Economically Developing Countries (EDC) Project
Memorandum of Understanding

Please note this document contains guidelines and examples to assist you when filling in each section. The instructions (highlighted in blue italics) should be deleted when completing this application form.

Declaration by the International Society of Biomechanics (ISB):

The ISB is dedicated to supporting international initiatives that will promote research, education, and the provision of healthcare in the field of biomechanics. The objectives of the ISB, with regards to the advocacy of projects in EDC regions, include the following:

- To make the Society truly international.
- To help develop skills of, and/or opportunities for, clinicians and researchers in EDC who do not have the resources available to do so on their own.
- To provide collaborative learning opportunities for students and researchers in developed countries to help them understand the challenges faced in the developing world.
- To enable donating organizations to do something beneficial with equipment that is no longer needed by them.
- To help provide a sustainable initiative that will allow biomechanics skills and knowledge to flourish in developing regions.
- To enable clinicians and researchers in developing countries to solve biomechanics-related problems specific to their own region.

The ISB would like to ensure the long-term sustainability and overall success of all EDC projects. As such, all participants must be clear on the objectives of the EDC participating organization(s) and the supporting organization(s), in addition to the outcomes each party wishes to achieve. This Memorandum of Understanding is intended to help clarify this for all participants. It is also the framework by which the ISB will evaluate the success of the project in the short and long-term and to find out whether the expected outcomes have been achieved, thereby enabling improvement of this process for future projects.

Participants:

Please list all organizations involved in this project (include those that are supporting the EDC participant by way of equipment donations, technical or financial support, or other resources) and their primary contacts.

	Name of Organization	EDC Participant OR	Supporting Organization	Primary Contact(s)	ISB Member Number*	E-mail
1.	*MGM School of Physiotherapy*	☒	☐	*Dr. Rajani Mullerpatan*	*5043*	*rajani.kanade@gmail.com*
2.	*Indian Institute of Technology, Mumbai*	☐	☒	*Prof. B. Ravi* *Mr. Rupesh Ghyar*	*N/A* *In progress*	*b.ravi@iitb.ac.in*
3.	*Cardiff University*	☐	☒	*Prof. Robert van Deursen*	*1974*	*vandeursenR@cardiff.ac.uk*
4.	*International Society of Biomechanics (ISB)*	☐	☒	*John Challis*	*1192*	*jhc10@psu.edu*

* A minimum of one primary contact from each organization must be a member of the ISB.

MGM School of Physiotherapy NAVI MUMBAI

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act)
Navi Mumbai- 410 209

Project Proposal:

To be completed by the **EDC participant**:

1. What is the overall mission of your organization *(e.g. to improve the independence and wellbeing of physically disabled people...)* and how does this project help to support it?

The overall mission of MGMIHS is to provide healthcare services, research and higher education particularly in the area of medicine, nursing, physiotherapy and health management. Within physiotherapy/rehabilitation, training and research in the area of Biomechanics is essential to help maximize functional independence of people with physical impairments resulting from a wide spectrum of conditions i.e. repetitive stress, congenital, developmental and degenerative conditions precipitated by traumatic, vascular and pathologic origin. Precise and complete kinesiological assessment of such conditions will guide clinical decision making for accurate conservative, surgical, prosthetic/orthotic and ergonomic management for maximal functional outcome.

2. What is the primary strategic objective(s) of this project? [Please specify details about one or more of the areas listed below. In formulating your objectives, consider specific results you would like to achieve.]

   a. Teaching/educational programs:

   - To design and seek approval for a postgraduate degree course in Biomechanics designed at a level of global merit (to enable qualified postgraduates to participate in projects conducted worldwide) and local value to meet specific functional needs of our population emerging from a lifestyle influenced by exclusive Indian culture far different from Western lifestyle.
   - Establish training for students from various disciplines such as Physiotherapy, Bio-engineering, Mechanical engineering, Prosthetics - Orthotics and Orthopedics at graduate, postgraduate and PhD level.
   - Enhance skills in clinical biomechanics of faculty members of MGMSOP

   b. Research programs:

   - Produce high end research in the area of human movement science related to clinical questions; to offer health care solutions global in nature and specific to the Indian population.

   c. Clinical assessment – diagnosis and treatment:

   - Provide precise and complete kinesiological assessment of congenital, developmental and degenerative conditions precipitated by traumatic, vascular and pathologic origin which will guide clinical decision making for accurate conservative, surgical, prosthetic/orthotic and ergonomic management.

   d. Other (please specify):

   (Include additional lines if necessary)

3. What initiatives/actions (project design and/or management strategies) will be implemented to achieve the results outlined in Question 2?

a) Teaching/Educational programs:

- Curriculum for postgraduate course in Biomechanics will be designed and sought approval from MGMIHS and IIT Mumbai.

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- A circular will be sent to Bio-engineering, Mechanical Engineering, Prosthetics and Orthotics and Orthopedics departments within the above mentioned Institutes to inform students from respective disciplines training schedule in biomechanics.
- Training will be imparted to faculty members in form of continuing professional development.

b) Research programs:

- Collaborative research projects between the 3 organizations will be developed to produce high end research studies encompassing fundamental and clinical biomechanics. PhD students will be appointed on appropriate research projects. Broad areas of research are-
  i. Barefoot walking and the risk of plantar ulceration (in collaboration with IIT Mumbai, Cardiff University)
  ii. Foot and knee instability and the development of OA (in collaboration with Cardiff University and the University of Sydney)
  iii. Yoga postures and their effect on the musculoskeletal system (in collaboration with IIT Mumbai and Cardiff University)

c) Clinical assessment –

- Diagnosis and treatment: Information pertaining to available clinical biomechanical evaluation tools will be circulated to various departments within and outside the hospital within Mumbai and Navi Mumbai. Referred patients will be assessed using biomechanical tools to arrive at precise measurement of impairments. Income generated through such services will be used for financial viability of the center. Expenses incurred for annual maintenance of laboratory equipment will be covered partly from the income generated by the center and partly from the funding acquired for research projects.

4. Who will benefit from this project? *(e.g. Students, patients, etc)*

- Undergraduate and postgraduate students from Physiotherapy, Bio- engineering, Mechanical Engineering, Prosthetics and Orthotics and Orthopedics department will benefit from training. Training will be imparted to students within India and across continents. Every effort will be made to enroll students from within India and countries abroad.
- Faculty members from MGMIHS will benefit from skill development in clinical biomechanics
- A Biomechanics Center with expert input from biomechanics specialists worldwide operated in India will offer global merit training at subsidized cost thereby making it affordable for students from several developing countries.
- Patients with congenital, developmental and degenerative conditions of traumatic, vascular and pathologic origin will benefit from biomechanical evaluation.

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5. What are the expected benefits for each group listed in Question 4? *(e.g. Exposure to state-of-the-art methods of...)*

- Students will be exposed to globally used state-of-the-art valid and reliable methods used for biomechanical studiessuch as quantitative movement analysis and plantar pressure measurement. They will receive hands-on training and have opportunities to use various biomechanical tools to conduct research in biomechanics. Such training of global merit will be available at affordable cost to students from developing countries.
- Patients will benefit from precise and complete kinesiological assessment which will guide clinical decision making for accurate conservative, surgical, prosthetic/orthotic and ergonomic management.
- Faculty members will benefit from acquiring skills for biomechanical evaluation which will be applied in both clinical practice and student training.
- The biomechanics center will benefit from financial viability through the above mentioned expected benefits.

6. Please list proposed milestones – associated with the actions, individuals, and benefits given in Questions 3, 4, and 5, respectively – together with a timeline of events. Milestones should include specific outcomes that the collaborators wish to achieve.

Key Milestones	Time period
1. Establish Biomechanics Center: installation of equipment and pilot start	*December 2013*
2. Collaborative research projects	*Already started. Ongoing*
3. Design the curriculum for Masters degree course in Biomechanics and seek approval from the above mentioned contributing organizations	*September 2014*
4. Commence the course in clinical biomechanics	*January 2015*
5. Commencement of clinical service to patients	*March 2014 onwards*

7. What other authority/administrative body, such as government or college administration officials, must approve this initiative to ensure resources are allocated to the intended recipients? Has approval already been sought *(please provide evidence of any approvals)*?

- Administrative/competent authorities of 3 above mentioned institutes have approved development of the research activities proposed at MGM Center for Biomechanics.
- Additionally, approval will be sought for curriculum for Masters Course in Biomechanics by University Grant Commission, India and Academic Council of MGMIHS.
- The opportunity to develop and approve transnational education in association with Cardiff University will be investigated.

8. What commitments will your organization make to ensure:
   a. Recognition of contributions provided by supporting organizations? *(e.g. Website acknowledgment, progress reports)*

- Publications and patents arising out of collaborative projects with Cardiff University and IIT Bombay will be shared by all 3 above mentioned organizations.
- MGMIHS will acknowledge the support and contribution provided by IIT

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Mumbai and Cardiff University on its website.

- Technical support provided by IIT Bombay will be acknowledged in relevant presentations and publications.
- Secondly, IIT Bombay will have an opportunity to conduct clinical trials at MGM Center for Biomechanics in collaboration with host organization which will be acknowledged in related reports.
- MGMIHS will acknowledge the support and contribution provided by IIT Mumbai, Cardiff University, ISB and AMTI on its website and in relevant publications
- MGMIHS will provide agreed upon (to be decided) educational materials to ISB to further share with ISB members in support to the EDC educational program
- MGMIHS will provide a brief "Project History" for the ISB website

b. Long-term sustainability of the project (including personnel required to ensure continuation of project into the future)? *(e.g. Staff training, technical support, security and maintenance, etc)*

- The host organization i.e. MGM Center for Biomechanics will provide ongoing security and maintenance of equipment.
- Technical guidance for equipment selection and experimental data analysis will be provided by II Bombay. The equipment maintenance will be sought via annual maintenance contract from the respective vendors.
- Staff training will continue as an ongoing process which will be partially supported by MGM Center for Biomechanics.
- Any agreed joint transnational education programs would facilitate staff development.
- Income generated through clinical services will aid financial viability of MGM Center for Biomechanics. For e.g. annual maintenance of equipment and expenses incurred towards consumables.
- Income generated through tuition fees for Masters Course in Biomechanics and PhD program will partially support salary of some staff members.
- Income generated through any agreed joint initiatives would be negotiated as appropriate.
- PhD students will be recruited as research assistants on certain projects.

Supporting Organizations – Commitments and Anticipated Benefits:

What contributions will be made by the supporting organizations? Please list all support that each participant has agreed to provide *(e.g. financial, in-kind, training, etc)*, the period over which they have committed this support, estimated costs for the organization, and how they will benefit *(e.g. publicity)*.

