



MGM INSTITUTE OF HEALTH SCIENCES

(Deemed to be University u/s 3 of UGC Act, 1956)

Grade 'A' Accredited by NAAC

MGM SCHOOL OF PHYSIOTHERAPY

Sector-1, Kamothe, Navi Mumbai – 410209

APPLICATION FOR SEED MONEY/RESEARCH GRANT

Date: 16th December 2021

Name of Principal Investigator: Miss Niyati Dharmendra Desai

Name of co-investigator/s : Dr. Amrita Gosh (PT)

Title of the project: Effects of telerehabilitation on people with Parkinson's Disease - A systematic review and meta-analysis (MGM/DCH/IEC/61/2021)

Name of Department: MGM School of Physiotherapy

Name of the Institution: MGM Institute of Health Sciences, NM

Designation: Associate Professor

E-mail address: agosh@mgmsopnm.edu.in

Mobile :9916273631

List of important publications of last 5 years of the all the investigators in the relevant fields : Nil

Duration of the project : 36 months

Approval from Scientific Advisory Committee Yes

Ethics committee Clearance Yes

Budget requirements (as per the format as Annexure 1B)

| | Year I | Year II | Total (INR) |
|----------------------|----------------|----------------|----------------|
| Recurring | | | |
| a. Consumables | 2500 | 2500.00 | 5000.00 |
| b. Travel | - | - | - |
| c. Contingency | - | - | - |
| Non-recurring | - | | - |
| | 2500.00 | 2500.00 | 5000.00 |

Signature

Principal Investigator

N. D. Desai



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Signature
Co-Investigator

Amrita

Signature
Head of Department

RJ



INSTITUTIONAL ETHICS COMMITTEE
MAHATMA GANDHI MISSION'S DENTAL COLLEGE & HOSPITAL
Junction of NH-4 and Sion Panvel Expressway,
Sector-01, Kamothe, Navi Mumbai- 410 209
Tel: 022- 27436604; Fax: 91-22-27433185; E-Mail:mgmdch@mgmmumbai.ac.in

MGM/DCH/IEC/ 61 /2021

Date:- 12 / 7 /2021

To,
Miss Niyati Dharmendra Desai
PG Student, MGM School of Physiotherapy
Guide - *Dr. Amrita Ghosh (PT)*
Kamothe, Navi Mumbai- 410209

Reference:

1. Your submission of study protocol
2. Study Title: "Effects of telerehabilitation on people with Parkinson's Disease - A systematic review and meta-analysis"
3. IEC-MGMDCH referenceno *MGM | DCH | IEC | 61 | 2021*

Dear Miss Niyati Dharmendra Desai

The IEC- MGMDCH has received and reviewed your submission

Following documents were reviewed in the meeting held on date *9 / 7 / 2021*

1. Application to IERC MGMDCH dt. *25 / 5 / 21*
2. Summary of research protocol ✓
3. Research protocol (Version *6* dt *7 / 6 / 2021*)
4. Amendments to research protocol (Version - Dt *1 - / 2021*)
5. Informed consent document (ICD) in English (Version.....dt. *1 / 2021*) - *NA*
6. ICD in Hindi language translated from English (Versiondt. *1 / 2021*) - *NA*
7. ICD in Marathi language translated from English (Version.....dt. *1 / 2021*) - *NA*
8. Back translations of ICD from Hindi to English (Version. *1 / 2021*) - *NA*
9. Back translations of ICD from Marathi to English (Version.....dt. *1 / 2021*) - *NA*
10. Amendments to the ICD (Versiondt. *1 / 2021*) -
11. Case Record Form (CRF) / Study Questionnaire / Study Proforma ✓
12. Principal investigators Current Curriculum Vitae (signed and dated) ✓
13. Subject recruitment procedures: advertisement, letters to doctors, notices
14. Investigator Brochure (IB) – applicable for investigational new drugs (IND)
15. Ethics Committee clearance of other study centers (Total No.)
16. Insurance policy if any
17. Drugs Controller General (India) [DCG(I)] clearance if applicable
18. Investigator's undertaking to DCG(I) if applicable
19. Health Ministry Screening Committee (HMSC) approval if applicable
20. Bhabha Atomic Research Centre (BARC) approval if applicable
21. Genetic Engineering Advisory Committee (GEAC) approval if applicable
22. Director General of Foreign Trade (DGFT) approval if applicable
23. FDA marketing/manufacturing license for herbal drugs. if applicable
24. Other Documents(specify.....)

PageNo.

MGM School of Physiotherapy
MGMIHS, Navi Mumbai
Inward / Outward No. *200*
Date *15 / 7 / 2021*
Receiver Signature



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MGM/DCH/IEC/ 61 /2021

Date:-12 / 7 /2021

The following members of the Ethics committee discussed the study documents and voted at the meeting:

| Sr. | Name | Role and Responsibility |
|-----|---------------------------|-------------------------|
| 1. | Dr. Deepak Langade | Chairman, Scientific |
| 2. | Dr. Srivalli Natarajan | Secretary, Scientific |
| 4. | Adv. Dr. Karuna Malaviya | Scientific, Legal |
| 5. | Dr. Shilpa Patel | Scientific, Woman |
| 6. | Dr. Ravindranath VK | Scientific |
| 7. | Dr. Ashvini Padhye | Scientific, Woman |
| 8. | Dr. Jyoti Nadgere | Scientific, Woman |
| 9. | Dr. Sumanthini MV | Scientific |
| 10. | Ms. Nithya Eldho Varghese | Lay person |
| 11. | Mrs. Rupali Gujar | Social worker |

Approved
DECISION

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INSTITUTIONAL ETHICAL COMMITTEE
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Date:- 12 / 7 /2021

Based on the discussion of the submitted documents for the scientific and ethical review, we approve the research protocol to be conducted and its presented form subject to the following conditions:

1. Applicable and mandatory regulatory permissions to be obtained prior to commencement of the study i.e. registration at clinical trial registry of India.(www.ctri.nic.in)
2. The investigators and other participants should be adequately trained on the protocol and its related procedures, the Good Clinical Practices (GCP) guidelines prior to commencing the study.
3. Participating subjects should be adequately enlightened about the protocol during informed consent process and under insurance coverage in an event of any trial related injury/accident.
4. Participating subjects should not be put to additional financial burden related to the study protocol.

The validity of this approval is for two years from date of approval. Within this period, the Institutional Ethics Committee expects to be periodically informed about the following:

- The progress of the study
- Any Serious Adverse Event (SAE) occurring in the course of the study
- Any significant changes in the protocol/patient information/ informed consent
- Update on safety of the investigating product or procedure

To provide an abridge copy of the final report after completion of the study.

Thanking You,

Yours Sincerely



Dr. Srivalli Natarajan

Member Secretary

Dr. Srivalli Natarajan

Member Secretary

IERC MGMDCH

Kamothe, Navi Mumbai-410 209.