



YENEPOYA

(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

Details of the Collaborative Activity

2020-21

Name of the Collaborating Institute: Indian Institute of Technology (IIT), Bombay

Name of the Collaborating Department from YDU: Yenepoya Research Center


Joint Clinical Project:

Dr. Shaheena Yassir, Dr. Prabha Adhikari, Dr. Indira Puthran from Yenepoya Medical College collaborated with Dr. Prof. A M Pradeep, Indian Institute of Bombay and formulated a joint project

Title: A single centre, open-label, prospective, clinical validation study of Tropcheck-a Novel, Non-Invasive class C point-of-care In-Vitro Diagnostic medical device for detection of cardiac Troponins T and I in the venous blood

A collaborative agreement for the same signed on 16th Feb 2021.

ATTESTED


Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore- 575 018, Karnataka



YENEPOYA

(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

Details of the Collaborative Activity

2019-20

Name of the Collaborating Institute: Indian Institute of Technology (IIT), Bombay

Name of the Collaborating Department from YDU: Yenepoya Research Center

Activities:

Joint Research and Training –PhD Scholar

Mr. Saketh Kapoor, Senior Research Fellow, Yenepoya Research Center, visited the Indian Institute of Technology (IIT), Bombay for Mass Spectrometric analysis and data analysis of a project on stem cells derived from different germ layers.

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Ref: No. Y/REG/ACA/JRF/2019

24.08.2019

Mr. Saketh Kapoor
Senior Research Fellow
Yenepeya Research Centre

Sub: Request for on duty leave from 23rd August to 2nd September 2019

Ref: Your letter dated 21.08.2019

Permission is granted to you to visit Indian Institute of Technology (IIT), Bombay from 23rd to 2nd September 2019 for taking peptide samples for data acquisition & mass spectrometric analysis. There shall be no financial implication to the University.

The period of absence from 23rd August to 2nd September 2019 shall be treated as on duty.

Joint paper


REGISTRAR 24/8
mj

Copy to:

1. Dy. Director, YRC
2. File copy


ATTESTED

Dr. Gangadhara Somayaji K.S.
Registrar
Yenepeya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka



Dr Bipasha Bose <bipasha.bose@gmail.com>

Request for sample submission for Mass spectrometry analysis

11 messages

Sat, Jul 27, 2019 at 11:19 AM

Saketh Kapoor <sakethk@yenepoya.edu.in>

To: massfiitb@gmail.com

Cc: Bipasha Bose <bipasha.bose@gmail.com>, sudhir shenoy <shenoy2000@yahoo.com>

Respected Prof. Srivastava,

Kindly allow me to introduce myself. I am Saketh Kapoor and I am currently carrying out my Ph.D. at the Stem Cells and Regenerative Medicine Centre, Yenepoya (Deemed to be University), Mangalore under the guidance of Dr. Bipasha Bose. I may inform you that I had participated in the "Targeted Proteomics International Symposium" on February 25th, 2018 at Indian Institute of Technology, Bombay. I had the privilege to meet Mr. Brendan MacLean and also, I had also won the third prize in the quiz competition organized in the symposium.

As a part of my Ph.D., I have to carry out the global proteomics analysis of specific stem/progenitor cells isolated from BALB/c mice. I am writing to you as we wish to carry out mass spectrometric analysis at your proteomics facility. I am briefly describing here the workflow we have used for the sample preparation. We have isolated the stem cells based on a progenitor marker using Fluorescence-activated cell sorting (FACS) technique. The isolated cells were then pelleted and proteins were isolated. We have carried out the trypsin digestion of the sample (100µg) and then fractionated the peptides into 6 fractions using SCX StageTips method. Similarly, we have processed two other sets of sample. So, in total, we have 18 samples and each sample will be acquired in triplicate. The details are as follows:

1. Six SCX fractions of Sca-1+ cells directly sorted from BALB/c mice muscle tissue (6 Samples)
2. Six SCX fractions of Sca-1- cells directly sorted from BALB/c mice muscle tissue (6 samples)
3. Six SCX fractions of Sca-1+ cells grown in primary culture after sorting from BALB/c mice muscle tissue (6 samples)

For analyzing the data, we wish to use the Proteome Discoverer 2.3 suite and search the data using both, Sequest and Mascot. We also plan to search the data with different modifications, therefore, we may have to search the same data multiple times.

