☎ : 0522-2253154

KING GEORGE'S MEDICAL UNIVERSITY U.P.
Department of Surgery (General)
Lucknow - 226003 U.P., India

Ref. .....1264 Date 21/5/22

To,
The Dean,
Research and Development,
Institutional Ethics Committee,
King George's Medical University,
Lucknow, U.P.

Subject: **Request for expedite process of ethical approval of study.**

Respected Ma'am,

With due respect, I, *Mr. Vaibhav Singh, third year student of MBBS 2019* batch under the guidance of *Prof. Vinod Jain, Professor, Department of General Surgery, KGMU* **who is superannuating on 05/10/2022,** wish to submit the following project for ethical clearance – ***"Barriers to Breast Cancer Screening in a cohort of urban Indian women."***
This is to inform you that this project has been selected under ***ICMR STS (Indian Council of Medical Research, Short Term Studentship) Programme, 2022*** vide letter No.21/2/2022/HRD-STS Dated: 17/05/2022 and for the fund release with other clearances. We are submitting for official ethical clearance of this project. In view of his (Prof Vinod Jain) superannuation on 05/10/2022 we need to expedite process of approval for ethical clearance. I am attaching all the enquired documents of this project for your kind perusal and needful action.
I request you to kindly consider the project for review by the Ethical Committee and expedite the process of approval.

I shall be grateful to you for your early, kind and just action.

Thanking you,

Your sincerely,
Vaibhav Singh
MR. VAIBHAV SINGH,
MBBS 2019

Forwarded by:

21/5/2022
HOD,
Department of General Surgery,
King George's Medical University,
Lucknow, India.
Head of Department of Surgery (Gen.)
K.G. Medical University U.P., Lucknow.

PROF. VINOD JAIN,
Professor,
Department of General Surgery,
King George's Medical University,
Lucknow, India.
Dr. Vinod Jain
Professor
Department of Surgery
K.G.M.U., U.P., Lucknow

KING GEORGE'S MEDICAL UNIVERSITY, LUCKNOW, U.P.

Scientific Review Committee

Faculty of Medical Sciences

Department of General Surgery, KGMU

Date: ___/___/20__

Members Present:

S.No.	Name	Designation	Signature
1	Dr. Parijat Suryavanshi	Prof. J. Gr	Parijat
2	Dr. Avanish Kumar	Professor	
3	Dr FARAZ AHMAD	Prof J Gr.	
4	Dr. Kushagra Gaur	Asst prof	
5	Dr Jitendra Kr	Resident	

The Proposal entitled: ***"Barriers to Breast Cancer Screening in a Cohort of Urban Indian Women."***

Presented by: ***Mr. Vaibhav Singh*** under guidance of Arvind Jain PI/ ~~Resident/ Student~~

The committee reviewed the proposal and comments are as given below:

	Heading	***Specific Comment***
A	Background & Rationale	Satisfactory
B	Hypothesis & Objectives	Satisfactory
C	Methodology (Study/Design/Data Collection/Sample Size/Data Analysis Plan)	Satisfactory
D	Competency of Investigation Team	Satisfactory
E	Budget	Satisfactory
F	Data Collection Instruments	Satisfactory
G	Informed Consent Form (Patient Information sheet & Consent Form)	Satisfactory

Decision:

(1) The proposal is Scientifically sound can be forwarded for ethical review
or

(2) Proposals needs revision on the points below:
(i)
(ii)