Organization	Commitments	Duration	Estimated Costs	Objectives/Benefits
MGMIHS	*Allotted infrastructure for Biomechanics Center*	*Ongoing*	*Approx 1 million USD*	*Supports objectives outlined on pg 1.*
	Allotted one competent Professor	*Ongoing*	*Salary is paid by MGMSOP (15,000 USD)*	
	Will recruit one research assistant & one laboratory technician	*Ongoing*	*Salary will be paid by MGMIHS (6000 USD)*	
	Already purchased some equipment such as emed pressure platform, activity monitoring system, Silicon coach etc.			
	Staff training	*2 weeks*		
Cardiff University	*Send Prof. van Deursen for 4-visits*	*4 visits:* *Nov 2013* *May 2014* *Nov 2014* *May 2015*	*Covered by ISB*	*Collaborative Research projects.* *Biomechanics lab design, installation of equipment.* *Provide expertise in curriculum design related to clinical biomechanics.*
IIT Bombay	*Technical guidance and collaborative research projects*	*ongoing*		*Using the MGMIHS Biomechanics lab for purpose of clinical testing of the products which are developed by IIT Bombay.*
ISB	*Financial support to send Prof. van Deursen to MGMIHS*	*4 visits*	*7,503 USD*	*Supports objectives outlined on pg 1; acknowledgment in appropriate media; support for development of EDC educational material.*
	Coordinate donation of two second-hand, re-calibrated force platforms from AMTI with technical support for 5 years	*As soon as available*	*Approx. 30,000 USD*	*AMTI acknowledgment in appropriate.* *MGMIHS and ISB media will strengthen relationship with AMTI.*

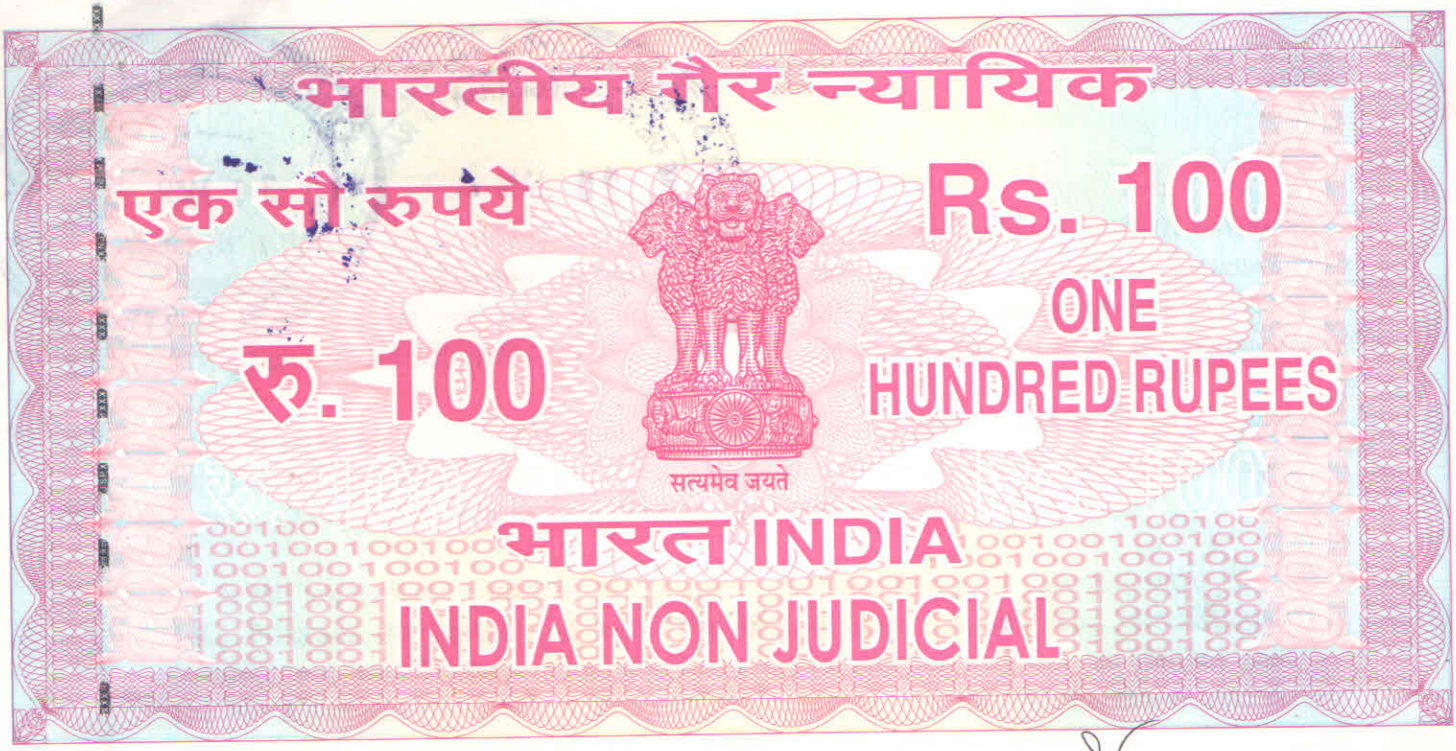
Budget

Before any project can be endorsed by the ISB, a detailed budget for all costs involved for each participating organization must be approved by the ISB President, EDC Project Officer, and ISB Treasurer. In the budget, please consider monetary costs involved in establishing/initiating the project plus ongoing costs to ensure the project is sustainable. Please include the budget as a separate document.

Signatures of primary contact from each participating organization:

Dr. Rajani Mullerpatan	RPMullerpatan	25 July 2013
Name (please print)	Signature	Date
Prof. B. Ravi		1 August 2013
Name (please print)	Signature	Date
Prof. Robert van Deursen		9 August 2013
Name (please print)	Signature	Date
Prof. John Challis		22nd Oct. 2013
Name (please print)	Signature	Date

(Include additional lines if necessary)



తెలంగాణ तेलंगाना TELANGANA

B 506817

Sl. No. 5798 Date 14/05/2015 Rs. 100/-

Sold to Nagendra

S/o Narayana R/o Secbad

For whom M/s IKP Knowledge Park

NAKKA NAGESHWAR
Licensed Stamp Vendor. Lic. No. 15-07-010/2013
Flat No. 211, 2nd Floor, Silver Oak Apartments,
CHERLAPALLY - 500 051 (R.R. Dist.)
Cell : 9949 110 435

Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

For IKP Knowledge Park
Authorised Signatory

GRAND CHALLENGES IN TB CONTROL AWARD AGREEMENT

THIS AGREEMENT is executed at Hyderabad on this 14th day of December 2015

BETWEEN

IKP KNOWLEDGE PARK, a Company registered under the Company's Act, 1956, having its registered office at Genome Valley, Turkapally, Shameerpet, Ranga Reddy District, Hyderabad 500 078 hereinafter referred to as 'IKP' or 'IKP Knowledge Park' (which expression shall mean and include unless repugnant to the context, its successors, assigns and legal representatives) of the ONE PART represented by its authorized representative, Mrs Deepanwita Chattopadhyay, Chairman & CEO.

AND

MGM Institute of Health Sciences, a deemed university registered under Section 3 of UGC Act, 1956, and having its registered office at MGM Institute of Health Sciences, MGM Educational Campus, Sector - 1, Kamothe, Navi Mumbai 410 209 referred to as the 'Recipient' (which expression shall mean and include unless repugnant to the context, its successors, assigns and legal representatives) of the SECOND PART, represented by its authorized representative, Dr. Sudhir N Kadam, Vice Chancellor

For IKP Knowledge Park
Authorised Signatory

Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

ANNEXURE 3

AWARD NO: GCTBC/C2P1/2015/.12/14/06.....

RECIPIENT: "Non-Invasive TB Triage and patient mapping platform using breath via low-cost Titanium Dioxide Nanotube Sensor"

Expense Heads / Month	1	2	3	4	5	6	7	8	9	10	11	12	Total
Capital Expenses	1,520,000												1,520,000
Rentals													-
Consumables	245,000			500,000		425000							1,170,000
Salaries	80000	80000	80000	80000	80000	80000	80000	80000	80000	110000	110000	110000	1,050,000
IP / Legal Expenses													-
Travel	37500	37500	37500	37500	37500	37500	37500	37500	37500	37500	37500	37500	450,000
Test setup													-
Contingency			50000			50000			50000			50000	200,000
Volunteer Compensation			120000			120000			120000				360,000
Utilities	20000	20000	20000	20000	20000	20000	20000	20000	20000	20000	20000	20000	240,000
												Total	4,990,000
Milestone 1		Approvals & Design of trials											
Milestone 2				Healthy volunteers tested									
Milestone 3							Groups 2 to 5 tested						
Milestone 4										Completion of data collecction			
Milestone 5												Final Report	

Budget:

*Excluding service tax

** Regarding Host Government taxes refer 17(C)(1)(C)

B. Funds Disbursement:

Disbursement will be made in 6 tranches at the following times -

Signing of contract - 40%

Month 2 - 20%

Month 4 - 15%

Month 7 - 10%

Month 10 - 10%

Completion of project - 5% **

Expenses will be reimbursed at cost. Recipient will invoice IKP Knowledge Park with service tax as applicable prior to each tranche. Payment to the Recipient shall be subject to deduction of taxes and levies, as applicable from time to time under various laws in India. Payment to the Recipient by IKP shall be released after verification of the Milestones and expenses incurred. In the normal course payment will be released within 30 days from the date of receipt of the Invoice/Bill along with the requisite documents, complete in all respects.

For IKP Knowledge Park

Authorised Signatory

Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s GC Act, 1956)
KAMOTHE, NAVI MUMBAI

All amounts will be credited by IKP Knowledge Park to the no lien current account No. 0183104000236140 of MGM Institute of Health Sciences, IDBI Bank, IFSC Code IBKL0000183

For IKP Knowledge Park

Authorised Signatory

Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s [illegible]C Act, 1956)
KAMOTHE, NAVI [illegible]BAI

L'INSTITUT INDO-CANADIEN SHASTRI INDO-CANADIAN INSTITUTE

SHASTRI RESEARCH GRANT (SRG)
Final Report 2015-2016

This report contains three sections, i.e. Section A , B and C.
Section A is to be filled in by the Lead Applicant (and Co-Applicant).
Section B and C are to be filled in by the Canadian and Indian Student/ Research Assistant respectively (when applicable).

SECTION: A

1	Name of Lead Applicant: Dr. Andrea Hemmerich Telephone (land): 613-533-2648 Mobile: 613-301-6354 Fax: 613-533-6489 E-mail: andrea.hemmerich@queensu.ca	Name of Co-Applicant: Dr. Nancy Fernandes Pereira Telephone (land): 91-022-22031879/22087422 Mobile: 9820524750 Fax: 22087422 E-mail: nancyfernandesltcn64@gmail.com
	Name of Lead Applicant's Institution: Queen's University Mailing Address of Lead Institution: 130 Stuart St., Kingston, ON, K7L 3N6, Canada	Name of Co-Applicant's Institution: S.N.D.T. Women's University Mailing Address of Co-Applicant's Institution: Leelabai Thackersey College of Nursing, S.N.D.T.Women's University, New Marine Lines, Churchgate, Mumbai 400 020
2	Name of Canadian student or research assistant (if any): Ms. Emily Geens	Name of Indian student or research assistant (if any): Ms. Shobha Gaikwad
	Name of the Institution: Queen's University Academic Level: Undergraduate Subject of Study: Kinesiology (continuing in Midwifery) Mailing Address : Kingston ON Telephone (land): Mobile: Fax: E-mail: 12elsg@queensu.ca	Name of the Institution: Leelabai Thackersey College of Nursing,S.N.D.T.Women's University,New Marine Lines,Churchgate,Mumbai 400 020 Academic Level: PhD Subject of Study: Labour comfort- Obstertric Nursing Mailing Address : Same as above Telephone (land): 91-022-22031879/22087422 Mobile: 9892130703 Fax: 22087422 E-mail: shobha.gaikwad14@gmail.com
3	Project Title: The effects of labour and birth positioning on pelvic dimension: gaining further insight to improve the birth experience	
4	Project Period: From: Jan 2016 To: Nov 2016	

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
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Navi Mumbai- 410 209