Further, I also request you to please allow me to visit your lab during the data acquisition of my samples. I will personally bring the samples to your lab. I will be extremely grateful if you could let us know the time slot for data acquisition and it's associated costs for each mass spectrometric run.

I may inform you that I formerly worked for about 2.5 years with Dr. T. S. Keshava Prasad at Yenepoya (Deemed to be University) and I have experience in proteomics sample preparation and preliminary knowledge in handling mass spectrometer and using Proteome Discoverer. I am also a co-author in the article entitled "Integrated Multi-Omic Analysis of *Mycobacterium tuberculosis* H37Ra Redefines Virulence Attributes" published in *Frontiers in Microbiology* (PMID: 29971057).

The samples are extremely precious to us as we have spent over 2 years to standardize the isolation as well as FACS procedure for the isolation of this specific population of cells. Proteins from these cells were even more precious for me! I will be extremely grateful if you could consider my request.

Regards,
Saketh

—

Saketh Kapoor
Graduate Student
Stem Cells and Regenerative Medicine Centre
Yenepoya University
Mangalore- 575 018
Ph: +91 81050 97846
Email id: sakethk@yenepoya.edu.in

Yenepoya (Deemed to be University) | University Road, Deralakatte | Mangalore 575018 | Karnataka | India
T:+91-824-2206000 | F: +91-824-2204667 | www.yenepoya.edu.in

⚠ Please don't print this e-mail unless you really need to.

DISCLAIMER: This e-mail and any attachment are for authorized use by the intended recipient(s) only. It may contain proprietary material, confidential information and/or be subject to the legal privilege of Yenepoya (Deemed to be University) Mangalore. If you have received this e-mail in error, please notify the originator immediately. If you are not the intended recipient, you are notified that you are strictly prohibited from retaining, using, copying, altering or disclosing the contents of this e-mail.



YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognised under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

YENEPOYA ETHICS COMMITTEE - 1

UNIVERSITY ROAD, DERALAKATTE, MANGALORE - 575 018, INDIA

Phone : +91 824 220 4668 / 69 / 70

www.ethics.edu.in/eth-com.html

YEC-1 Approval Letter

Reference: Protocol no. YEC-1/2020/077 titled, "A single-centre, open-label, prospective, clinical validation study of Tropecheck- a Novel, Non-Invasive class C point-of-care In-Vitro Diagnostic medical device for detection of cardiac Troponins T and I in the venous blood"

Names of all research team members

No	Name	Role in the research team	Designation/ Affiliation
1	Dr. Shaheena Yassir	Principal Investigator	Assistant Professor, Biochemistry, YMC
2	Dr. Prabha Adhikari	Co-Investigator	Professor and Head, Geriatric Medicine
3	Dr. Indira Puthran	Co-Investigator	Laboratory Director, Clinical Laboratory

It is hereby confirmed that neither the PI nor any of the research team members have participated in the decision making process of YEC-1.

The following YEC-1 member(s) declared a conflict of interest for the protocol and recused themselves.

No	Name	Position in YEC-1	Designation
	None		

The YEC-1 reviewed the protocol and related documents as listed below:

No	Document Name	Version	Date
1	Protocol	1.1	03-12-2020
2	Waiver of consent	-	-
3	Case report form	1.1	03-12-2020

YEC-1 hereby approves the protocol no. YEC-1/2020/077 and the related documents as listed above and this approval is valid from 09-12-2020 to 08-06-2021.

Any data collected before or beyond the validity period shall be considered as protocol deviation and liable to action.