19/5/22

Signature of Chairperson

Head of Department of Surgery
K.G. Medical University U.P., Lucknow

734	2022-05947	Ms. Anshika Dhananjay Verma	Approved
735	2022-05953	Ms. Sharvari Sameer Kulkarni	Approved
736	2022-05961	Ms. Shreya Namdev Sonawane	Approved
737	2022-05991	Mr. Ritvik Vinit Rau	Approved
738	2022-06003	Mr. Sujoy Bose	Approved
739	2022-06010	Ms. Hashmita Das	Withheld
740	2022-06013	Ms. Varsha R N	Withheld
741	2022-06018	Mr. Vraj Jigarkumar Rangrej	Withheld
742	2022-06025	Ms. Ragini Parida	Approved
743	2022-06036	Mr. Yashas Bp	Approved
744	2022-06038	Ms. Poornima Kumaran	Approved
745	2022-06045	Mr. Vinayaka Korishetty	Approved
746	2022-06046	Mr. Sonu Kumar	Approved
747	2022-06061	Mr. Rudra Verma	Approved
748	2022-06082	Ms. Anandi Gupta	Withheld
749	2022-06090	Ms. Nishtha Mahajan	Approved
750	2022-06092	Mr. Nikhil Kumar Mishra	Approved
751	2022-06093	Mr. Ajay Unnikrishnan	Approved
752	2022-06095	Ms. Nazia Fatima	Approved
753	2022-06099	Ms. Himanika Amol Paliwal	Approved
754	2022-06109	Mr. Sagar Anil Fulkey	Withheld
755	2022-06134	Mr. Leroy Dsouza	Approved
756	2022-06138	Ms. Harshavardhini Thangarajan	Withheld
757	2022-06143	Mr. Happy Dagar	Approved
758	2022-06151	Mr. Rushabh Jayantilal Gosar	Approved
759	2022-06159	Ms. Piuli Nandy	Approved
760	**2022-06169**	**Mr. Vaibhav Singh**	**Approved**
761	2022-06176	Ms. Shreya Kamesh Sheth	Approved
762	2022-06183	Ms. Nitha Nasrin K V	Withheld
763	2022-06190	Ms. D Vandana	Approved
764	2022-06191	Mr. Yathisha M A	Approved
765	2022-06198	Mr. Ajay D	Approved
766	2022-06213	Ms. Naency Changal	Approved
767	2022-06217	Mr. Pranoy Barman	Approved
768	2022-06219	Ms. Devashree Vinay Joshi	Approved
769	2022-06233	Mr. Soumyajit Mandal	Approved
770	2022-06234	Ms. Rajeshwari Mangesh Karad	Approved
771	2022-06240	Mr. Abhishek Kumar	Withheld
772	2022-06250	Ms. Parijat Ghosh	Approved
773	2022-06251	Ms. Anya Shetty	Withheld
774	2022-06252	Ms. Hafsah Rehman Sharieff	Withheld
775	2022-06263	Ms. Minal Pramod Karhade	Approved
776	2022-06267	Ms. Aishwarya A	Withheld
777	2022-06269	Mr. Rakesh Kumar P	Approved
778	2022-06284	Ms. Niharika Mehra	Approved
779	2022-06287	Mr. Divya Darshan Panigrahi	Approved

Title of Project:

"Barriers to Breast Cancer Screening in a Cohort of Urban Indian Women."

Principal Investigator: ***Mr. Vaibhav Singh****, Third year student of MBBS 2019 Batch, KGMU*

Guide: ***Prof. Vinod Jain****, Professor, Department of General Surgery, KGMU*

Role of Principal Investigator:

Data curation, Funding acquisition, Conceptualization, Resources, Visualization, Writing original drafts

Role of Guide:

Methodology, Project administration, Resources, Supervision, Validation, Visualization, Review and editing of final draft.

ANNEXURE: 1-RV-1/2019 (SOP-IEC-KGMU)

KING GEORGE'S MEDICAL UNIVERSITY, LUCKNOW, UP

FORM TO BE FILLED BY THE PRINCIPAL INVESTIGATOR (PI) FOR SUBMISSION TO INSTITUTIONAL ETHICS COMMITTEE (IEC)

(for attachment to each copy of the proposal)

* Ref. Code No. of IEC:

* to be filled by Office of IEC

Proposal Title:

"Barriers to Breast Cancer Screening in a Cohort of Urban Indian Women."

	Name, Designation & Qualifications	Departmental Tel No. & Email ID	Signature
PI	**MR VAIBHAV SINGH,** MBBS 2019, FACULTY OF MEDICAL SCIENCES	MOB: 8429367353 Email: vaibhav1816.19@kgmcindia.edu	Vaibhav Singh
GUIDE	**PROF. VINOD JAIN,** PROFESSOR, DEPARTMENT OF GENERAL SURGERY, KGMU, LUCKNOW, INDIA.	MOB: 9335135702 Email: vinodjain@kgmcindia.edu	Dr. Vinod Jain Professor Department of Surgery K.G.M.U., U.P., Lucknow

Please attach Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years) not working at KGMU. The investigators should sign their CV.