MGM School of Physiotherapy NAVI MUMBAI

3	Project Title: The effects of labour and birth positioning on pelvic dimension: gaining further insight to improve the birth experience	
4	Project Period: From: Jan 2016 To: Nov 2016	
5	a) Please give a brief summary of your project including key research questions.(300 words) Obstructed labour is a leading cause of maternal and newborn mortality. In India where maternal mortality rates are among the highest globally, squatting – a position shown to increase pelvic dimensions – is also more common during daily life. The primary objective of this project was to use a motion capture device to investigate the effects of birthing position on pelvic dimensions in a group of non-pregnant, Indian subjects. A secondary objective was to better understand rural Indian women's current experiences and aspirations around childbirth. A human motion analysis study conducted at the MGM Centre of Human Movement Science (India) will enable calculation of clinically-relevant pelvic dimensions from digitized landmarks using an optical motion capture system. Dynamic analysis of motion, including joint loading and muscle activity, will help explain pelvimetry findings. Three-dimensional positional information generated by the MRI will be used to validate the pelvimetry measurements from motion capture equipment in upright and supine positions. A field study in the rural community of Wauanje allowed investigators to gain insight into actual practices related to childbirth in rural India; women who had recently given birth and obstetrics care providers within the community were asked to guide us through their birth experiences. b) Please describe the major findings-results. (350 words) A) Human motion analysis Magnetic resonance imaging (MRI) data were collected from three participants at Queen's University's MRI Facility. MRI measurements have demonstrated an increase in all pelvic dimensions in the kneel-squat position (used to simulate an upright birth posture) when compared with supine. The largest increase in the sagittal plane was the anteroposterior outlet (0.45 cm) and in the transverse plane the bituberous diameter (0.25 cm). Analysis of laboratory digitizing trials from which pelvimetry measurements are estimated must be further refined to improve accuracy in all positions. Data from three participants demonstrate the greatest consistency between MRI and laboratory measurements in the standing and lithotomy positions. Preliminary results from motion trials show substantial hip and lumbosacral joint extension moments in squatting (greater than 100 Nm and 60 Nm, respectively), while a flexion moment is exhibited at the lumbosacral joint in the all-fours position. Such moments could potentially open the pelvic outlet in squatting while increasing the inlet anteroposterior diameter in all-fours. Further analysis is required to evaluate forces acting on the pelvis in the supine position. Laboratroy digitizing and motion analysis data have been collected from 30 participants to date. B) Perceptions of childbirth in a rural Indian community Interviews were conducted with five healthcare personnel -- including one auxiliary nurse midwife (ANM) and four accredited social health activists (ASHA workers) -- as well as seven mothers in Wavanje village's community centre. Mothers generally described pleasant experiences; the ANM with over 30 years of experience and ASHA workers described normal deliveries without complications and were confident with their skills. Delivery positions were always supine (lying on their backs); neither care providers nor women were aware of other methods of delivery. A tour of the primary health sub-centre in the village revealed sparse surroundings with only the bare minimum in medical technology resources. Only one labour room and one small delivery room having two beds was available for a community serving approximately 4000 people. Pharmacological pain medication is not available at the sub-centre and women have very little space to move around once inside the facility. Instrumental deliveries, including caesarean section, were not conducted at the sub-centre, but rather at the tertiary care facility, MGM Hospital, Kalamboli, located half an hour away from the village. c) How did you measure the results? (250 words) A) MR images were acquired using a 3-Tesla Siemens scanner from each subject in two positions: kneel-squat (yoga child's pose) and supine. Images were segmented and 3D reconstructed using Mimics software. Clinically	

	Number of Canadian faculty members visiting to India	1 Postdoctoral fellow. (1 faculty member's visit was supported by a separate grant)
	Number of Indian faculty members visiting to Canada	0
	Number of Canadian and Indian students or research assistants involved in your project (if any)	1 Canadian, 4 Indian
	Number of Canadian students visiting India (if any)	0
	Number of Indian student visiting Canada (if any)	0
8	What are your plans for your institutions' future research collaboration based on the activities completed under this project? Further addressing maternal health through women's empowerment, for example, introducing women to squatting position during delivery in rural Indian community (teach and facilitate delivery in squatting position).	
9	What other research collaboration activities are being planned by your institution over the coming 12 to 18 months? 1. Further qualitative field work. Possibilities include: - interviewing Indian women and care providers who have experienced complications during childbirth that occur more commonly in India; - comparison with Canadian women's experiences; - comparative study of birthing experience among two different economic strata. 2. Refinement of quantitative analysis methods; finalizing analyses of quantitative data.	
10	Please describe how dissemination of project information and showcasing of research/project results are done at various levels throughout the project period. (400 words) Local (Canada) - presentations at Queen's University, Ottawa Birth and Wellness Centre; Local (India): - Wauanje Community Centre; plan to conduct a workshop to disseminate the findings to health care providers so that it can be incorporated into practice. - Presentations and discussions with students at SNDT Women's University and MGM Institute of Health Sciences about the research. International - ISB2017 conference, peer-reviewed journals (not during project period).	
11	Is there any success stories with your research/project that you would like to share? Please attach relevant photographs. The seed for this project was initially planted before the birth of my daughter while considering the link between various cultural birthing practices and biomechanical benefits to maternal health. Including the qualitative research component to ensure the relevance and long-term impact of the overall project was crucial. The three-way collaboration between Nancy Fernandes Pereira (SNDT University), Rajani Mullerpatan (MGM Inst of Health Sciences), and my postdoctoral supervisor and I at Queen's University was actualized through the Shastri Research Grant. Travelling to India to meet with my collaborators solidified our mutual understanding of goals and strategies and allowed me to better understand the context of our work. This collaboration was further enhanced through new relationships developed with students and colleagues of the primary collaborators, which will -- undoubtedly! -- pave the way for future research together. - Andrea Hemmerich, August 2016 (Photograph of collaborators prior to Wauanje village visit in April is attached.)	
12	Were there any reports, publications or other educational materials produced as a result of the project? If so, please attach a copy of these documents to your report (Please note that the Institute reserves the right to use relevant information from those documents in its public communication without any further consultation) SNDT report (attached); Conference and journal publications for both qualitative and quantitative parts of the study are anticipated.	

13	Please attach 2-3 high resolution digital photographs from your SRG project that could be featured in the Shastri Institute's public communication (i.e., annual report, newsletters, etc.) Photos attached: Yes: Yes
14	Please provide a quote based on the experience of your SRG project work that could be used by the Institute for the above purposes. Simplicity of expectation and experience of birthing: a natural process (as viewed by women in rural India). The SRG provided an opportunity for both Canadian and Indian researchers to understand women's birthing experiences from a cultural and biomechanical perspective.
15	**Please note the following for your Financial Reporting:** - **Fill in and attach the financial report form available on the website.** - **Submit scanned copies of all invoices and proof of payments to support your financial report.**
16	Signatures

Signature of Lead Applicant	Signature of Co-Applicant
Date: 07 DEC 2016.	**Date:** 07 Dec 2016

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act)
Navi Mumbai- 410 209

UNIVERSITY OF UTAH SUBCONTRACT

NO. 10040842-01

BY AND BETWEEN

THE UNIVERSITY OF UTAH

AND

SUBCONTRACTOR

This subcontract (Subcontract) is entered into and effective as of Jan. 27th, 2016 by and between the University of Utah, an institution of higher education for the State of Utah ("University") and Mahatma Gandhi Mission Institute of Health Sciences having their principal place of business at MGM Educational Campus, Sector-1 Kamothe, Navi Mumbai 410209("Subcontractor").

RECITALS

WHEREAS, University wishes to have certain services performed in accordance with the scope of work outlined in this Subcontract; and

WHEREAS, the performance of such services is consistent, compatible and beneficial to the role and mission of Subcontractor; and

WHEREAS, Subcontractor is qualified to provide such services required under this Subcontract.

AGREEMENT

NOW, THEREFORE, for and in consideration of the mutual covenants, conditions and undertakings herein set forth, the parties agree as follows:

1. Scope of Work: Subcontractor agrees to perform for University certain services ("Services") described in the Scope of Work set forth in Appendix A, which is attached hereto and incorporated herein by this reference.

2. Period of Performance. This Subcontract commences on January 27, 2016 and will continue until January 31, 2017("Project Period").

Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Dean
MGM Medical College, Navi Mumbai

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Budget

Sr. No.	Staff	Cost US $
1	Staff Salary, Compensation, Honorarium	44,400
2	Chemicals , Consumables, Test	30,000
3	Transportation of samples, Travel by Investigators	10,600
4	Volunteer Compensation	8,000
5	Ethical Committee Fee	750
6	Insurance	750
7	Overhead	5,550
	Total	1,00,000

The total budget for the project is $1,00,000 and will be allocated based on the milestones as follows:

- Subcontract $ 50,000
- Milestone 2 $ 45,000
- Milestone 3 $ 5,000

Exhibit B – Background IP

IP Owned by the University

- PCT Patent Application: PCT/US2013/067319
  - Titled: Functionalized nanotube sensors and related methods (filed October 29, 2013)
- Trade secrets
  - Titanium dioxide nanotube sensor production and manufacturing
- Data Platform:
  - IP related to the storage, transmission, or mapping of TB data.

IP Owned by Subcontractor

Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

(16)

Grand Challenges Canada™
Grands Défis Canada™

Progress Report (RMAF and PF)

General Information (all blue cells are required)

Funding number	R-ST-POC-1808-17043
Program	STARS IN GLOBAL HEALTH HEALTH ROUND 9
Legal (official) name of Institution/ Organization	MGM INSTITUTE OF HEALTH SCIENCES
Project title	Project 'inj-TR2SERVE': A comprehensive program to train, triage, and improve services for unintended childhood injuries in India

Name of Project Lead 1	First:	MANINDER SINGH	Last:	SETIA
Name of Project Lead 2	First:		Last:	
Project Team	First:	PAUL	Last:	BRASSARD
	First:	BAGESHREE	Last:	SETH
	First:	REVATHY	Last:	N
Project Period	Start:	1-Apr-18	End:	31-Jul-19
Duration of project (in months)	18			
Was a no-cost extension approved? If Yes, updated end-date?	Y/N	N	End:	
Reporting Period	From:		To:	
Date report updated				
Funding Amount (CAD)	98545			
Project currency	INDIAN RUPEE			
Project Lead Country	INDIA			
Implementation Country(ies)	INDIA			
Project Overview	We propose to develop a computer and mobile application that will help in effective recording, care, and management of unintended childhood injuries. We also plan to develop training programmes for parents, teachers, and community members to prevent injuries at these places. We will also train health care workers for effective management of these injuries			
For Internal Use Only:	Health Priority		Health Platform	

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Testing Agreement

This Testing Agreement ("**Agreement**") dated 13th day of September Two Thousand Eighteen ("**Effective Date**")

by and between Sancheti Institute College Of Physiotherapy, Sancheti Healthcare Academy, 12, Thube Park, Shivajinagar, Pune – 411005 represented by its authorized signatory Dr Nilima Bedekar **(Hereinafter referred to as the Institute)**

AND

MGM Institute of Health Sciences, Navi Mumbai through the MGM School of Physiotherapy having its office at MGM Educational Campus, Sector 1, Kamothe, Navi Mumbai, 410209 **(Hereinafter referred to as the Organization).**

WHEREAS

1. The Institute has submitted an exercise protocol which involves three types of Suryanamaskar namely traditional, chair and wall Suryanamaskar (the "**Exercise protocol**") which could be used for enabling mobility in persons with impairments (the "**Purpose**")

2. Dr Apurv Shimpi(PT), Professor, from Sancheti Institute College Of Physiotherapy, Sancheti Healthcare Academy, Pune at the Institute together with certain research scholars at the Institute have developed the Exercise Protocol, the intellectual property which is owned exclusively by the Institute.