It is the responsibility of the Principal Investigator to:

1. Provide correct, updated contact details and respond to YEC-1 communications without delay.
2. Adhere to the current regulatory guidelines
3. Adhere to the undertaking signed by the PI.
4. Adhere to the approved version of the protocol (and related documents).
5. Adhere to the compensation plan as per the approved protocol
6. Restrict recruitment to the approved sample size of 100 left over plasma sample only.
7. Obtain written approval of YEC-1 before any proposed change in the protocol (amendment) is implemented in the prescribed format (Ann01/SOP9B/v3)
8. Report to YEC-1 any deviation from the guidelines/approved version of the protocol without delay (including change in research team members) in the

YEC-1/2020/077

ATTESTED

Page 1 of 2

Dr. Jangadhara Somayaji K S
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018, Karnataka.

Chairperson

Dr. Vikram Shetty

Secretary

Dr. Uma Kulkarni
(+91 94481 50032)
umakulkarni@yenepoya.edu.in
ethcom@yenepoya.edu.in

Members

Mr. Saduddin M Salihi

Fr. Teji Thomas

Dr. Sayeegeetha

Dr. Sachidananda Adiga MN

Mr. Y M Khurshid

Dr. Ravi Vaswani

Dr. Nagapati Bhat

Dr. Laxminarayan Sonde

Dr. Mohammed Guthigar

Ms. Viji Prasad C



YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognised under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

YENEPOYA ETHICS COMMITTEE - 1

UNIVERSITY ROAD, DERALAKATTE, MANGALORE - 575 018, INDIA

Phone : +91 824 220 4668 / 69 / 70

www.ethics.edu.in/eth-com.html

Chairperson

Dr. Vikram Shetty

Secretary

Dr. Uma Kulkarni
(+91 94481 50032)
umakulkarni@yenepoya.edu.in
ethcom@yenepoya.edu.in

Members

Mr. Saduddin M Salihi
Fr. Teji Thomas
Dr. Sayeegeetha
Dr. Sachidananda Adiga MN
Mr. Y M Khurshid
Dr. Ravi Vaswani
Dr. Nagapati Bhat
Dr. Laxminarayan Sonde
Dr. Mohammed Guthigar
Ms. Viji Prasad C

- prescribed format (Ann01/SOP11/v3 - Initial report and Ann02/SOP11/v3 - Detailed report)
9. As per the current regulatory guidelines, report to YEC-1 all serious adverse events in the prescribed format (Ann01/SOP12 v3 - Onsite SAE and Ann02/SOP12/v3 - Offsite SAE) and their follow-up actions.
10. Submit the periodic review as specified by YEC-1 in the prescribed format (Ann04/SOP10/v3)
11. Submit continuing review form one month before the end of validity of this approval (Ann04/SOP10/v3)
12. Report to YEC-1 an adverse event/change in risk to participants (excluding SAEs) that may occur during the study in the periodic review
13. Submit a completion report to YEC-1 when the data/sample collection is completed in the prescribed format (Ann01/SOP13/v3)
14. Submit a summary of the study when the data analysis is completed.
15. Maintain the privacy of the participants/ samples and confidentiality of data.
16. Securely retain the original of YEC-1 approval letter, as issuing duplicate approval letter is liable to a fee
17. Respond to any communication from YEC-1 pertaining to the study/ auditing/ site monitoring/ others.

All communications with YEC-1 should be sent by email to ethcom@yenepoya.edu.in
YEC-1 functions in accordance with Declaration of Helsinki (2013), National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017) and New Drugs and Clinical Trials Rules (2019).

YEC-1 is re-registered with the Office of the Drugs Controller General of India with Re-Registration no. ECR/521/Inst/KA/2014/RR-20 valid from 04/09/2020 to 03/09/2025 and re-recognized by Forum for Ethical Review Committees for Asia and the Western Pacific Region (FERCAP) for a period of 3 years from 26 November 2019.


Dr. Uma Kulkarni

Member-Secretary, YEC-1

Date: 09-12-2020

Secretary
Yenepoya Ethics Committee-1

Important Dates:

Date of YEC-1 approval:	09-12-2020 to 08-06-2021
Date of continuing review/study completion report	07-06-2021

ATTESTED

Dr. Mangadhara Somayaji KS

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018, Karnataka.