Sponsor Information: N/A

1. Indian	a) Government ☐ b) Private ☐	Central ☐	State ☐	Institutional ☐
2. International	**N/A**			
3. Industry	**N/A**			
4. Contact address of sponsor: N/A				
5. Budget N/A				

1. Type of study	Epidemiological ☑	Basic Sciences ☐	Behavioral ☐
	Clinical ☐	Single Centre ☐	Multicentric ☐
2. Status of review	New ☑	Revised ☐	

3. Clinical Trials

Drug/Vacancies/Device/Herbal Remedies N/A

i. Does the study involve use of

Drugs ☐ Devices ☐ Vaccines ☐

Indian systems of Medicines / or Alternate systems of Medicine ☐ Any other ☐ None ☐

ii. Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐ N/A

Other countries, specify

iii. Does it involve a change in use, dosage, route of administration? Yes ☐ No ☐

if yes, whether DCGI's/Any other Regulatory Authority's permission obtained? Yes ☐ No ☐

If yes, copy of permission attached. Yes ☐ No ☐ N/A

iv. Is it an Investigational New Drug? Yes ☐ No ☐ N/A

If yes,

a. Investigator's Brochure enclosed Yes ☐ No ☐

b. Preclinical studies data available (if yes, provide summary) Yes ☐ No ☐

c. Clinical studies data available (if yes, provide summary) Yes ☐ No ☐

d. Clinical study is Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ N/A ☐

e. DCGI's permission obtained Yes ☐ No ☐

If yes, copy of letter enclosed Yes ☐ No ☐

4. Brief description of the proposal-aim(s) and objectives, justification for study, methodology describing the potential risks and benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words)

5. Subject selection:

i. Number of subjects: ***385* subjects will be enrolled.**

ii. Duration of a) Study: **2 MONTHS** b) Subject participation: 2 MONTHS

iii. Will subjects from both sexes be recruited **Yes** ☐ No ☑

iv. Inclusion/exclusion criteria given **Yes** ☑ No ☐

v. Type of subjects Volunteers ☑ Patients ☐

vi. Vulnerable subjects Yes ☐ No ☑
(Tick the appropriate boxes)

Pregnant Women ☐	Children ☐	Elderly ☐
Fetus ☐	Illiterate ☐	Handicapped ☐
Terminally ill ☐	Seriously ill ☐	Mentally Challenged ☐
Economically & socially backward ☐	Any other ☐	

vii. Special group subjects Yes ☐ No ☑
(Tick the appropriate boxes)

Captives ☐	Institutionalized ☐	Employees ☐
Students ☐	Nurses / Dependent ☐	Armed Forces ☐
Any other ☐	Staff ☐	

6. Privacy and confidentiality

i. Study Involves
- Direct Identifiers ☐
- Indirect Identifiers/Coded ☐
- Completely Anonymized / Delinked ☑

ii. Confidential handling of data by staff Yes ☐ No ☑

7. Use of biological / hazardous materials N/A

i. Use of fetal tissue of aborts. If yes provide details Yes ☐ No ☐

ii. Use of organs or body fluids. If yes provide details Yes ☐ No ☐

iii. Use of recombinant / gene therapy products Yes ☐ No ☐

if yes, has Institutional Biosafety Committee approval for rDNA products been obtained? Yes ☐ No ☐

iv. Use of pre-existing/stored/left over samples Yes ☐ No ☐

v. Collection for banking / future research Yes ☐ No ☐

vi. Use of ionizing radiation / radioisotopes Yes ☐ No ☐

If yes, has Institutional Biosafety Committee approval for Radioactive Isotopes been obtained? Yes ☐ No ☐

vii. Use of Infectious / biohazardous specimens Yes ☐ No ☐

viii. Proposal disposal of material Yes ☐ No ☐

ix. Will any sample collected from the patients be sent abroad? Yes ☐ No ☐
If yes, give details and address of collaborators N/A

a. Sample will be sent abroad because (Tick appropriate box)
- Facility not available in India ☐
- Facility in India inaccessible ☐
- Facility available but not being accessed ☐

If so, reasons

b. Has necessary clearance been obtained — Yes ☐ No ☐

8. **Consent** — *** Written** ☑ **Oral** ☐ **Audio-Visual** ☐

i. Patient Information Sheet attached: (Tick the included elements) — Yes ☑ No ☐

Understandable language	☑	Alternatives to participation	☑
Statement that study involves research	☑	Confidentiality of records	☑
Sponsor of study	☑	Contact information	✓
Purpose and procedures	☑	Statement that consent is voluntary	☑
Risks & discomforts	☑	Right to withdraw	☑
Benefits	☑	Consent for future use of material biological	☐ N/A
Compensation for participation	☑	Benefits if any on future commercialization e.g. Genetic basis for drug development N/A	☐