3. The Institute contemplates that after the development of the **Exercise protocol**, it will be necessary to test the said **Exercise protocol** in certain controlled conditions (the "**Testing**").

4. The Organization has the facilities to conduct the test and is willing to participate in the Testing of the **Exercise protocol** with the Institute upon terms and conditions as set out herein. The Institute has inspected the said available infrastructure, facilities, interacted with the staff and employees, is satisfied with and has approved the same.

The Parties hereto have therefore mutually agreed as follows:

1. SCOPE OF WORK

1.1 Conduct of the Testing.

The parties agree to conduct the Testing in a controlled environment based upon the

terms and conditions contained in this Agreement and in terms of the protocol to be mutually agreed between the Institute and the Organization prior to the time of the Testing. The organization shall get clearance from the Institutional Review Board and Ethics committee and communicate the same to the Institute, which will be final and binding on both the parties.

1.2 Care and Skill:

The Organization, its employees and staff will:-

a) exercise all due care, diligence and skill necessary for carrying out testing activities;
b) use reasonable endeavours to complete the agreed work within the time specified or extended time as agreed by the parties in writing;
c) allocate sufficient staff time during one year between January 2018 to December 2018 (amounting to 360 hrs/ 50 working days) (with suitable qualification/experience) for the testing;
d) obtain the Informed Consent of the concerned participants ;
e) keep the records of the participants and the Institute confidential;

1.3 Principal Investigator.

Dr. Apurv Shimpi, Professor, Sancheti Institute College Of Physiotherapy, of the Institute will serve as the principal investigator ("**Principal Investigator**") for the Testing. The Principal Investigator is not a party to this Agreement and acts solely as an employee of Institute.

1.4 The Institute will supply the necessary materials to conduct the Testing, and also information for the purpose of the Testing. The Organization is responsible for proper conduct of the Testing under the supervision of its domain expert. The parties agree that their respective authorized representative shall remain present at the time of testing, participate therein and sign the daily report/daily work done report as a mark of approval of the quality and procedure of testing done by the Organization. The said daily report/daily work done report shall be evidence of the fact that the testing has been done as per the approved procedure, methods and standards operating procedures of MGM Center of Human Movement Science, Navi Mumbai.

1.5 The Organization shall provide a list of participants who have provided their written consent for participating in the testing of the Exercise Protocol after being informed by the organization of the Exercise Protocol , its purposes, the probable inherent risks involved in the use of the Exercise Protocol etc (the "**Informed Consent**") to the Testing of the Exercise Protocol. The Organization acknowledges that it has been and shall ensure that it will fully inform the participants about the Exercise Protocol, the Testing Protocol and the Purpose of the Exercise Protocol before obtaining the participants Informed Written Consent. The Testing Protocol will contain the details of the number of Exercise Protocols to be used during the Testing. The written consent format as approved by the parties hereto and generally accepted by the Ethical Committee for Research on Human Subjects, MGMIHS is enclosed herewith. A short write up of the information (as approved by the parties) to be provided to the participants is annexed hereto as Annexure 1.

1.6 Testing Report.

All the reports (including the Testing Report) testing data and materials used for the purpose of this Agreement shall be owned by the Institute and the Organization. With the prior mutual consent, the Institute or the Organization may use the Testing Report for any purpose as deemed necessary including internal research, teaching, archival purposes and publication. The Organization will keep, maintain and regularly update the testing report and shall upon demand in writing by the Institute, through their authorized representatives provide copies as requested. The final testing report will be submitted to the Institute as required by the Institute. The Organization will create a testing report at the beginning of the Testing and will include in the report the details in terms of the Testing Protocol including outputs of the Testing, financial reports, the originals of the Informed Consent obtained, comments from the participants etc (the "**Testing Report**").

2. MEETING OF THE EXPENSES

Costs and Expenses.

The Institute will pay an amount of INR 86,000 (50% of the cost of testing which is INR 1,72,000) at the time of signing the agreement. Further, the Institute will meet the costs of testing (to the extent of the approved budget), within a period of 30 -45 days from date of receipt of the bills from the Organization. The payments shall be made in the name of MGM Centre of Human Movement Science. The Institute agrees and undertakes to pay interest @ of 18% for the delay in payment of the bills beyond the period of 45 days from the date of receipt of the bills from the Organization.

3. INTELLECTUAL PROPERTY

3.1 Pre-existing Intellectual Property.

Ownership of inventions, discoveries, works of authorship, and other developments existing as of the Effective Date and all patents, ("**Pre-existing Intellectual Property**") is not affected by this Agreement. Neither party shall have any claims to or rights in any Pre-existing Intellectual Property of the other party, except as may be expressly provided in any other written agreement between the parties.

3.2 Intellectual Property Agreements.

Intellectual Property (IP) generated as part of or as a consequence of the Testing shall be jointly owned by the parties. The Organization and the Institute will inform each other if any IP is created and will co-operate and provide consent for sharing of IP rights, making applications for registration including provisional registration etc.

4. TESTING DATA

4.1 Testing Data.

Organization shall own and maintain all the Testing results and may use it for any purpose including for research, teaching, educational, archival or auditing purposes. Original Testing data in entirety remains the sole property of the organization. The Institute cannot share these results with any third party without prior written consent of the Organization.

4.2 Exercise Protocol for Testing.

Institute shall provide the Exercise Protocol to enable the Organization to conduct the Testing. The Organization is responsible for proper conduct of the test under the supervision of domain expert. Title and ownership of the **Exercise Protocol** will at all times remain with the Institute.

5. CONFIDENTIAL INFORMATION

5.1 Institute and Organization recognize that conducting the Testing may require the transfer of confidential or proprietary information between the parties. All documents, information, materials and data provided to Organization by the Institute will be considered confidential information of the Institute only if marked as "confidential" ("**Confidential Information**"). The Organization shall ensure that the information is shared only with those employees, staff or parties who have a need to know the Confidential Information and shall procure confirmation that all such parties agree to be bound by this Confidentiality Clause and terms of this Agreement. In consideration of the disclosure of any Confidential Information to the other, the Institute and the Organization agree that, for a period of this Agreement, which is one year from January 2018 to December 2018, and for a further period of three (3) years from the date of expiry of this Agreement, they will:

(a) Not use the Confidential Information except as allowed in this Agreement;
(b) Not use the Institute's Confidential Information without an appropriate participant authorization and/or consent and as allowed in this Agreement.
(c) Not disclose to third parties any of the Confidential Information belonging to the other party without the express written consent of the disclosing party except in accordance with this Agreement; and
(d) Take precautions as normally taken with the receiving party's own confidential and proprietary information to prevent disclosure to third parties.

5.2 The obligation of confidentiality does not apply to Confidential Information that is:
(a) publicly available through no fault of recipient;
(b) disclosed to the recipient by a third party;
(c) already known to the recipient at the time of disclosure;
(d) developed by the recipient without reference to the Confidential

Information; or

(e) required to be disclosed by law, regulation, or court order.

For the purposes of this Agreement, the Testing Report shall be deemed to be the Confidential Information of the Institute, however original data in entirety shall be deemed to be Confidential Information of the Organization.

6. PUBLICATION

6.1 The basic objective of research activities at Institute is the generation of new knowledge and its expeditious dissemination for the public's benefit. Organization will provide all reasonable cooperation with Institute in meeting this objective.

6.2 Notwithstanding any terms to the contrary in this Agreement, Institute and Organization retain the right at their discretion to publish/present results of the Testing with mutual consent. The parties agree that the publication is a joint publication.

7. TERMINATION

The Testing will continue until the Testing is completed by the Organization or to the maximum limit of one year extending from January 2018 to December 2018. Similarly the termination can be done by the Organization, if the Institute fails to make payment of bills within the specified period of 30—45 days after testing, from the date of receipt of the bill by the Institute, or if the Institute fails to provide appropriate and proper information for carrying out the testing, or for any breach of the terms of this testing agreement and it becomes effective upon e-mail communication from the person who had signed this agreement or equivalent or above authorized person. The Institute may terminate this Agreement if the Organization breaches this Agreement or does anything to delay or hinder the Testing process; termination will be immediately effective upon the receipt of written notice from the Institute to the Organization. It is further provided that such notice will not be served unless there is serious breach by the Institute.

8. NOTICES

Any notices given under this Agreement will be in writing and delivered by e-mail or speed post or by hand addressed to the parties as follows:

Sancheti Institute College of Physiotherapy,
Sancheti Healthcare Academy,
12, Thube Park, Shivajinagar, Pune – 411005

MGM School of Physiotherapy
MGM Institute of Health Sciences
Sector 1, Plot No 1&2,Kamothe, Navi Mumbai, India

9. PUBLICITY

9.1 Neither party will identify the other in any promotional advertising or other promotional materials to be disseminated to the public or use the name of any faculty member, employee, or student or any trademark, service mark, trade name, or symbol of the other, including without the other party's prior written consent.

9.2 Notwithstanding anything to the contrary, Organisation agrees to allow publicly registered information about the Testing to appear on Institute Directory website.

10. INDEMNITY

The Institute will indemnify and hold harmless the Organization, its employees, Investigator, staff and students from any loss, damage, claim (including legal costs) that may arise due to the negligence or default of the Organization.

11. NO WARRANTIES

The Institute/Organization make no warranties, express or implied, as to any matter whatsoever, including, without limitation, on the Exercise Protocol or the results of the testing or any invention, process or product, whether tangible or intangible, conceived, discovered, or developed by it.

12. LIMITATION OF LIABLITY

The Organization shall not be liable for any indirect, consequential or other damages suffered by Institute or any of the testing participants including, damages arising from loss of data or delay or termination of the testing, or from the use of the results of the testing, or any such invention or exercise protocol.

13. FORCE MAJEURE

The parties will not be liable for any failure to perform as required by this Agreement, if the failure to perform is caused by circumstances reasonably beyond Organization's control, such as accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, thefts, or other such occurrences.

14. MISCELLANEOUS

14.1 **Assignment.** Neither party may assign this Agreement without the prior written consent of the other party.

14.2 **Survival.**

Any of the sections that include any other rights and obligations under this Agreement which by their nature should survive, shall survive the expiration or termination of this Agreement.

14.3 Divisibility.
If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable, such provision will be divisible from this Agreement and will be deemed to be deleted from this Agreement. If such deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the parties.

14.4 Independent Contractors.
Institute and Organisation are independent contractors and neither is an agent, joint venture partners, or partner of the other.

14.5 Order of Precedence.
In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated herein or any other agreement concerning this Testing between the Parties and their employees, the terms of this Agreement will prevail.

14.6 Entirety.
This Agreement represents the entire agreement and understanding between the parties and their employees with respect to its subject matter and supersedes any prior and/or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

14.7 Amendments.
The Amendments or changes to this Agreement must be in writing and signed by duly authorized representatives of the parties.

14.8 Counterparts.
This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same Agreement, and the signature pages from any counterpart may be appended to any other counterpart to assemble fully executed counterparts.

IN WITNESS WHEREOF, these duly authorized representatives of the parties hereby execute this Agreement, including all the terms and conditions which follow.

