Institute of Post Graduate Medical Education & Research
244, A.J.C. Bose Road, Kolkata – 700020.

IPGME&R Research Oversight Committee

(Institutional Ethics Committee)

Memo No. IPGME&R/IEC/2023/048R

Date: 28.01.2023

Dr. Sujoy Ghosh
Professor
Department of Endocrinology
IPGME&R, Kolkata

Dear Dr. Ghosh,

A meeting of the Institutional Ethics Committee of IPGME&R, Kolkata, was held on 23.01.2023 at 12:00 Noon in the Office of the Dean, IPGME&R, Kolkata. In this meeting the members considered the protocol related to your project:

Biomarker identification: multi-omics approaches to differentiate between diabetic and non-diabetic kidney disease and identification of markers of progression in chronic kidney disease.

The following additional documents were scrutinized:

- Informed consent documents in English.
- Informed consent documents in Hindi.
- Informed consent documents in Bengali.

After deliberations and review the committee took the following decision regarding your project:

Approved

Please note the following:

- The committee understands that your study does not have any commercial sponsor.
- However, it is proposed to be submitted for funding to Indian Council for Medical Research (ICMR).
- Your Co-Investigators for the project will be **Prof. Soumen Kanti Manna**, Saha Institute of Nuclear Physics, Kolkata, and **Prof. Raghunath Chatterjee**, Indian Statistical Institute, Kolkata.

It is placed on record that the decision regarding your proposal was unanimous and therefore did not require any voting procedure. List of members who attended this meeting is provided on the next page. Members absent have reviewed the same documents and have not sent any note of dissent or objection regarding your proposal. It is also recorded that neither you nor any other member of your research team participated in the decision-making process.

Additional points, if any, mentioned on Page 2 are also to be noted.

Continued on Page 2

Continued from Page 1

Additional points to be noted:

- Clinical trials must be registered prospectively with Clinical Trials Registry India (CTRI).
- IEC approval for the study, in its present form, is valid for a period of 3 years from 21.01.2023. The Committee expects that any amendments to the Study Protocol, Informed Consent documents or other relevant documents would be brought to its notice.
- The Committee reserves the right to inspect informed consent documents and other study related documents, visit study sites, and, if necessary, interact with study participants to ensure that rights, safety, and well-being of study participants are not being compromised.
- A brief project completion report is to be submitted to the IPGME&R Research Oversight Committee. If project duration exceeds 1 year from commencement, a brief annual progress report should also be submitted.
- IPGME&R Research Oversight Committee is registered with Central Drugs Standard Control Organization (CDSCO), Government of India, in consonance with Rule 122D of the revised Drugs & Cosmetics Rules 1945 – Registration No. ECR/35/Inst/WB/2013/RR-19. It functions in accordance with New Drugs and Clinical Trials Rules 2019 under the Drugs & Cosmetic Act and Indian Council of Medical Research (ICMR) guidelines.

List of institutional ethics committee members who attended the meeting on 21.01.2023

SN	Name & role in the committee	Gender	Designation
1	**Dr. Hemanta Kumar Majumder** [Scientist & Chairperson]	Male	Senior Scientist, Indian Institute of Chemical Biology, Kolkata
2	**Prof. Amal Kanti Das** [Basic Medical Scientist]	Male	Professor, Dept. Pharmacology, IPGME&R
3	**Prof. Bijay Kumar Majumdar** [Clinician]	Male	Consultant Plastic Surgeon; Former Head, Department of Plastic Surgery, IPGME&R
4	**D. Amal Kumar Santra** [Basic Medical Scientist]	Male	Scientist, Formerly of Department of Gastroenterology, IPGME&R
5	**Dr. Sananda Pati** [Clinician – Pediatrician]	Female	Assistant Professor, Department of Pediatrics, IPGME&R
6	**Mr. Debdut Mukherjee** [Legal expert]	Male	Advocate, Calcutta High Court
7	**Mr. Arunangshu Shekhar Jana** [Social worker]	Male	Social worker, Mahendraganj, Dist. South 24 Parganas
8	**Dr. Nila Majumdar** [Lay person]	Female	Bengali teacher, Kolkata
9	**Prof. Avijit Hazra** [Pharmacologist & Member secretary]	Male	Professor, Department of Pharmacology, IPGME&R

28/01/2023

Dr. Avijit Hazra – Member Secretary
IPGME&R Research Oversight Committee

Member Secretary
Institutional Ethics Committee
Institute of Postgraduate Medical
Education & Research (IPGME&R)
Kolkata-700020

RSSDI

Research Society for the Study of Diabetes in India

RSSDI/HQ/Grants/2018/510 Date- 19.04.2018

To,
Dr.Sujoy Ghosh,
Associate Professor,
Dept.of Endocrinology and Metabolism,
4th Floor, Ronald Ross Building,
IPGMER & SSKM Hospital, Kolkata-20.
Mobile No – 9674625823

Sub:- Disbursement letter for the Research project entitled "Identification of non-invasive signatures for differential diagnosis of biopsyproven diabetic nephropathy and non-diabetic kidney disease by metabolomics and peptidomics approach" with a project duration of 2 year.