Compensation for study related injury ☐ N/A

Translation of information sheet in local language ☑

ii. If healthy volunteers will be included, information sheet for them attached — Yes ☑ No ☐

iii. Consent form in English	☑	Hindi	☑
iv. Who will obtain consent (PI/Co-PI)	☐	Nurse / Counselor	☐
Research Staff	☐	Any other	☐

* If written consent is not obtained, giver reasons:

9. **Will any advertising be done for recruitment of Subjects?**
(Posters, flyers, brochure, websites – if so attach a copy) — Yes ☐ No ☑

10. **Risks & benefits**

i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country? — Yes ☑ No ☐

ii. Is there physical / social / psychological risk / discomfort? — Yes ☑ No ☐

if yes, Minimal or no risk ☑

More than minimum risk ☐

High risk ☐

iii. Is there benefit	a) to the subject?	Yes ☑	No ☐
		Direct ☑	Indirect ☐
	b) to the society?	Yes ☑	No ☐

11. Data monitoring

i. Is there a data & safety monitoring committee/Board (DSMB)?	Yes ☐	No ☐
ii. Is there a plan for reporting of adverse events? N/A	Yes ☐	No ☐
if yes, reporting will be done to		
Sponsor ☐ IEC ☐	DSMB ☐	
iii. Is there a plan for interim analysis of data?	Yes ☐	No ☐

12. Is there compensation for injury? N/A — Yes ☐ No ☐

If yes, by

Sponsor	☐	Investigator	☐
Insurance Company	☐	Any other	☐

13. Do you have conflict of interest? — Yes ☐ **No** ☑
(Financial / Non-financial)

If yes, specify	
Check list for attached documents:	
Project proposal – 05 copies	
Curriculum Vitae of non KGMU Investigators	☐
Brief description of proposal/summary	☑
Copy of the Protocol / Project and questionnaire (if any)	☑
Investigator's Brochure	☐
Copy of Patient information sheet & Consent form in local language	☑
Copy of Advertisements/Information brochures	☐
DCGI/DBT/BARC clearance if obtained	☐
Copy of Insurance Policy	☐
Copy of Clinical trial agreement	☐
Copy of IEC proforma	☐
Copy of PI undertaking	☑
Copy of Case Report Form	☐

Vaibhav Singh

Signature of PI

Dr. Vinod Jain
Professor
Department of Surgery
K.G.M.U., U.P, Lucknow

Signature of GUIDE with stamp

Date: ___/___/20__

21/5/2022

Signature of HOD with stamp

Head of Department of Surgery (Gen.)
K.G. Medical University U.P., Lucknow.

ANNEXURE: 2-RV-1/2019 (SOP-IEC-KGMU)

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

1) **NAME OF THE PROJECT:**

"Barriers to Breast Cancer Screening in a Cohort of Urban Indian Women."

2) **NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR:**

MR VAIBHAV SINGH, *Third year student of MBBS 2019 Batch*

3) **OTHER MEMBERS OF THE RESEARCH TEAM:**

PROF. VINOD JAIN, *Professor, Department of General Surgery, KGMU*

4) **NAME AND ADDRESS OF ANY OTHER MEDICAL INSTITUTE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE**

5) **NUMBER OF ONGOING PROJECTS/CLINICAL TRIALS IN WHICH YOU ARE PI: 1**

- I confirm that I will initiate the study only after obtaining all regulatory clearances.
- I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest.
- I confirm that the CO-PI and other members of the study team have been informed about their obligations and are qualified to meet them.
- I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under ICMR and National Regulatory Guidelines are adhered to.
- I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, Regulatory authorities, Sponsors or their authorized representatives.
- I will inform the IEC and the Sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.
- I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
- I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
- I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.

Vaibhav Singh

Signature of Principal Investigator

Dr. Vinod Jain
Professor
Department of Surgery
K.G.M.U., U.P., Lucknow

Date: 21/05/2022

ANNEXURE: 7-Rev V-1/2019 (SOP-IEC-KGMU)