Sancheti Institute College Of Physiotherapy
Sancheti Healthcare Academy,
12, Thube Park, Shivajinagar,
Pune – 411005

MGM Institute of Health Sciences,
Navi Mumbai

Mrs. Nilima Bedekar
Sancheti Institute College of Physiotherapy
16, Shivajinagar, Pune - 5.
PRINCIPAL

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Name : Dr Nilima Bedekar

Designation : Principal

Date : 15/10/2018

Dr Rajesh Goel

Registrar

28/9/2018

Principal Investigator

Institute:

Name : Dr. Apurv Shimpi
Department :
Sancheti Institute College Of Physiotherapy , Pune

Date : 15/10/2018

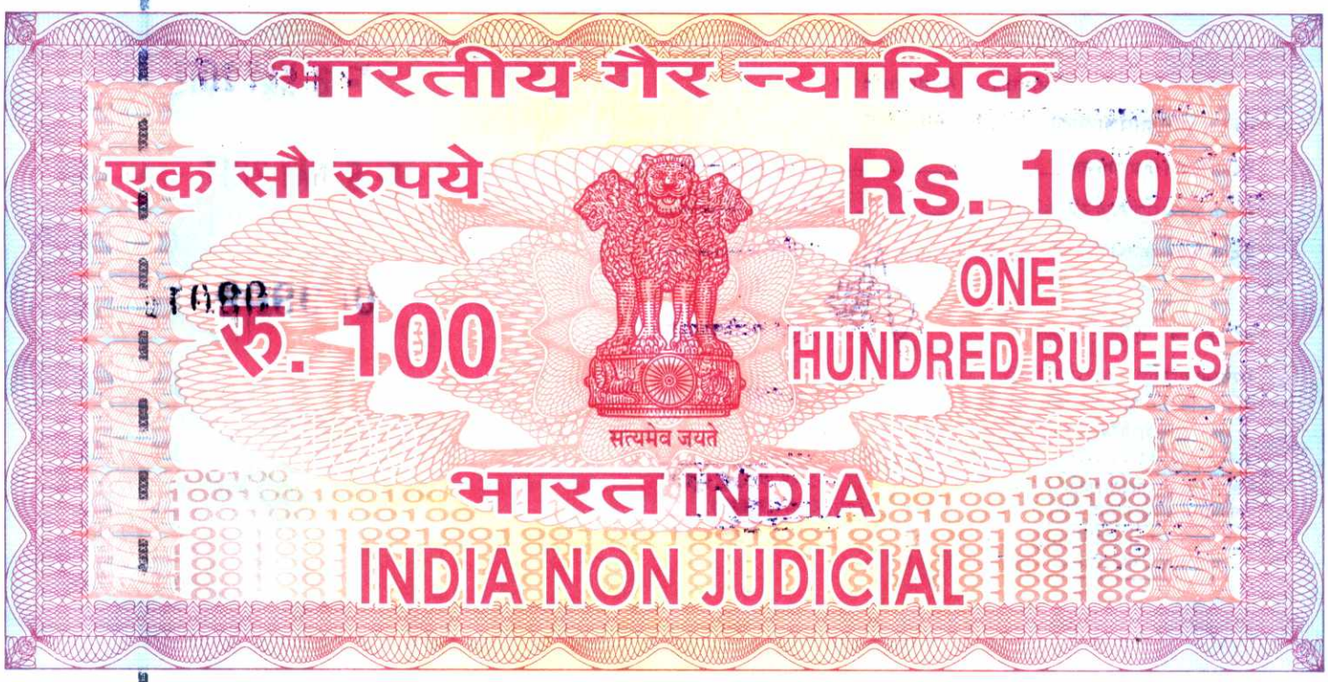
Organization:

Dr. Rajani Mullerpatan

MGM School of Physiotherapy, Navi Mumbai.

Professor - Director
MGM School of Physiotherapy
MGMIHS, Navi Mumbai

Date : 28-9-2018



महाराष्ट्र MAHARASHTRA ◑ 2017 ◑ RW 447661

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. ८०००००३
- 5 MAY 2017
सक्षम अधिकारी

AGREEMENT FOR FUNDING/ FACILITATING INVESTIGATOR INITIATED STUDY

प्र. ज. को. पाटील

This Funding / Facilitating Investigator Initiated Study agreement ("Agreement") is made as of this 05th day of May 2017(the "Effective Date") by and among

Wockhardt Limited a Company organized and existing under the Indian Companies Act, 1956 and having its registered office at D-4, MIDC, Chikalthana, Aurangabad-431006, and Global headquarters at Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai – 400 051, which expression shall unless repugnant to the context or to the contrary to the meaning thereof, be deemed to mean and/or include its successors in business and permitted assigns ("Wockhardt") and

Dr Nimain C Mohanty associated as Professor of Paediatrics with Mahatma Gandhi Medical College (MIHS) situated at Sector 1 Kamothe, Navi Mumbai 410209, Maharashtra India.

Wockhardt is a pharmaceutical Company engaged inter alia in the business of manufacturing and/or marketing of various active pharmaceutical ingredients and pharmaceuticals in finished dosage forms.

Investigator is an individual from a health care institution engaged inter alia in the business of undertaking clinical studies including but not limited to Interventional clinical studies, Prospective observational clinical studies, Retrospective (records based) human subject research. Investigator has also represented that it has obtained all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement and that all such licenses, authorizations and permissions are in full force and effect, at present and during the term of this agreement.

For Investigator Initiated Study (IIS), Wockhardt would fund/ facilitate the Investigator Initiated Study in form of Grants, investigational products, resources, materials or support in developing study documents and/ or manuscript/ poster based on the study results IIS from time to time, to support the conduct of investigator-initiated study entitled "A prospective, randomised, parallel group, single centre study to evaluate efficacy & safety of Bacillus clausii (2 Billion Spores per 5 mL) suspension as an add on therapy to standard of care in acute viral diarrhea in children" by the Investigator at the Institution.

Wockhardt, Institution and Investigator agree as follows:

I) Responsibilities of Investigator and Institution

a. The Investigator shall conduct IIS (as defined below) at the Institution mutually agreed upon by Wockhardt and Investigator specified in writing from time to time, in accordance with this Agreement, IIS proposal, Protocol for the study, Good Clinical Practices (GCP) and all applicable laws, rules and regulations and with the standard of care customary in the area of clinical research.

b. Institution will ensure that the investigator complies with Institution's policies and procedures, including any applicable financial policies as well as applicable regulations. Institution will notify Wockhardt if there is any conflict between the terms of this agreement or any Investigator Initiated Study (IIS) Concept/ Proposal form and any such policy or procedure or applicable regulations and the parties will attempt to reach and appropriate accommodation.

c. IIS will be conducted by the investigator at the institution with the necessary prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all requirements of the institution and all applicable laws and regulations.

d. Each IIS would be conducted in accordance with the protocol developed by the Investigator. If required, Investigator can also request Wockhardt to extend its support in protocol and other essential document preparation on submission of its idea or proposal in "Outline of Investigator Initiated Study (IIS) Concept/ Proposal" form.

e. Investigator agrees not to implement any deviation from or changes to the Protocol without prior ethics committee approval, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study.

f. Investigator shall promptly report to Wockhardt any significant developments that may occur during the Study, including but not limited to adverse events, serious adverse events related to Wockhardt's investigational product. In case of serious adverse events, Investigator shall address any further information request by Wockhardt's Pharmacovigilance department to meet applicable regulatory requirements.

g. Investigator and the institution agree to permit representatives of Wockhardt and other regulatory authorities having jurisdiction over the Study to examine at any reasonable time during normal business hours (i) the facilities where the Study is being conducted, (ii) raw study data and (iii) any other relevant information necessary for Wockhardt or other regulatory authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations. Investigator shall notify Wockhardt immediately if regulatory authority schedules or, without scheduling, begins such an inspection.

Investigator is an individual from a health care institution engaged inter alia in the business of undertaking clinical studies including but not limited to Interventional clinical studies, Prospective observational clinical studies, Retrospective (records based) human subject research. Investigator has also represented that it has obtained all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement and that all such licenses, authorizations and permissions are in full force and effect, at present and during the term of this agreement.

For Investigator Initiated Study (IIS), Wockhardt would fund/ facilitate the Investigator Initiated Study in form of Grants, investigational products, resources, materials or support in developing study documents and/ or manuscript/ poster based on the study results IIS from time to time, to support the conduct of investigator-initiated study entitled "<<IIS project title>>" by the Investigator at the Institution.

Wockhardt, Institution and Investigator agree as follows:

I) Responsibilities of Investigator and Institution

a. The Investigator shall conduct IIS (as defined below) at the Institution mutually agreed upon by Wockhardt and Investigator specified in writing from time to time, in accordance with this Agreement, IIS proposal, Protocol for the study, Good Clinical Practices (GCP) and all applicable laws, rules and regulations and with the standard of care customary in the area of clinical research.

b. Institution will ensure that the investigator complies with Institution's policies and procedures, including any applicable financial policies as well as applicable regulations. Institution will notify Wockhardt if there is any conflict between the terms of this agreement or any Investigator Initiated Study (IIS) Concept/ Proposal form and any such policy or procedure or applicable regulations and the parties will attempt to reach and appropriate accommodation.

c. IIS will be conducted by the investigator at the institution with the necessary prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all requirements of the institution and all applicable laws and regulations.

d. Each IIS would be conducted in accordance with the protocol developed by the Investigator. If required, Investigator can also request Wockhardt to extend its support in protocol and other essential document preparation on submission of its idea or proposal in "Outline of Investigator Initiated Study (IIS) Concept/ Proposal" form.

e. Investigator agrees not to implement any deviation from or changes to the Protocol without prior ethics committee approval, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study.

f. Investigator shall promptly report to Wockhardt any significant developments that may occur during the Study, including but not limited to adverse events, serious adverse events related to Wockhardt's investigational product. In case of serious adverse events, Investigator shall address any further information request by Wockhardt's Pharmacovigilance department to meet applicable regulatory requirements.

g. Investigator and the institution agree to permit representatives of Wockhardt and other regulatory authorities having jurisdiction over the Study to examine at any reasonable time during normal business hours (i) the facilities where the Study is being conducted, (ii) raw study data and (iii) any other relevant information necessary for Wockhardt or other regulatory authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations. Investigator shall notify Wockhardt immediately if regulatory authority schedules or, without scheduling, begins such an inspection.

h. Investigator agrees to maintain records and data related to the IIS in compliance with all applicable laws and regulations.

i. An adverse event is considered to be an unintended and noxious clinical occurrence or laboratory test result observed in a Subject receiving a drug, which is related in time but not necessarily caused by the administration of the Study Material. It is considered as "serious" if the adverse event is life - threatening, requires or prolongs hospitalization, causes persistent relevant disability or incapacity, consists of congenital anomaly, results in death or requires intervention to avoid any of the mentioned serious medical outcomes. Furthermore, any event is to be evaluated if that event could affect the safety of the Subject or the conduct of the Study. The Institution and Investigator is obliged to inform Ethics committee and of any adverse events or serious adverse events occurring during IIS in accordance with the applicable rules and regulations.

j. The progress and results of the IIS will be collected, analyzed, and adequately reported to Wockhardt by the Investigator, including, at a minimum, submission of periodic progress, final study report and safety information.

k. The Investigator takes full responsibility for the design, initiation, management, data analysis and reporting of the study (including local regulatory obligations). Based on scientific merit and request by the IIS investigator, Wockhardt may consider providing on a case-by-case basis additional support (e.g., laboratory analysis, vendor for data management).

l. The provision of funding or facilitation by Wockhardt does not create any liability, explicit or implicit, on Wockhardt in respect of the manpower engaged in the Project by the Investigator or Institution.

m. In case of unilateral decision by any Investigator or Institution to abandon the project of any of the terms and conditions, the unutilized amount to be paid back to Wockhardt or for breach of any of the terms and conditions by any Investigator or Institution, the entire amount released by Wockhardt with interest to be paid back.

n. Cooperate with the Monitoring Committee / Wockhardt / its representative by providing it the requisite information and if requested, access to the premises where the project activity is being carried out;

o. Assist wherever necessary, the Monitoring Committee / Wockhardt / its representative with requisite technical inputs / facilities to help accomplish the objectives of the project;

p. Abide by the decision of the Monitoring Committee / Wockhardt / its representative on the assessment of the progress in the project and the modification in the objectives, outputs, milestones, targets, funding, as also the foreclosure of any activity or subproject;

q. In case of reorganization of Institution through merger, acquisition, termination, closure etc, the Institution undertakes to settle the Wockhardt's fund, even prior to initiating such measures.

