferric Oxyhydroxide Chewable Tablet (Dynulta™) in patients with chronic kidney disease on dialysis)"

Subject: Ethics Committee approval for the study of the above referenced clinical trial study at K R Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysore-570001, Karnataka, India.

This is with reference to your submission letter dated 03 Jun 2021, for the clinical trial study no. ECTS/20/002 (Version No. 01, Dated 14 DEC 2020) **Amendment to Protocol** (Version 001, Dated 12 MAR 2021 .In the Ethics Committee meeting dated 18 Aug 2021, the below mentioned study documents for the study no. ECTS/20/002 (Version No. 01, Dated 14 DEC 2020) **Amendment to Protocol** (Version 001, Dated 12 MAR 2021) were reviewed and discussed.

Submission letter dated 03 Jun 2021 contains following Documents:

Sr. No.	Documents	Version and Date
1.	Study Protocol	Version 01, 14 Dec 2020
2.	Amendment to Study protocol	Version 001, 12 Mar 2021

[redacted]

Ref : MMC Ec 116/21

Date : 20/8/21

3.	Protocol Signature Page (Signed on 27 Mar 2021)	Version 001, 12 Mar 2021
4.	Investigator Brochure	-
5.	Subject Information Sheet and Informed Consent Form – English	Version 02, 02 Apr 2021
6.	Subject Information Sheet and Informed Consent Form – Hindi (Translated from English to Hindi on 07 Apr 2021)	Version 02, 02 Apr 2021
7.	Subject Information Sheet and Informed Consent Form –Kannada (Translated from English to Kannada on 07 Apr 2021)	Version 02, 02 Apr 2021
8.	Back Translated Subject Information Sheet and Informed Consent Form - Hindi to English (Translated on 07 Apr 2021)	Version 02, 02 Apr 2021
9.	Back Translated Subject Information Sheet and Informed Consent Form - Kannada to English (Translated on 07 Apr 2021)	Version 02, 02 Apr 2021
10.	Subject Information Sheet and Informed Consent Form Translation and Back Translation Certificate - Translated from English to Hindi - Back Translated from Hindi to English - Translated from English to Kannada - Back Translated from Kannada to English	-
11.	Screening Case Report Form	Version 00, 28 Apr 2021
12.	Case Report Form	Version 00, 28 Apr 2021
13.	Unscheduled Visit Case Report Form	Version 00, 28 Apr 2021
14.	Subject Diary – English	Version 00,02 Apr 2021
15.	Subject Diary – Hindi	Version 00,02 Apr 2021

[redacted]

Ref: MMC EC 116|21 Date: 20|8|21

	(Translated from English to Hindi on 07 Apr 2021)	
16.	Subject Diary – Kannada (Translated from English to Kannada on 07 Apr 2021)	Version 00,02 Apr 2021
17.	Back Translated Subject Diary (Hindi to English) (Translated from Hindi to English on 07 Apr 2021)	Version 00,02 Apr 2021
18.	Back Translated Subject Diary (Kannada to English) (Translated from Kannada to English on07 Apr 2021)	Version 00,02 Apr 2021
19.	Subject Diary Translation and Back Translation Certificate - Translated from English to Hindi - Back Translated from Hindi to English - Translated from English to Kannada - Back Translated from Kannada to English	-
20.	Regulatory Documents - Approval Letter - DCGI Notification of Amendment(Amendment Ver. 001 Dated 12 MAR 2021)	-
21.	CV and MRC of Principal Investigator	-
22.	Investigator Undertaking (Signed on 27 Mar 2021)	Version 001, 12 Mar 2021
23.	Clinical Trial Insurance Policy	-
24.	Draft Clinical Trial Agreement	-

The following members were present during the **Virtual meeting (Webex)** held on Wednesday,18 Aug 2021 at 16:00 at Pathology, Lecture Hall, K.R. Hospital, Mysore.

[redacted]

[redacted]

Ref : MMC EC 116/21 Date : 20/8/21

#	Name	Role in the EC	Designation	Gender
01	[redacted]	Basic Scientist	Chairperson	Male
02		Basic Scientist	Member Secretary	Male
03		Lay Person	Member	Male
04		Clinician	Member	Male
05		Social Scientist	Member	Male
06		Legal Expert	Member	Male
07		Pharmacologist (Basic Medical Scientist)	Member	Female
08		Scientific Member	Member	Male
09		Basic Medical Scientist	Member	Male
10		Clinician	Member	Male
11		Educationist	Member	Female

The Ethics Committee approved the study as discussed in the meeting held on 18 Aug 2021.