Dear Dr.Sujoy Ghosh,

Please find enclosed cheque no"834426" dated 19/04/2018 in favour of **"STUDY OF DIABETIC NEPHROPATHY"** - for sum of **Rs. 747500 /- (Seven Lakh Fourty Seven Thousand Five Hundred Only)** drawn on Punjab National Bank for your project entitled "Identification of non-invasive signatures for differential diagnosis of biopsyproven diabetic nephropathy and non-diabetic kidney disease by metabolomics and peptidomics approach" as 1st year Installment of 6 months.

You are requested to submit the complete report of your work along with the Utilization Certificate and Statement of Expenditure at the end of 1st year of the project.

Kindly acknowledge receipt of the same.

With Regards,

Yours Sincerely,

Dr .Brij Mohan Makkar,
Secretary, RSSDI

RSSDI Secretariat :
Dr. Makkar's Diabetes & Obesity Centre
A-5B/122, Paschim Vihar, New Delhi-110063 (India)
Tel: 91-11-27061022, Mobile : +91 9811077419, 9999070356
Email: rssdihq@gmail.com
Website:www.rssdi.in

Abstract 16

Urinary metabolic signatures for differential diagnosis of diabetic and non-diabetic kidney disease

Madhurima Basu, S K Ramiz Islam[1], Subhashis Neogi, Smartya Pulai[2], Mainak Banerjee, Sanghamitra Sengupta[3], PradipMukhopadhyay, Nitai Pada Bhattacharyya, Arpita Roychoudhury[2], Soumen Kanti Manna[1], Sujoy Ghosh

Background: Renal involvement in T2DM can be due to diabetes per se (Diabetic Kidney Disease) or causes other than diabetes (Non-diabetic kidney disease). Currently available clinical, biochemical and radiological markers fail to differentiate DKD from NDKD and renal biopsy remains gold standard for correct diagnosis. While urinary signatures may provide a non-invasive alternative to that end, no study has been reported on urinary metabolomics of biopsy-confirmed DKD and NDKD subjects.

Aims: To identify the expression of urinary metabolic signatures as putative marker for differentiation of biopsy-confirmed DKD and NDKD subjects.

Methods: Consecutive patient with renal involvement were subjected to biopsy and classified as per ISN/RPS Classification. Morning urine sample were collected for analysis by Gas Chromatography and mass spectrometry. Features were extracted and analysed using appropriate statistical method.

Results: Urinary metabolites (M1, M2, M3, M4) were found to be depleted in patients with kidney disease ($P < 0.004$, <0.006, and < 0.01, <0.03 respectively). M5 was exclusively depleted in NDKD (n=16). The level of M6 (<0.01), M7 (<0.03) increased and M8 (<0.05), M9 (0.03), M10 (0.02) were decreased in DKD subjects (n=34) .

Conclusion: Our pilot study suggests that urinary metabolomics analysis may help to distinguish DKD and NDKD subjects. Our results warrant validation in another cohort.

Table 1: The summary of all the above four cases

	Patient 1	Patient 2	Patient 3	Patient 4
Age	79	61	41	67
Sex	Female	Female	Female	Female
Presentation	Blackouts, loss of consciousness	Sweating, loss of consciousness	Palpitations, sweating Loss of consciousness	Giddiness, palpitations, shortness of breath
Comorbid conditions	HTN, coronary artery disease	Diabetes, HTN	-	Hypothyroidism HTN
At diagnosis				
Rbs	34	34	49	23
Insulin levels	39440	3000	2489	24000
C peptide level	87.5	4.35	19.19	16.2
Insulin antibody	1070 units/ml (normal <12)	36 nmol/L, N (0-0.02 nmol/L)	300 units/ml (normal <12)	87.2units/ml (normal <12)
Highly sensitive insulin antibodies	>100 u/ml (ref range <1) Insulin free <2.5 uu/ml (ref range 4.0-20.0)			
Treatment	Diet and steroids	Diet and steroids	Diet and steroids	Diet, steroids, rituximab
After treatment				
Insulin levels	2000 uiu/ml	-	45 uiu/ml	203miu/ml
Insulin antibody		Normalised	20 units/ml (<12)	1.63 units/ml (<12)

HTN: Hypertension

EASD Abstract:

https://www.easd.org/media-centre/home.html#!resources/urinary-metabolomics-to-distinguish-diabetic-kidney-disease-from-non-diabetic-kidney-disease-1d5f1164-afc5-4c3a-bec1-bfdf187b64ba

Endocrine abstracts:

https://www.endocrine-abstracts.org/ea/0090/ea0090RC1.2