YEC-1/2020/077

Page 2 of 2

Agreement
Between
Indian Institute of Technology Bombay
And
Yenepoya Medical College & Hospital

This Memorandum of Agreement is entered and executed on 16th February, 2021, by and between **Indian Institute of Technology Bombay**, located at Powai, Mumbai – 400076, Maharashtra, India (referred to as 'IITB') and **Yenepoya Medical College & Hospital**, (through Dr. Shaheena Yassir, Assistant Professor of Biochemistry) located at Deralakatte, Mangaluru 575018 (referred to as 'YMC').

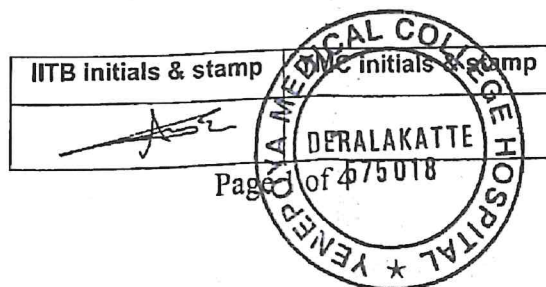
Recitals:

IITB is a research and educational institution set up by a Special Act of the Parliament of India and recognized by the Government of India as an Institute of Eminence having expertise in various areas of science, engineering, design, management and humanities.

YMC is a research and medical educational institution dedicated to research and development in field of medicine and healthcare owned by Yenepoya University, a status granted by University Grants Commission under section 3A of the UGC Act 1956 in 2008.


IITB has received funding from Indian Council for Medical Research (ICMR), Government of India, for taking a project on 'A single-center, open-label, prospective, clinical validation study of tropcheK - a novel, non-invasive class C in-vitro point-of-care diagnostic medical device for detection of cardiac troponins T and I in the venous blood' (referred to as Study) has to be taken up.

YMC has resources related to Troponin reader and is desirous of collaborating with IITB to take up the above Study.



ATTESTED

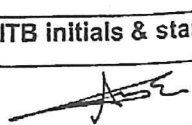
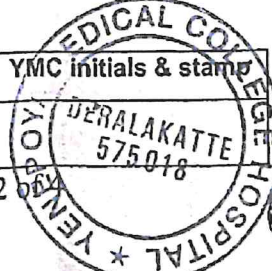

Dr. Gangadhara Somayaji K.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka


Dr. Shaheena Yassir

IITB and YMC (each individually a 'Party' and collectively as 'Parties' hereinafter) are interested to take up a joint research programme / project pertaining to perform the Study as per the scope more specifically contained and detailed in Annexure A hereto.

The Parties hereto agree to the following terms and conditions for the above collaboration:

- 1. Scope, Purpose of Activity:** The scope of the Project is to collaborate on the proposed study on "A single-center, open-label, prospective, clinical validation study of tropchek - a novel, non-invasive class C in-vitro point-of-care diagnostic medical device for detection of cardiac troponins T and I in the venous blood" as attached in the Annexure A (annexed hereto).
- 2. Intellectual Property (IP):** Based on contributions from inventors of the respective Party, knowledge and/or intellectual property (IP) which can be covered by patents and other IP Rights will be owned either individually or jointly (as the case may be), on a case to case basis, based on contributions of each of the Parties and under mutually agreed to terms. Provided however, that either Party may make use of, all information and data generated during this collaborative activity hereunder for its own internal research and academic purposes. Further, both Parties will be subject to the terms and conditions of ICMR, the funding agency.
- 3. Publications:** Any research findings arising from this collaborative activity may be published / presented at national or international conferences. Acknowledgement of the contribution of the authors towards such publications will be made, as appropriate. However, the terms and conditions for such publications shall be mutually agreed upon.
- 4. Confidentiality:** IITB and YMC agree to hold in confidence all information/data designated as confidential, which is obtained/disclosed from the other Party or created during the performance of this agreement and will not disclose the same to any third party without written consent of the other Party.
- 5. Non-Exclusive:** This relationship is on a non-exclusive basis and either YMC or IITB are free to enter into other relationships or alliances with other partners.
- 6. Term and Termination:** The term of this agreement shall be for a period of One (1) year from the date of execution hereof unless terminated earlier by a written notice of thirty (30) days, by a Party seeking such termination, to the other Party hereto.
- 7. Changes:** Any changes / alterations to this agreement / understanding shall be made by the Parties hereto by mutual agreement, in writing, by the authorized representatives of both the Parties