Remarks/Suggestion:

1. The IEC/IRB hereby approved the research proposal to be conducted in it's presented from only.
2. The IRB/IEC expects to be informed immediately (within 24 hrs) in case of nay Serious Adverse Events (SAEs).
3. The IEC/IRB expects to be informed about study related information (new or changed or updated) that may affect safety of subjects and /or conduct of the study.
4. PI /study team/ Member are not a part of voting process.
5. Changes to protocol in ICF cannot be initiated without approval of EC.
6. Copy of final study report has to be provided to EC.
7. The IEC/IRB expects to be informed about the progress of the study at six (6) months once from date of its first approval letter and case basis for pharmacodynamic study, pharmacokinetics study, etc.
8. Member of IEC/IRB will have right to monitor study site and conduct of study with prior intimation.

[redacted]

[redacted]

Ref: MMC EC 116/21

Date: 20/8/21

9. Notification letter regarding initiation, on-going and completion of the study should be informed.
10. Our ethics Committee operates in accordance with applicable ICMR guidelines for Biomedical Research on Human Subejcts-2017, India GCP & ICH-GCP guidelines which govern GCP & IEC/IRB operations, declaration of Helsinki (Brazil, 2013) and 21 CFR Part 56 and 21 CFR part 50 and New Drugs and Clinical Trail Rules 2019.

Note: You are requested to check the Approval Letter thoroughly. If any Discrepancy is noted, it may be brought to the notice of the undersigned not later than one week (7 days) after issue of the letter. No correspondence regarding discrepancies will be accepted after one week (7 days) of issue of letter.

Approval Authority:

Ethics Committee Chairperson/Member Secretary:

Name:	[redacted]
Signature & Date:	[redacted]

[redacted]

[redacted]

Dr. Sanjay's
Center For
Kidney &
Diabetes

No. 357/B, B.B. Road,
Opp. R.R. Gold Palace,
Yelahanka Old Town,
Bengaluru - 560 064.
Karnataka. INDIA
[redacted]

Date:

Date: 01/07/2021

To,

[redacted]
Principal Investigator
Dr. Sanjay's Center for Kidney and Diabetes
357/B, Bangalore Bellary Road,
Parallel to new airport road, Yelahanka,
Bengaluru, Karnataka- 560064 India

Protocol Title: An open label, multicentric, non-comparative clinical study to investigate the Efficacy, safety and tolerability of Sucroferric Oxyhydroxide Chewable Tablet (Dynulta™) in patients with chronic kidney disease on dialysis.

Protocol Number: ECTS/20/002 (Version No. 01, Dated 14 DEC 2020)
Amendment to Protocol (Version 001, Dated 12 MAR 2021)

Subject: Clinical Study Documents for Ethics Committee approval for the referred clinical study.

[redacted]

With reference to your study documents submitted for EC review, the below documents were reviewed and approved by EC.

The following documents submitted for the above-mentioned clinical project: -

No. 357/B, B.B. Road,
Opp. R.B. Gold Palace,
Yelahanka Old Town,
Bengaluru - 560 064.
Karnataka. INDIA
[redacted]

Sr. No.	Documents	Date: Version and Date
1.	Study Protocol	Version 01, 14 Dec 2020
2.	Amendment to Study protocol	Version 001, 12 Mar 2021
3.	Protocol Signature Page (Signed on 10 Apr 2021)	Version 001, 12 Mar 2021
4.	Investigator Brochure	-
5.	Subject Information Sheet and Informed Consent Form – English	Version 02, 02 Apr 2021
6.	Subject Information Sheet and Informed Consent Form – Hindi (Translated from English to Hindi on 07 Apr 2021)	Version 02, 02 Apr 2021
7.	Subject Information Sheet and Informed Consent Form –Kannada (Translated from English to Kannada on 07 Apr 2021)	Version 02, 02 Apr 2021
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10.	Subject Information Sheet and Informed Consent Form Translation and Back Translation Certificate - Translated from English to Hindi - Back Translated from Hindi to English - Translated from English to Kannada - Back Translated from Kannada to English	-
11.	Screening Case Report Form	Version 00, 28 Apr 2021
12.	Case Report Form	Version 00, 28 Apr 2021
13.	Unscheduled Visit Case Report Form	Version 00, 28 Apr 2021
14.	Subject Diary - English	Version 00,02 Apr 2021
15.	Subject Diary – Hindi (Translated from English to Hindi on 07 Apr 2021)	Version 00,02 Apr 2021
16.	Subject Diary – Kannada (Translated from English to Kannada on 07 Apr 2021)	Version 00,02 Apr 2021