II) Responsibilities of Wockhardt

a. Wockhardt agrees to provide funding or facilitation to the Investigator Initiated Study IIS as mutually agreed upon by the Investigator and Wockhardt and as mentioned in Outline of Investigator Initiated Study (IIS) Concept/ Proposal form. IIS Grants would be provided to the Institution and not directly to the Investigator. IIS Grants shall be solely used for the purpose as defined in this agreement.

b. Wockhardt will monitor the IIS investigators compliance and adherence to their contractual obligations related to disclosure of IIS findings, agreed upon milestones, and safety information reporting.

c. Wockhardt does not request any subject level data that could include protected health information as that termed defined in the privacy rule enacted pursuant to the health insurance portability and accountability ACT of 1996 from IIS supported with IISG from Wockhardt. However, Wockhardt shall gain access to the IIS data generated from IIS supported by Wockhardt that included protected health information for the purpose of ensuring that the funds/ facilitation is being utilized by the investigator and institution for the IIS as per the terms of this agreement. Wockhardt will take appropriate measures to protect the confidentiality and security of that protected health information during this process.

III) Financial Conditionalities

a. The Institution shall ensure that the Wockhardt's funds of the project are utilized only for the project as per this Agreement. Without the approval of Wockhardt, the institution will not affect re-appropriation of funds from one budget head to other.
b. The institution shall immediately refund to Wockhardt any funds released by Wockhardt remaining with it unutilized on foreclosure or completion of the project.
c. Wockhardt shall retain the right to transfer the capital assets acquired (with Wockhardt funds) during the tenure of the project or after completion of the project.
d. The provision of the loan/grant to the institution does not create any liability explicit / implicit on Wockhardt of the manpower engaged by the industry for the project.

IV) IIS Review Committee

a. IIS Review Committee shall monitor the project for achieving the defined objectives in the time and costs projected. The terms of reference to the IIS Review Committee are:

    i. To review and examine the progress of the project in conformance with the deliverables/milestones, targets and objectives set as contained in the agreement;
    ii. revising the funding support to any / or all implementing parties;
    iii. To advise on issues related to publications and securing of IPR individually or severally by the implementing parties; and
    iv. Any other matter as referred to by Wockhardt

V) Completion

The project envisaged shall be deemed to have been successfully completed, as assessed by IIS Review Committee. In case, during the tenure of the project, it is found that the project or any project component is not likely to lead to successful completion, the IIS Review Committee may decide to foreclose the project or the project component as warranted. The decision of the IIS Review Committee is fully binding on all the participants.

VI) Term and Termination

a. The term of this Agreement shall begin on the Effective Date and terminate upon the completion of the Study and the submission of all information and reports as described in the Protocol or upon expiry of two (2) years, whichever is later, unless sooner terminated as provided herein. The validity period of this Agreement may be extended or amended or renewed by express mutual consent of the parties conveyed in writing.

b. The Agreement may be terminated by the Wockhardt at any time upon thirty (30) days prior written notice, except that the Investigator may terminate the Study immediately upon written notice to the other parties if necessary to protect the health, welfare or safety of any research subject.

c. That Wockhardt will terminate this Agreement if there is a material breach of this Agreement and also there is violation of clauses VII, VIII, X, XI of this Agreement.

d. In the event that Wockhardt receives notice from Investigator or otherwise becomes aware that a debarment action has been brought against or threatened against Investigator, Wockhardt may terminate this Agreement immediately. In the event of termination hereunder, Investigator shall without undue delay deliver to Wockhardt all data required under this Agreement.

e. Total grant payable by Wockhardt pursuant to this Agreement shall be equitably prorated for actual work performed to the date of termination with any unexpended funds previously paid by Wockhardt to Investigator being refunded to Wockhardt.

f. Upon termination or expiration of this Agreement, neither Investigator/Institution nor Wockhardt shall have any further obligations under this Agreement, or in the case of termination or expiration of a IIS proposal, under such Proposal, except that (a) Investigator/Institution shall terminate all Services in progress in an orderly manner as soon as practical and in accordance with a schedule agreed to by Wockhardt , unless Wockhardt specifies in the notice of termination that Services in progress should be completed, (b) Investigator/Institution shall deliver to Wockhardt any Materials in its possession or control that was supplied by Wockhardt for the IIS, (c) Wockhardt shall pay Investigator/Institution any monies due and owing Investigator/Institution, up to the time of termination or expiration, for Services actually performed, all authorized expenses actually incurred (as specified in the applicable IIS proposal) and any additional fees associated which were duly approved by Wockhardt with the termination, (d) Investigator / Institution will refund or adjusted /reduced invoice of any payment made by Wockhardt for which Investigator/Institution is not able to provide the Services and e) Investigator/Institution shall immediately return to Wockhardt all Wockhardt's Confidential Information and copies thereof provided to Investigator/Institution under this Agreement or under any IIS proposal which has been terminated or has expired.

VII) Intellectual Property / Ownership and Use of Data .

a. All clinical data, case report forms, documents, information, clinical specimens and results prepared and developed by the Investigator in connection with the IIS or this Agreement whether in written or electronic form (collectively the "Information") shall remain the property of Investigator or Institution. However, Investigator shall provide brief summary of results of the IIS to Wockhardt and permit Wockhardt to use the same any way it deems legally appropriate. Further, investigator and institution agrees to provide Wockhardt a copy of any article/ abstract/ poster published or presented based on the resulted on this IIS for their internal use.

b. All Materials provided to Investigator/ Institution by Wockhardt for the performance of Services and all associated intellectual property rights shall remain the exclusive property of Wockhardt. Investigator/ Institution shall use materials provided by Wockhardt under any IIS proposal solely for rendering the Services under the applicable IIS proposal. Wockhardt will provide Investigator/ Institution with any relevant occupational safety information known by Wockhardt, including a Material Safety Data Sheet (MSDS). Any Materials remaining upon completion of the Services under IIS proposal shall be, at Wockhardt's direction, either returned to Wockhardt or destroyed.

c. In the event that Investigator/ Institution conceives, produces and/or reduces to practice inventions relating to any Material transferred to Investigator/ Institution in the course of or in connection with the Services, including without limitation any new uses or formulations of or improvements to such Material, the parties hereto acknowledge and agree that Wockhardt shall share, title and interest in such improvements and shall share all related documents to the Wockhardt without any cost.

d. Investigator/Institution hereby assigns and agrees to share with Wockhardt title to the Results, including any intellectual property rights embodied in or derived from such Results (whether or not protectable under patent, copyright, trade secret or similar laws).

e. Investigator/Institution shall maintain all materials and all other data and documentation obtained or generated by Investigator/ Institution in the course of IIS duration hereunder, including all computerized records and files (the "Records") in a secure area reasonably protected from fire, theft and destruction and shall make them available for review by Wockhardt as and when requested.

f. All Records shall be (i) retained by Investigator/ Institution for a period of five (5) years, or as a matter of law or regulation or (ii) disposed of, at their discretion, unless such Records are otherwise required to be stored or maintained by Investigator/ Institution as a matter of law or regulation. In no event shall Investigator/ Institution dispose of any such Records without first giving Wockhardt sixty (60) days' prior written notice of its intent to do so for the purpose of any verification or review prior to disposal as it deems appropriate. Notwithstanding the foregoing, Investigator/ Institution may retain copies of any such Records as are reasonably necessary for regulatory or insurance purposes, subject to Investigator/ Institution's obligation of confidentiality.

VIII) Confidential Information

a. The Investigator/ Institution ("Receiving Party") acknowledges that certain confidential information and data relating to the Wockhardt ("Disclosing Party") and its activities shall be furnished in connection with the purpose. Such information and data shall hereinafter be referred to as "Confidential Information" and shall include collectively and individually all or any proprietary and confidential information and data in any form whether oral, written or in electronic form relating to plans, products, intellectual property (including but not limited to information related NCE, patents, patent applications, trademarks, copyrights, know-how, rights on software and rights on databases), analyses, projects, processes, testing methods, technical data, formulations, techniques, trade secrets, know-how, data, reports, methodology, equipment, systems, marketing, information regarding sources of supply, business plans and the existence or scope of activities of any research, development, manufacturing, marketing or other projects of Wockhardt (including negative developments), research or development activities, non public corporate information and all technical or scientific information or know-how of Wockhardt relating to the purpose. Information disclosed by Disclosing Party to Receiving Party in the course of the discussions between the Parties shall constitute "Confidential Information".

b. The Receiving Party agrees that the Confidential Information disclosed by the Disclosing Party under this Agreement shall remain confidential and it shall not without the Disclosing Party's prior written consent disclose the same to any third party nor shall use the same for any purpose other than the fulfilment of its obligations under the terms of this Agreement.

c. Confidential Information will not include information that:

(i) is known to the Receiving Party, as evidenced by the Receiving Party's written records, before receipt of it under this Agreement

(ii) is disclosed to the Receiving Party by a third party having a right to make such disclosure; or

(iii) is or becomes part of the public domain through no fault of the Receiving Party; or

(iv) is independently developed by or for the Receiving Party, without recourse to such Confidential Information disclosed under this Agreement as evidenced by the Receiving Party's written records.

d. The Receiving Party agrees that:

(i) It will not use any Confidential Information received from a Disclosing Party except for the purposes of performing this Agreement.

(ii) It shall maintain Confidential Information of the Disclosing Party in strict confidence and follow the procedures to prevent unauthorized disclosure or use of the Disclosing Party Confidential Information and prevent it from becoming disclosed or being accessed by unauthorized persons.

(iii) It shall immediately advise the Disclosing Party of any unauthorized disclosure, loss, or use of Confidential Information

The Receiving Party may disclose the Confidential Information if required by law or by any court, tribunal, regulator or other authority with competent jurisdiction, provided to the extent practically possible and permissible under the law, gives notice to the Disclosing Party of such disclosure and shall disclose only that portion of Confidential Information which is required to be disclosed under the law. The Receiving Party agrees not to disclose any Confidential Information received from the Disclosing Party to any third party without the prior written consent of the Disclosing Party, except to its Affiliates, employees, agents, consultants, subcontractors, directors and officers on a need to know basis to effectuate the purpose of this Agreement (a "Representative"); provided, that in every Representative of the Consultant shall be informed of the confidentiality provisions of this Agreement.

e. The Receiving Party shall within fifteen (15) days of written request either before or after termination of this Agreement (for whatever reason), return to the Disclosing Party all materials, Confidential information (in whatever form) incorporating, embodying or recording any such Confidential Information in its possession or control and, if requested by the Disclosing Party, certify in writing that it has done so.

f. The confidentiality and non-use obligation under this Agreement shall survive for period of this Agreement and for a period of [10 (ten)] years following its expiration or termination.

