



Bhausahab Mulak Charitable Trust's
Bhausahab Mulak
Ayurved College & Research Hospital

P-73 R&C Zone MIDC; Butibori, Nagpur. 441122 ♦ Cell : 9673843111
♦ Email:- bmctbutibori@gmail.com ♦ Website:- www.bmacrhbutibori.com



Smt. Sumanmala B. Mulak
President

Shri. Rajendra B. Mulak
Secretary

Shri. Yashraj R. Mulak
Treasurer

Dr. Madhusudan Gupta
Principal

Ref. No. : —

Date : 06 June 2022

MEMORANDUM OF UNDERSTANDING

BETWEEN

VIRTUOUS INSTITUTIONAL MEDICAL RESEARCH ETHICS COMMITTEE

(First Institution/ First Party)

AND

PRINCIPAL INVESTIGATOR/ SPONSOR/CRO

(Second Institution/ Second Party)

This Memorandum of Understanding [MOU] is entered into by Virtuous Institutional Medical Research Ethics Committee (VIMREC), herein referred to as First Institution/Party, AND Bhausahab Mulak Ayurved College & Hospital herein referred to as Second Institution/Party; in regards to Clinical Research activities as on (01/04/2022) to specify the terms and conditions under which both the parties would voluntarily agree till specified term.

Through First Institution/Party, VIMREC is duly-authorized Institutional Ethics Committee (VIMREC) that works under Shrikrishna Hrudayalaya and Critical Care Centre, IVth Floor, Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur-440012, Maharashtra, India that shall serve as the Supervising Committee for Clinical Research activities conducted at Bhausahab Mulak Ayurved College & Research Hospital, Butibori, Nagpur under the Second Institution/Party.

1] Purpose of MOU

The terms of this Memorandum of Understanding are applicable specifically to the Clinical Research activities under the existing and applicable guidelines by competent regulatory authority/authorities. These include (but not limited to) ICH-GCP, ICMR guidelines CDSCO/DCGI guidelines including 'The New Drugs and Clinical Trials Rules', 19 March 2019

(as per CDSCO Gazette Notification, GSR 227-E); and/or similar standard guidelines as required and updated by concerned regulatory authority

(ies) from time to time conducted at mentioned above clinical research site in association with Second Institution/Party NAME OF PI/ INSTITUTION under supervision of First Institution/ Party, VIMREC.

II] Aim of MOU

The aim of this MOU shall be as under (but not limited to):

- To facilitate the continued collaboration between both the parties
- To provide for the efficient review of research protocols.
- Second Party wishing to authorize the VIMREC to be the sole Institutional Ethics Committee for Clinical Research Protocol / Thesis/ Academic projects Observational Studies approval and continued oversight of research activities.

III] Responsibilities of First Party/ Institution

- Conduct initial and continuing IEC review, monitoring of Serious Adverse Events/ unanticipated events review in the form of CIOMS/SUSARS/ Safety FU Events within specified timelines, Protocol Amendments/ Addendums review, DSMB Reports, Biannual Study Reports, Clinical Trial Agreements, Regulatory Approvals/Notifications, Deviations/ Violations, Waivers, Non-compliance issues and review of various other clinical and non-clinical protocol related documents as and when available with the Institutional research identified above in accord with the terms and conditions applicable laws, regulations, policies and Standard Operating Procedures (SOPs).
- First Institution shall inform about any changes/ updates such as in the members or SOP or other research related communication, queries, etc in writing/ email/ fax or any other suitable mode of communication at that time period that might affect Second Party/ Institution reliance on First Party/Institution or performance of the research on site. OR may require a requisition mentioning the same from the Second Party/ Institution.
- First Institution serves the rights of Suspension/Termination of approved Research Protocol for cause of negligence, non-compliances or any unanticipated problems involving risks to research subjects or others related to the approved research which are reported to the IEC. OR Additional concern(s) if any related to the conduct of the approved research that First Party Institution believes should be relied.

IV] Responsibilities of Second Institution/Party

- Second Party / Institution shall serve as the educated, experienced and delegated personnel/ institution that shall conduct research identified above in accord with the terms and conditions of applicable laws, regulations, institutional/sponsor policies, standard operating procedures (SOPs), and IEC requirements.
- Provide all the relevant research related documents as mentioned in the VIMREC SOP during initial, interim phase & close out of study through letters/ email or via suitable mode / method that must be fulfilled from time to time.
- Obtain and maintain other protocol specific approvals based on local institutional policies or other applicable laws, regulations or requirement.
- Second Party / Institution shall promptly notify the IEC about SAEs, unanticipated events involving risks to subjects, continuing non-compliance, negligence, deviations, violations, etc... by staff members of Second Institution.
- IEC requirements or applicable laws/regulations/ policy for protection of human subjects, patient confidentiality, any additional concern(s) related to conduct of approved research that both parties/ Institutions believe should be relied.
- Second Party / Institution will assure that all personnel involved in the research complete appropriate human subjects protection education and trainings.
- Second Institution/Party shall inform about any changes/ updates such as in the team members or SOP or other research related communication, queries, etc in writing/ email/ fax or any other suitable mode of communication that might affect First Party/Institution reliance on Second Party/Institution or that might affect IEC willingness or ability to serve as supervising committee covered under this agreement.

V] Record Retention and Access

- Both the parties/ institution shall comply with applicable laws, regulations, and policies for research record retention as per applicable laws and regulations of the regulatory authorities released from time to time.
- Both the parties shall provide access to their records as necessary to conduct audits and investigations of the IEC approval process whether for cause and as permitted by law upon valid and reasonable request in writing.
- Both the parties shall be bound by applicable laws, regulations as per regulatory / Institutional policies for the protection of confidential information.

VI] Term and Termination

- The initial term of this agreement shall commence on the Effective Date and shall continue for three years thereafter, unless otherwise terminated in writing by either party as provided that
- Either party may terminate the agreement upon 30 days written notice to other party.
 - In the event of a material breach of any of the terms of this agreement, any party may terminate the agreement upon filing written notice of any material breach of its terms with the other party, and affording the breaching party 30 business days to rectify the breach to the noticing party's satisfaction.
 - In the event of any termination, the parties shall cooperate to minimize the disruption to ongoing research and to ensure the protection of human subjects.
 - This agreement may be modified/cancelled/ renegotiated upon mutual consent, at any time, through an amendment signed by authorized representatives of institutions.
-

VII] Miscellaneous


This MOU along with subsequent amendments in original copies will be kept securely with both the Institutions/Parties to reflect delegation to the IEC of responsibility for the review, approval, and oversight of research as specified in this agreement.

VIII]. Signatures:

First Institution/Party:

Name: DR LALIT KHANDWANI

Title: member Secretary

Signature: 

Date: 06 June 2022

Address: Shrikrishna Hrudayalaya
Congress Nagar, Nagpur

Stamp:

Virtuous Institutional Medical
Research Ethics Committee
Regn. No. ECR/548/Inst/MH/2014
Congress Nagar, Nagpur-440012.

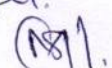
Second Institution/Party:

Name: Bhausahab Mulak Ayurved

College & Research Hospital,

Butibori, Nagpur

Title: Principal.

Signature: 

Date: 6/June/2022

Address: P-73 R & C zone, Butibari
Nagpur - 441122

Stamp:

Principal
Bhausahab Mulak Ayurved College
& Research Hospital, Butibori, Nagpur