No. 357/B, B.B. Road,
Opp. R.R. Gold Palace,
Yelahanka Old Town,
Bengaluru - 560 064.
Karnataka. INDIA
[redacted]

17.	Back Translated Subject Diary (Hindi to English) (Translated from Hindi to English on 07 Apr 2021)	Version 00,02 Apr 2021
18.	Back Translated Subject Diary (Kannada to English) (Translated from Kannada to English on07 Apr 2021)	Version 00,02 Apr 2021
19.	Subject Diary Translation and Back Translation Certificate - Translated from English to Hindi - Back Translated from Hindi to English - Translated from English to Kannada - Back Translated from Kannada to English	-
20.	Regulatory Documents - Approval Letter - DCGI Notification of Amendment(Amendment Ver. 001 Dated 12 MAR 2021)	-
21.	CV and MRC of Principal Investigator	-
22.	Investigator Undertaking (Signed on 10 Apr 2021)	Version 001, 12 Mar 2021
23.	Clinical Trial Insurance Policy ***(Policy No.: 120500362005000000001,effective from 23 Jun 2020 till 22 Jun 2021)***	-
24.	Draft Clinical Trial Agreement	-

The following members of the Ethics Committee were present at the meeting held on 29.June.2021at 10:00 am at Dr. Sanjay's Center for Kidney and DiabetesBangalore.

Name	Qualification	Designation/ Title	Affiliations as to the Institution Yes/No
[redacted]	MBBS, MD (General Medicine)	Physician	NO
	B D S	MEMBER SECRETARY	YES
	BACHELOR OF ENGINEERING	Chairman	NO

No. 357/B, B.B. Road,
Opp. R.R. Gold Palace,
Yelahanka Old Town,
Bengaluru - 560 064.
Karnataka. INDIA
[redacted]

	(MECH) MBA		Date:
[redacted]	MBBS, M.D, DNB (PATHOLOGY)	MEMBER SECRETARY	NO
	MASTER OF ARTS, MSW	SOCIAL SCIENTIST	NO
	DIPLOMA IN PHARMA	PHILOSOPHOR	NO
	BSC, LLB	LEGAL EXPERT	NO
	M.SC PSYCHOLOGY	SOCIAL SCIENTIST	NO
	BA	LAY PERSON	NO

We approve the trial to be conducted in its presented form. The clinical study should not be initiated at the clinical center without the DCGI approval letter and we expect to notify the DCGI approval letter to the ethics committee before initiating the trial.

*We*expect 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.

We hereby confirm that the *our Committee*isorganized and operates as per GCP and applicable regulations.

Thanking you,

Yours sincerely,

[redacted]

Member Secretary: -
[redacted]
CRA (Ethics):-
1. Ms. Jyotsana Sharma
2. Ms Twinkle Mazumdar
Tel: 011-42251614

Ethics Committee
Sir Ganga Ram Hospital

Date: 10th September 2021

[redacted]
Chairman,
Department of Nephrology,
Sir Ganga Ram Hospital,
New Delhi- 110060.

Sub: Ethics Committee meeting.

EC/07/21/1926

"Protocol no ETCS/20/002 - "An open label, multicentric, non-comparative clinical study to investigate the efficacy, safety and tolerability of Sucroferric Oxyhydroxide Chewable Tablet (DynultaM) in patients with chronic kidney disease on dialysis."

[redacted]

The Ethics Committee reviewed the following documents of the above project proposal:-

1. Study protocol version 01 dated 14 Dec 2020
2. Amendment to study protocol version 001, dated 12 Mar2021
3. Protocol signature page (Signed on 01 Apr 2021) version 001, 12 Mar 2021
4. Investigator brochure Version 00, dated 04 May 2021
5. Subject Information Sheet and Informed Consent Form – English version 02, dated 02 Apr 2021
6. Subject Information Sheet and Informed Consent form – Hindi (Translated from English to Hindi on 07 Apr 2021 version 02, dated 02 Apr 2021
7. Back Translated Subject Information Sheet and Informed Consent Form-Hindi to English (Translated on 07 Apr 2021) version 02, dated 02 Apr 2021
8. Subject Information Sheet and Informed Consent Form Translation and back translation certificate
   -Translated from English to Hindi
   -Back Translated from Hindi to English
9. Screening Case Report Form version 00 dated 28 Apr 2021
10. Case Report Form version 00, 28 Apr 2021
11. Unscheduled Visit Case Report Form version 00, dated 28 apr2021
12. Subject Diary – English Version 00, dated 02 Apr2021
13. Subject Diary –Hindi (Translated from English to Hindi on 07 Apr 2021 version 00, 02 Apr 2021
14. Back Translated Subject Diary (Hindi to English) (Translated from Hindi to English on 07 Apr 2021) version 00, 02 Apr 2021
15. S. Diary Translation and back Translation Certificate
    -Translated from English to Hindi
    -Back Translated from Hindi to English
16. Regulatory Documents
    -Approval Letter
    -DCGI Notification of Amendment (Ar[redacted]