IX) Investigator Initiated Study Grants (IISG)

a. Wockhardt agrees to provide funds/ facilitation to the investigator, Investigator Initiated Study (IIS) in accordance with IIS proposal and as amended from time to time upon mutual agreement and in writing.

b. No component of the IIS funds/ facilitation will be provided to the investigator until Wockhardt has received the necessary documents identified in IIS proposal form.

c. Investigator will use IIS funds solely for the purpose of the Investigator Initiated study specified in this agreement. IIS funds will not be used to pay physician referring potential subjects for enrolment in the study. At the completion of the study, investigator will confirm in writing that Wockhardt IIS funds have been used only to support the Investigator Initiated study.

d. If a particular IIS proposal calls for Wockhardt to provide a Wockhardt Product/ other medicines/ equipment/ materials, Wockhardt will provide, free of charge, sufficient supplies of the same to conduct the Study as per mutual agreement documented in proposal.

e. Investigator will maintain appropriate control of the Wockhardt Product/ other medicines/ equipment/ materials and will not provide it to anyone else except research staff who are directly involved in investigator initiated study conduct.
f. Except for, and limited to, the use specified in the Protocol &/or proposal form for the applicable Study, Wockhardt grants Investigator no express or implied intellectual property rights in the Wockhardt Product or in any methods of making or using the Wockhardt Product. Investigator will use Wockhardt Product/ other medicines/ equipment/ materials only as specified in the Protocol &/or proposal form for the applicable Study. Any other use of the Wockhardt Product/ other medicines/ equipment/ materials constitutes a material breach of this.
g. Investigator will not charge study subjects for Wockhardt Products/ other medicines/ equipment/ materials.

X) Investigator/ Institutions Representations, Warranties & obligations.

a. The Investigator/ Institution confirms having obtained the written approval of the appropriate authority/authorities for the study Protocol prior to conduct of such study.
b. The Investigator/ Institution shall not at any time during or after the expiration of the term divulge or allow to be divulged to any person any confidential information relating to the business or affairs of Wockhardt or any of the Material/ Product or the trials or studies conducted pursuant to this Agreement without the prior written consent of the Wockhardt. Further, if any confidential information was disclosed to the Investigator/ Institution prior to the date of this Agreement in anticipation of the parties entering into this Agreement, such confidential information shall be subject to the terms and conditions of this Agreement.
c. Investigator/ Institution shall take all reasonable precautions in dealing with the Material/Product and with any information documents and papers provided to it by Wockhardt so as to prevent any unauthorized person from having access to such Product, information, documents or papers or to any report on or records of any non-clinical/ Clinical Studies carried out.
d. Investigator/ Institution shall conduct the clinical studies in compliance with rules/ guidances issued by the competent authority and to the Protocol agreed to by Wockhardt and given approval by such competent authority.
e. Investigator/ Institution agrees to apply quality control to each of data handling and ensure that all data provided by it to Wockhardt is reliable.
f. Investigator/ Institution agrees that time is the essence of the contract and undertakes to complete the studies within the term as specified in each IIS proposal.
g. Investigator/ Institution undertakes not to terminate the trials prematurely without the consent of Wockhardt.
h. Investigator/ Institution warrants that it has qualified and experienced personnel to assume responsibility for the proper conduct of the studies/ trial and shall maintain a list of such qualified persons to whom it has delegated significant trial related duties.
i. Investigator/ Institution warrants that it is thoroughly familiar with the appropriate use of the Material/ Product.
j. Investigator/ Institution warrants that it is aware of and shall comply with the Guideline for Good Clinical Practice and other regulatory requirements.
k. Investigator/ Institution warrants that it shall submit the protocol to appropriate authority/authorities for approval and start the study only after the approval from appropriate authority/authorities is obtained.

l. Investigator/ Institution warrants that it is aware that the Wockhardt has agreed to provide its services/ funds/ products based upon the aforesaid declarations and warranties.

XI) Investigator initiated Study Data and Publication Rights

a. Investigator shall share the data generated from investigator initiated study with Wockhardt for but not limited to support data management, clinical study report preparation, manuscript publication/ abstract or poster presentation.

b. Investigator can publish the results of the investigator initiated Study ("Study Data"), and use study data generated from the investigator initiated study for their own research and educational purposes and programs after obtaining written consent from Wockhardt. Any third party other than the investigator and Wockhardt, will not use or permit others to use non-public or unpublished raw Study Data from any Study that involves the use of a Wockhardt Product for the commercial benefit of any third party.

c. Investigator shall have the right, consistent with academic standards, to publish or present the results of the Study provided that the manuscript, abstract or other material proposed to be published or presented ("Proposed Publication") shall be submitted to Wockhardt at least sixty (60) days prior to submission for publication or presentation to permit Wockhardt to request removal of any Confidential Information contained therein and to protect its rights to any patentable Invention. Wockhardt shall complete its review within thirty (30) days after receipt of the Proposed Publication. If Wockhardt believes that any Proposed Publication contains any information relating to any patentable Invention, the disclosure of such Proposed Publication shall be delayed for up to two (2) years from the date of receipt of the Proposed Publication to permit the filing of a patent application. If Wockhardt believes that any Proposed Publication contains Confidential Information, Wockhardt shall so notify Investigator, and they shall remove any such Confidential Information prior to publication or presentation.

d. Investigator will comply with recognized ethical standards concerning publications and authorship.

e. Investigator will disclose Wockhardt's support of the Study in any publication of Study results

f. If Wockhardt wishes to disclose results or other study information, Study Data or parts or all of the Study Report earlier than indicated above, Wockhardt may submit a request to Investigator in writing. Investigator will consider any such request in good faith. Any such request must identify the results or other Study information, Study Data or parts of the Study Report that Wockhardt wishes to disclose and how and where it would be disclosed. In any publication by Wockhardt of the results of the Study, Wockhardt will acknowledge the roles and efforts of Investigator in the Study.

XII) Indemnification

a. Wockhardt shall take the full responsibility of any issues/ events related to the Wockhardt product, when it is used within limits of recommendations of product's latest package insert/ leaflet and indemnify investigator against all losses, claims, or damages arising from such usage of the Wockhardt product within the investigator initiated study or otherwise, except that the foregoing indemnity shall not apply to any liability arising from investigator's intentional deviation or omission or negligence in the performance of its obligation under this agreement or any use of the product beyond recommendations of product's latest package insert/ leaflet.

b. Wockhardt shall guarantee that no Wockhardt product/ other medicines/ equipment/ materials shipped to investigator in connection with the Study covered by this Agreement will be adulterated or mislabelled.

c. Investigator agrees to keep all accountability of all Wockhardt product/ other medicines/ equipment/ materials

d. Investigator and Institution agrees at their own cost and expense to indemnify, defend and hold harmless Wockhardt and its Affiliates, employees, officers, and directors (Wockhardt Indemnities) from and against any and all losses, costs, expenses and damages, including but not limited to reasonable attorney's fees, based on a personal injury and/or for damage to or loss of property incurred as a result of Investigator/ Institution its officers', directors', agents', or employees'(including Principal Investigator's, and Sub-Investigators') (i) breach of its obligations including violation of clause VII, VIII, X, XI of this Agreement under this Agreement, including, but not limited to the Protocol; (ii) negligence or malfeasance or nonfeasance; and (iii) breach of any applicable local, state or federal law(s), rule(s), or regulation(s), including, but not limited to, applicable Regulatory Authority regulations, ICH-GCPs and other governmental requirements or any other governmental authority or agency (iii) from all actions, suits, claims, or demands brought by any third party based on or arising under this Agreement to the extent that such loss is caused by the negligence or willful misconduct or any use of the Wockhardt product beyond recommendations of product's latest package insert/ leaflet by the Investigator, Institution, their employees or agents.

e. Neither party will be liable for any loss or damage, including loss of profits, loss of goodwill or any other special, incidental, indirect or consequential damages whatsoever (and whether caused by the negligence of either party or its employees or agents or otherwise) arising out of or in connection with any act or omission of either party whether for breach of contract, tort (including negligence and strict liability), or otherwise relating this Agreement.

XIII) Insurance.

a. Investigator shall maintain such professional liability and other insurance as shall be reasonably necessary to insure himself against any claim or claims for damages, whether arising by reason of personal injury or death occasioned directly or indirectly in connection with the Study or services provided under this Agreement. Investigator shall provide evidence of such coverage to Wockhardt upon request.

XIV) Force Majeure.

a. A party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by any cause beyond such party's reasonable control, including but not limited to, acts of God, fire, explosion, disease, weather, war, insurrection, civil strike, riots, government action, or power failure (a "Force Majeure Event") provided the affected party gives the other party prompt written notice of the occurrence of any Force Majeure Event and the nature and the extent to which the affected party will be unable to perform its obligations under this Agreement. The affected party agrees to use commercially reasonable efforts to correct the Force Majeure Event as quickly as possible, to perform its obligations under this Agreement to the extent feasible given the Force Majeure Event, and to give the other party prompt written notice when it is again fully able to perform its obligations. Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure Event, provided that the Wockhardt may terminate this Agreement if such Force Majeure Event continues for a period of ninety (90) days or more. Any deadline or time for performance specified in this Agreement or the Protocol which falls due during or subsequent to the occurrence of a Force Majeure Event shall be automatically extended for a period of time equal to the period of the Force Majeure Event

XV) Agreement Modification.

a. This Agreement may not be altered, amended or modified except by a written document signed by all the parties.

XVI) Assignment.

a. This Agreement may not be assigned by the Investigator without the prior written consent of Wockhardt.

XVII) Successors and Assigns.

a. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

XVIII) Notice

a. Notices under this Agreement shall be duly given or forwarded by facsimile, by Certified Mail-Return Receipt Requested or by express courier service providing evidence of receipt to the parties at the addresses below or to such other addresses as the parties may from time to time indicate in writing.

If to Wockhardt:	Attn: Dr. Hanmant Barkate Wockhardt Limited Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India Facsimile:022 -26534242
If to Institution:	Attn: Dr . G.S. Narshetti MGM MEDICAL COLLEGE (MIHS), Sector 01 Kamothe, Navi Mumbai 410209, Maharshtra India. Facsimile: 022-27431093
If to Investigator	Attn: Dr. Nimain C Mohanty MGM MEDICAL COLLEGE (MIHS), Sector 01 Kamothe, Navi Mumbai 410209, Maharshtra India. Facsimile: 022-27431093

XIX) Severability.

a. If any provision of this Agreement shall be declared invalid for any reason whatsoever, that decision shall not affect any other provision of this Agreement, which shall remain in full force and effect; and to this end the provisions of this Agreement are hereby declared severable.

XX) APPLICABLE LAW AND COMPETENT COURTS

This Agreement shall be governed by Laws of India, under exclusive jurisdiction of courts of Mumbai.

