Memorandum of Understanding

This Agreement is made on 26th April 2016, by and between **"ARDENT CLINICAL RESEARCH SERVICES (ACRS)"**a company registered under company act 1956 having its office at Regus, level-2, Connaught Place, Bund Garden Road, Pune-411001, MH, India referred as a party-A**(here in after referred to as the "Ardent")**

And

MAHATMA GANDHI MISSION's, MEDICAL COLLEGE & HOSPITAL (MGM HOSPITAL), N-6 CIDCO, Aurangabad-431003, Maharashtra, India referred as a party –B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties hereto as follows

MGM College & Hospital Aurangabad appoints Ardent Clinical Research Services as a Site management organization **for period of 03 years w.e.f 1st April 2016 to 1st April 2019.**

Obligations of Ardent Clinical Research Services:

Ardent Clinical Research Services (ACRS) is a Clinical Research Organizations and Site Management Organization based in Pune providing end to end clinical research services to the Sponsors, Pharmaceutical and Biopharmaceutical industry, Institutions and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in Site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site Selection, Faster Patient Recruitment, Quality compliance& Maintenance, and Clinical Research Expertise in India.

Ardent Clinical Research Services is desirous of working with Institution for the purpose of conducting ICH-GCP complaint Phase I-IV clinical trials for new drug & treatment

Ardent Clinical Research Services shall play vital role in getting clinical trials to the hospital / institution from the sponsors and CROs and execute them in institution.

Ardent Clinical Research Services will manage Study Operations and Study services as directed by Study protocol for the duration of the clinical trial.

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Ardent Clinical Research Services will appoint a Clinical Research Coordinator (CRC)who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

Ardent Clinical Research Services will appoint Project Manager (PM) who will be responsible to co-ordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post –monitoring action elements and study training as per needs and frequent discussion with investigator & Sponsor/CRO on trial progress.

Ardent Clinical Research Services will appoint Quality Check Experts (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and quality management will be done by Ardent clinical research services. Ardent personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

Ardent Clinical Research Services will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by Ardent Clinical research services which includes telecommunication, travel cost, training cost at various centers across India or abroad.

Ardent Clinical Research Services will be conducting /managing all trial (Trials come from Ardent) at the Institution during the tenure of this agreement. This agreement will last for 03 (Three) year and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y Indian GCP and regulatory requirement
2. Preparation for Site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory Documents Collection
6. Patient Identification for assigned study from OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for Site Monitoring Initiation Visit (SMV) and resolving all action items generated during previous

9. Conduct study according to International Conference of Harmonization (ICH) E6 and Indian Good Clinical Practice (GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures
11. Ensure protocol &applicable regulatory guidelines compliance and adherence
12. Patients pre-screening, screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular telephonic contact with patients to preventing lost to follow-up and missed visits.
16. Managing clinical trial materials(CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site specific queries-medical, administrative, subject reimbursements and other
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, logistics log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Other duties as requested by Ardent Clinical Research Services Management

B. Institution Permits

1. Institution will give the space and required facilities to appointed CRC & ACRS in order to perform clinical trials activities under respected PI.
2. Institution will allow ACRS and Sponsors of clinical trials to access the facility to verify source documents.
3. Institution will allow ACRS to bring Sponsors of clinical trials to meet with SITE representatives at a mutually convenient time.

4. Institution permit all Clinical Trials (The trial which comes for Ardent) will exclusively manage by Ardent Clinical Research Services only.

C. Term of Agreement

The term of this Agreement shall be for a period of 03 year commencing on the effective date1th April 2016. However, this Agreement shall be reviewed annually by both parties.

D. Relationship of the Parties

1. Hospital and ACRS are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor did authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provide in this Agreement.

E. GCP, ICH and CFR Compliance

Institution agrees to comply with all requirements of Good Clinical Practices (GCP), International Conference of Harmonization (ICH) and Code of Federal Regulations (CFR) and any and all future regulations, requirements and writing promulgated there under.

F. Confidentiality

1. The parties hereto recognize and agree that due to the complex and competitive nature of the business, the confidentiality of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all information or information relative to the work or the business of either party without the written consent of either party. ACRS agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatsoever, without the prior written consent of SITE.

2. Institution shall not disclose to any third party any and all information about new studies received from ACRS.

G. Indemnification

Institution shall indemnify and hold harmless ACRS against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees. ACRS shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by ACRS, its agents, directors, or employees. In no

event will either party be required to indemnify or hold harmless the other for the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Institution, Principle Investigator, Ardent Clinical Research Services and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Institution.
2. All feasibilities and payments shall be routed through ACRS and pricing while bidding for the trial while bidding for the trials shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by Ardent Clinical Research Services for Smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Institution and /or Investigator is the responsibility of Ardent Clinical Research Services.
4. All payment will come to Ardent Clinical Research Services by the sponsors/CRO and Ardent Clinical Research Services will be payee for all trial related payment for each trial
5. All payment shall be due and payable to the Institution on the basis of funds received from the sponsor/CRO on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. A invoice will be requested from the hospital for study payment and all Study related payments will be done to MGM Medical College & Hospital Aurangabad, in a period of 15 working days after receiving the payment from the sponsor/CRO.

8. The details of study budget sharing in INR is as follows:
    - Payment per patient from Sponsor/CRO to ACRS:**100%**
    - Payment to Institute /Principal Investigator from ACRS:**65%**
    - Payment to Ardent Clinical Research Services:**35%**
    - Additional Payment to Institute as Institute Overhead Charges from ACRS: **20%** **(Of total Budget except patient compensation)**

(Note: study budget sharing will be revised after one year mutually agreed by both party)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving Sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use Personal Information or Statement

For good consideration, the undersigned authorizes SMO and it's assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in

clinical research including any specific details of my clinical research that do not conflict with a previously contracted privacy agreement.

The two parties shall consult with each other and mediate any disputes which may arise about the contract. If all attempts fail, the two parties can appeal to the organization of arbitration in judicial court of Aurangabad, MH, India.

MGM Medical College &Hospital Aurangabad

1) Signature: _____

Name:-Dr. Ajit G. Shroff
Title:- Dean
MGM Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003Maharashtra, India
Date:-_____

2) Signature: _____

Name:-Dr. Pravin R. Suryawanshi
Title:- Dy. Dean
MGM Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003Maharashtra, India
Date:-_____

3) Signature: _____

Name:-Dr. Deepak Bhosle
Title:- Professor & Head Department of Pharmacology
MGM Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003Maharashtra, India
Date:-_____

Ardent Clinical Research Services

1) Signature: _____

Name:-Mr.Chandu Devanpally
Title:- Founder & Director,
Ardent Clinical Research Services

M.G.M's Medical College Abad

Ardent Clinical Research Service Pune

Regus, level-2, Connaught Place, Bund Garden Road, Pune-411001, MH, India
Date:- 25/05/16

2) Signature: _____

Name:-Dr.Prasad Jadhav

Title:- Manager-Clinical Operations
Ardent Clinical Research Services
Regus, level-2, Connaught Place, Bund Garden Road, Pune-411001, MH, India
Date:- 25 MAY 2016

Ardent Clinical Research Service Pune

M.G.M.'S Medical College A'bad