Member Secretary: -
[redacted]
CRA (Ethics):-
1. Ms. Jyotsana Sharma
2. Ms Twinkle Mazumdar
Tel: 011-42251614

Ethics Committee
Sir Ganga Ram Hospital

17. CV and MRC of Principal Investigator (Signed on 17 Mar 2021)
18. Investigator Undertaking (Signed on 01 Apr 2021) Version 001, 12 Mar 2021
19. Clinical Trial Insurance (Policy No. 12050036200500000001 Effective from 23 Jun 2020 to 22 Jun 2021
20. Draft Clinical Trial Agreement
21. Committee Fee INR 86,400 in the favor of SIR GANGA RAM HOSPITAL by NEFT

The Ethics Committee in its meeting held on 30th July 2021 at 3.00 pm. in the GRIPMER, Board Room, Sir Ganga Ram Hospital, New Delhi reviewed the above project proposal.

1.	[redacted]	Chairman
2.		Member
3.		Member
4.		Member
5.		Member
6.		Member
7.		Member
8.		Member
9.		Member
10.		Member Secretary

Following observations were made:-

The DCGI approval is not PI and site specific. The PI is advised to provide/ notify EC-SGRH with a site & PI specific DCGI approval.

1. EC notes that the Insurance Provider (New India Insurance) is generic. The PI is requested to provide EC-SGRH with study, PI and site specific insurance for this study.
2. The PIS does not specify travel compensation in SGRH format. The PI is requested to provide 'travel compensation' in SGRH format, i.e. Rs. 750/- (for Delhiites) and 'as-per-actuals' (for those coming from outside Delhi).
3. The PIS is not PI and site specific. The PI is requested to provide a PI & site specific PIS.

The following members were present in the EC meeting held on 3rd September 2021 in the GRIPMER, Board Room, Sir Ganga Ram Hospital, New Delhi:

1.	[redacted]	Chairman
2.		Member
3.		Member
4.		Member
5.		Member
6.		Member
7.		Member
8.		ember

Member Secretary: -
[redacted]
CRA (Ethics):-
1. Ms. Jyotsana Sharma
2. Ms Twinkle Mazumdar
Tel: 011-42251614

Ethics Committee
Sir Ganga Ram Hospital

9.	[redacted]	Member
10.		Member
11.		Member
12.		Member
13.		Member Secretary

The Ethics Committee in its meeting reviewed and noted the following documents of above project proposal

- Response to query letter dated 9th August 2021 by the letter dated 18th August 2021
- PI and site specific DCGI Approval Letter
- PI and site specific Insurance Certificate
  Cert No. 0G-22-2001-3306-00000001-06
  Policy no: 1205003621050000001
  Period of insurance: from 9/6/2021 to 8/6/2022
- Updated ICF with travel compensationin SGRH format
- PI and site specific ICF
  (version. 02; Date: 02 APR 2021)
  Site specific ICF; ver.00; Date: 17 AUG 2021

The EC after carefully considering and reviewing the submitted documents provided; APPROVED the study from *ETHICAL ANGLE*.

You should conduct the study as per the recommended GCP guidelines. You are expected to provide EC with following:

i. Date of initiation of study.
ii. Six monthly progress report including protocol deviations & SAE's at the centre. SAE's at the centre to be reported within 24 hours.
iii. All amendments to the approved documents.
iv. SAE's at the other sites and reports of DSMB.
v. Study close out with status report.

You are requested to check the Approval Letter thoroughly. If any Discrepancy is noted, it may be brought to the notice of the undersigned not later than 10 days after issue of the letter. No correspondence regarding discrepancies will be accepted after 10 days of issue of letter.

We confirm that Ethics Committee functions based on ICH-GCP, ICMR and DCGI guidelines

[redacted]

Member Secretary: -
[redacted]
CRA (Ethics):-
1. Ms. Jyotsana Sharma
2. Ms Twinkle Mazumdar
Tel: 011-42251614

Ethics Committee
Sir Ganga Ram Hospital

Yours sincerely

[redacted]

[redacted]

Member Secretary
Ethics Committee,
Sir Ganga Ram Hospital,
New Delhi- 110060.
INDIA

[redacted]