If any question of dispute shall at any time during the term or thereafter arise between the Parties with respect to the validity, interpretation, implementation or alleged material breach of any provision of this Agreement or the rights or obligations of the Parties hereunder, or regarding any question including the question as to whether the termination of this Agreement by either Party has been legitimate, then the Parties shall attempt to settle such dispute amicably between them. In the event that such dispute has not been amicably settled within sixty (60) days, then such a question or dispute shall be referred to and finally resolved by arbitration under the Arbitration and Conciliation Act 1996, (as amended from time to time). The seat of the

arbitration shall be Mumbai. All proceedings of such arbitration, including without limitation, any agreements or awards, shall be in the English language.

XXI) Entire Agreement.

a. This Agreement constitutes the entire agreement between the parties and supersedes all prior agreements and understandings whether written or oral relating to the subject matter of this Agreement.

IN WITNESS WHEREOF, each of the parties hereto has caused this Agreement to be executed by its duly authorized representative as of the date written above.

[WOCKHARDT LIMITED]

By:

09/05/2017

Name: Dr. Hanmant Barkate

Its: Vice President – Medical Affairs

[INSTITUTION]

By:

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Name: Dr . G.S. Narshetti

Its: Dean – MGM Medical College, Kamothe.

[INVESTIGATOR]

By:

9/5

Name: Dr. Nimain C Mohanty

Its: Principal Investigator

Professor
Dept. of Paediatrics
MGM Medical College & Hospital,
Navi Mumbai

Exhibit A

Accepted Investigator Initiated Study (IIS) Proposal

(Attached)

Department of Pediatrics
MGM Medical College, Sector-1, Kamothe, Navi Mumbai 410209
MGM INSTITUTE OF HEALTH SCIENCES
(Deemed University u/s of 3 UGC Act, 1956)
Accredited by NAAC with 'A' Grade

Date: 02.05.2017

To,
VP- Medical Affairs & Clinical Research
Wockhardt Limited

Subject: Proposal for Investigator Initiated Study on Zeebon R

Dear Sir,

I hereby propose a study on Wockhardt product Zeebon R entitled " A prospective, randomised, parallel group, single centre study to evaluate efficacy & safety of Bacillus clausii (2 Billion Spores per 5 mL) suspension as an add on therapy to standard of care in acute viral diarrhea in children"

The study will be conducted to recruiting 60 evaluable subjects (age Group 06 months to 06 years) suffering from acute viral diarrhea.

The objective of the study is to evaluate impact of co-administering Bacillus clausii (2 Billion Spores per 5mL) suspension as add on to standard of care(Oral Rehydration Salt and Zinc) in treatment of acute viral diarrhoea in terms of :

- Time to resolution of diarrhea
- Time to normalization of stool consistency (Passage first well-formed stool)
- Time to normalization of stool frequency (Passage of stool < 3 times/ day)

I look forward to Wockhardt's support for the conduct and execution of this study in terms of (delete the not applicable)

- Funding (Tentatively Rs. 11,16000)
- Supplying Wockhardt product Zeebon R (Tentatively 900 bottles no.)
- Facilitating study activities, contracting vendors or documentation

Find enclosed the duly filled & signed IIS proposal for your consideration.

Regards,

Name: Dr. NIMAIN C. MOHANTY
Title: Professor, Emeritus Paediatrics
Institute: MGM INSTITUTE OF HEALTH SCIENCE, KAMOTHE, NAVI MUMBAI-410209

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai-410 209

Proposer	Name Dr Nimain C. Mohanty Title PROF OF PEDIATRICS MGM Institute of Health Sciences, Kamothe, Navi Mumbai Address MGM MEDICAL COLLEGE HOSPITAL NAVI MUMBAI 410209 Contact No. 09920410522_; Emailnimain.mohanty@gmail.com
Study type	Clinical☐ check ☐ obervational; ☐ interventional Animal☐ check ☐ disease model; ☐ toxicity; ☐ other In-vitro ☐
Request for*(Break-up of requirements for funds, medicine/ product/ material shall be enclosed)*	☐Funding specify tentative amount __11,16,000_____ ☐ Wockhardt product specify in the next section ☐ Other medicine specify in the next section ☐ Equipment specify function _____, Make _____& Model _____. ☐ Materials specify _____. ☐ Facilitate check the appropriate activities requiring support ☐ Protocol & study document development ☐ Study insurance (vendor search and qoutation validation) ☐ EC submission & approval ☐ Training of study team e.g. GCP, product use ☐ Clinical Data Management & Statistics(vendor search and qoutation validation) ☐ Study Report Writing(vendor search and qoutation validation) ☐ Preparation of manuscript/ abstract/ poster
Wockhardt product under study	Name: Zeebon R
	Formulation : Probiotic suspension
	Strength :Bacillus clausiiSpores IHS 2 x 109 Spores
	Quantity required : 900 bottles of 5 ml each
Other medicineto be	Name

Signature of Proposer

supplied	Formulation
	Strength
	Quantity required
Research sites*(for multiple sites, add details of all sites. CV & MRC of investigator shall be enclosed)*	Single ☐ Name of Investigator: Dr Nimain Mohanty Institute: MGM hospital , Navimumbai. Name of EC: MGM Institute of Health Sciences, Kamothe, Navi Mumbai EC Reg. No. ECR/Inst.457/INST/MH/2013dated 05_/ 09_/2013
Study Title*(Synopsis of the study shall be enclosed)*	A prospective, randomised, parallel group, single centre study to evaluate efficacy & safety of Bacillus clausii (2 Billion Spores per 5 mL) suspension as an add on therapy to standard of care in acute viral diarrhea in children
Study Rationale	There are variable reports on usefulness of probiotics in viral diarrhoea. Role of B. clausii needs ~~further~~ eva
Objectives	To evaluate impact of co-administering Bacillus clausii (2 Billion Spores per 5mL) suspension as add on to standard of care (Oral Rehydration Salt and Zinc) in treatment of acute viral diarrhoea in terms of • Time to resolution of diarrhea* * Resolution of diarrhea is defined as normalization of consistency (well-formed stool for child aged ≥ 1 year; return to the consistency existing prior to onset of diarrhea for infants) and frequency (<3 times/ day for child aged ≥ 1 year; return to the frequency existing prior to onset of diarrhea for infants) of passing stools. **Secondary Objective** To evaluate impact of co-administering Bacillus clausii (2 Billion Spores per 5mL) suspension as add on to standard of care (Oral Rehydration Salt and Zinc) in treatment of acute viral diarrhoea in terms of • Time to normalization of stool consistency (passage first well-formed stool) • Time to normalization of stool frequency (passage stool < 3 times/ day) Additionally, investigator also intends to undertake a subgroup analysis of the study patients to compare patients with • rota-virusdiarrhea vs. non-rota-virus diarrhea

Signature of Proposer

	• Reduction in stool Volume
Endpoints	**Primary Endpoints** • Time to resolution of diarrhea. **Secondary endpoints.** • Time to normalization of stool consistency • Time to normalization of stool frequency. • Reduction in stool Volume ***Safety endpoints.*** Adverse Events
Sample size	60 Evaluable subjects
Dosing regimen	SOC as per WHO guideline. Dosing of B. clausii - 10 ml twice daily for children > one year and 5 ml twice da < one year.
Duration of study	01 year including last patient last visit.
Planned study dates	01 June, 2017
Publication plans	

Signature of Proposer

Exhibit B

Outline of Investigator Initiated Study (IIS) Funding/ Facilitation Terms

Professional cost				
	Unit cost	# of visits	# of patients	total cost
Investigator grant (Enrolled cases)	2500	3	60	450000
Investigator grant (screen failure cases)	800	1	20	16000
Visit travel cost for subjects	100	3	60	18000
total professional cost				484000
Pass through cost				
Insurance	1	NA		250000
Lab assessments (Stool test & ELISA)	500	1	60	30000
EC fees				50000
Data Management	1		250000	250000
IP procurement				70000
total pass though cost				665000

Total budget value – 11, 49,000

Instalment terms for payment to Investigator			
Milestone Payments	**Milestones**	**Percentage of amount paid to Investigator**	**Actual Amount (Rs.)**
1st Milestone	Project Start up fees	-	**5,00,000**
2nd Milestone	Project Initiation (Recruitment of 1st patient)	20 % of 649000	**1,29,800**
3rd Milestone	Recruitment of 66 subjects	20 % of 649000	**1,29,800**
4th Milestone	Transfer of complete/ accurate data for data management (66 subjects)	20 % of 649000	**1,29,800**
5th Milestone	Signing of final CSR	40 % of 649000	**2,59,600**
Total Amount			**11,49,000**

Payment terms.

1. Payments will be released on Milestone basis.
2. Project Start-up payment will be released once the IIS agreement is signed and executed.
3. Investigational product Zeebon R will be provided to the investigator.
4. Tax deduction at source will be done.

Payments to be released in following account		
Payee account name	MGM Medical college Navi Mumbai Research society.	
PAN details of the Payee	AAATM4256E	
Bank account number	0183104000166669	IDBI bank Belapur IFSC : IBKL0000183

MGM INSTITUTE OF HEALTH SCIENCES
(Deemed University u/s 3 of UGC Act, 1956)
Grade 'A' Accredited by NAAC
MGM SCHOOL OF PHYSIOTHERAPY
Sector-1, Kamothe, Navi Mumbai – 410209

MGM/SOP/2018 Date: 14/02/2018

Validation of Actofit band for the measurement of Velocity during resistance training by comparing withoptical motion analysis system

The purpose of this study was to analyze the reliability of Actofit band to measure wrist movement velocity during various strength training exercises. Smartphone-based wearable devices which don't need PC software to work; are paired with a smartphone application to transfer data through Bluetooth or Wi-Fi connections in a simple way, which makes easier its setup and use in the field.

However, no studies analyzed a smartphone-based wearable device to track movement velocity during squat exercise. For this, the purpose of this study was to analyze the validity and reliability of a smartphone-based wearable device to measure movement velocity during various exercises.

Raw data acquired from gyroscope sensor was devised using discrete wavelet transform to accurately identify start and end point of each exercise repetition. Linear velocity in m/s is calculated from angular velocity in degree/sec. Velocity calculated from wrist worn device comprising IMU sensor is further compared with Motion data captured from VICON for validation purpose. Results showed a high correlation between the Vicon and wearable device mean and peak values.

It was observed that velocity calculated from IMU sensor matches with one calculated from VICON setup comprising sophisticated software which is gold standard in motion analysis. Rep-

Sector 1, Kamothe, Navi Mumbai , Tel.:022 65143108, E-mail: mgmschoolofphysiotherapy@gmail.com

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

MGM School of Physiotherapy NAVI MUMBAI

wise velocity provided information about workout intensity every repetition which is important matrix in exercise training. Existing motion analysis set up such as Vicon uses multiple cameras and markers along with sophisticated software system for motion analysis. This setup is very expensive as well less portable compared to our proposed solution. Device consisting of IMU sensor is very economical and highly portable solution for motion analysis without compromising accuracy and reliability.

These results were encouraging as velocity is important parameter for measuring workout intensity and this system provides portable and affordable solution for accurately tracking velocity while performing various kind of resistance training exercises which involves significant wrist movement.

Tracking velocity during Velocity based training exercises can help athletes to analyze his strength and workout intensity. The Actofit wearable device can be further modified to be used for applications such as tracking yoga exercises and in physiotherapy.

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act)
Navi Mumbai- 410 209

YUVRAJ SINGH.
(ASST. PROFESSOR)

TRIVENI SHETTY
(ASST. PROFESSOR)

Dr. Rajani Mullerpatan
Prof-Director