IITB initials & stamp	YMC initials & stamp
	 Page 2 of 2

 ATTESTED

Dr.Gangadhara Somayaji K
Registrar
Yenepoya(Deemed to be Univer
University, Deralakatti
Mangalore-575 018, Karnata



Dr. Shaheena

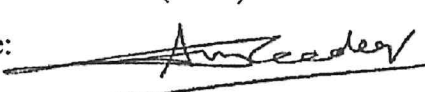
8. **Compliances:** Each Party agrees to perform its activities in compliance with all applicable statutes and regulations that are in force at that time
9. **Dispute Resolution:** Any and all disagreements / differences / disputes arising hereunder shall be resolved amicably by the designated senior executives / officers of the good offices of both Parties. Further, unresolved disputes, if any, shall be resolved by arbitration to be conducted under the Indian Arbitration and Conciliation Act 1996 in the English language at Mumbai.
10. Both the Parties agree to comply with the terms and conditions of the funding agency ICMR providing funds for the Study.

AGREED

Yenepoya Medical College & Hospital

Indian Institute of Technology Bombay

Name: **Dr. S. PADMANABHA**
 Title: **Med. Superdt**
 Signature: 
MEDICAL SUPERINTENDENT
YENEPOYA MEDICAL COLLEGE HOSPITAL
MANGALORE-575 018

Name: Prof. A M Pradeep
 Title: Associate Dean (R&D)
 Signature: 

सह संकायाध्यक्ष, शोध एवं विकास
 Associate Dean, Research and Development
 कृते निदेशक, आय आय टी मुंबई
 For Director, IIT Bombay

Date:

Date: 16-February-2021


Witness:


Witness: 

Name:

Name:

ATTESTED


 Dr. Gangadhara Somayaji K.S.
 Registrar
 Yenepoya (Deemed to be University)
 University Road, Deralakatte
 Mangalore-575 018, Karnataka

IITB initials & stamp	YMC initials & stamp
	

Page 3


 Dr. Shaheera Yaluri

Annexure A: Scope of collaboration:

Title of the study: "A single-center, open-label, prospective, clinical validation study of *tropchek* – a novel, non-invasive class C in-vitro point-of-care diagnostic medical device for detection of cardiac troponins T and I in the venous blood".

1. ACTIVITIES AND OBLIGATIONS OF YMC

- a. YMC personnel will review of study-related documents take appropriate steps to secure approval from Ethics committee of YMC for Biomedical and Health Research.
- b. YMC personnel will screen and enrol study subjects / use biological samples, collect relevant clinical data, collect and process the biological samples as per clinical study protocol.
- c. YMC personnel will work jointly with IITB personnel in interpretation of the results and report writing.
- d. YMC personnel will work with IITB personnel toward joint publication(s) of the results of the study in scholarly journals and conferences and under mutual agreement with IITB.

2. ACTIVITIES AND OBLIGATIONS OF IITB

- a. IITB will provide Lateral flow assay kit for Troponin I and Troponin T along with procedure to run this assay
- b. IITB shall obtain the clinical data from YMC through IITB authorized representative, who will analyse and write clinical study report
- c. IITB will perform statistical analysis and interpret the data as per statistical requirements.
- d. IITB personnel will work jointly with YMC personnel in interpretation of results and report writing.
- e. IITB personnel will work with YMC personnel toward joint publication(s) of the results of the study in scholarly journals and conferences and under mutual agreement with YMC.

3. FINANCIAL AND OTHER ARRANGEMENTS

Payment to be made to YMC for the above study will be made by IITB based on the terms of the funding agency ICMR and as per rules and norms of IITB for procurement.

ATTACHED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

IITB initials & stamp	YMC initials & stamp

Page 4 of 4

Dr. Shaheena Yasir

MEDICAL SUPERINTENDENT
YENEPOYA MEDICAL COLLEGE HOSPITAL
MANGALORE-575 018