KING GEORGE'S MEDICAL UNIVERSITY, LUCKNOW, UP

PARTICIPANT INFORMATION SHEET

1. **Study Title:** ***"Barriers to Breast Cancer Screening in a Cohort of Urban Indian Women."***
2. **Invitation:**
   You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.
3. **What is the purpose of the study?**
   To evaluate breast cancer screening practices in urban Indian women.
   To identify barriers of screening for breast cancer in a cohort of urban women.
   To assess various factors affecting screening practices.
4. **Why have I been chosen?**
   Because you are an Indian woman living in an urban area.
5. **Do I have to take part?**
   It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.
6. **What will happen to me if I take part?**
   You will be asked to fill out a questionnaire regarding socio-demographic variables (age, occupation, education, marital status), and Cancer screening related questions (about Breast Self-Examination, Clinical Breast Examination and Mammography).
7. **What do I have to do?**
   Nothing extra, other than what has been explained above.
8. **What is the drug or procedure that is being tested?**
   N/A
9. **What are the alternatives for diagnosis or treatment?**
   N/A
10. **What are the side effects of taking part?**
    None.
11. **What are the possible disadvantages and risks of taking part?**
    None.
12. **What are the possible benefits of taking part?**
    None.
13. **What if new information becomes available?**
    N/A
14. **What happens when the research study stops?**
    Since there is no drug/treatment involved in our study. So, it would not make any difference to the participant.
15. **What if something goes wrong?**
    Since there is no drug/treatment involved in our study. So, it would not make any difference to the participant.
16. **Will my taking part in this study be kept confidential?**
    All information collected about you during the course of the study will be kept strictly confidential.

17. **What will happen to the results of the research study?**
The research study will be published in a journal. Although, your data will be kept highly confidential.
18. **Who is organizing and funding the research?**
It is funded by ICMR, New Delhi. It is under the ICMR STS Programme, 2022.
19. **Who has reviewed the study?**
IEC (Institutional Ethics Committee) has reviewed the study.

20. **Contact for further information:**

Prof. Vinod Jain,
Professor,
Department of General Surgery,
King George's Medical University,
Shahmina Shah Road, Chowk,
Lucknow-226003, Uttar Pradesh, India.

Mr. Vaibhav Singh,
Faculty of Medical Sciences,
King George's Medical University,
Shahmina Shah Road, Chowk,
Lucknow-226003, Uttar Pradesh, India.

Vaibhav Singh

The Dean of Research and Development:
Prof. Shally Awasthi,
Office of the Dean of Research and Development,
Behind Shelby Hall,
King George's Medical University,
Shahmina Shah Road, Chowk,
Lucknow-226003, Uttar Pradesh, India.

Legally authorized representative
Legally authorized representative (LAR), under applicable law or judicial authority, can give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the ethics committee.

Date: 21/05/2022

Vaibhav Singh

Signature of Principal Investigator

एनेक्सचर: 7-रेव वी-1/2019 (एसओपी-आईईसी-केजीएमयू)

किंग जॉर्ज मेडिकल यूनिवर्सिटी, लखनऊ, उत्तर प्रदेश

सहभागी सूचना पत्र

1. अध्ययन का शीर्षक: "*शहरी भारतीय महिलाओं के एक समूह में स्तन कैंसर स्क्रीनिंग के लिए बाधाएं।"*

2. आमंत्रण:

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले आपके लिए यह समझना महत्वपूर्ण है कि शोध क्यों किया जा रहा है और इसमें क्या शामिल होगा । कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें और यदि आप चाहें तो दोस्तों, रिश्तेदारों और अपने इलाज के चिकित्सक/ पारिवारिक चिकित्सक के साथ इस पर चर्चा करें । हमसे पूछें कि क्या ऐसा कुछ है जो स्पष्ट नहीं है या यदि आप अधिक जानकारी चाहते हैं। आप भाग लेना चाहते हैं या नहीं, यह तय करने के लिए समय निकालें।

3. अध्ययन का उद्देश्य क्या है?

- शहरी भारतीय महिलाओं में स्तन कैंसर स्क्रीनिंग प्रथाओं का मूल्यांकन करने के लिए।
- शहरी महिलाओं के एक समूह में स्तन कैंसर के लिए स्क्रीनिंग की बाधाओं की पहचान करना।
- स्क्रीनिंग प्रथाओं को प्रभावित करने वाले विभिन्न कारकों का आकलन करना।

4. मुझे क्यों चुना गया है?

क्योंकि आप एक शहरी क्षेत्र में रहने वाली एक भारतीय महिला हैं।

5. क्या मुझे भाग लेना है?

यह आपको तय करना है कि भाग लेना है या नहीं। यदि आप भाग लेने का निर्णय लेते हैं, तो आपको यह सूचना पत्रक रखने के लिए दिया जाएगा और सहमति प्रपत्र पर हस्ताक्षर करने के लिए कहा जाएगा। यदि आप भाग लेने का निर्णय लेते हैं तब भी आप किसी भी समय और बिना कोई कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6. यदि मैं भाग लेता हूँ तो मेरा क्या होगा?

आपको सामाजिक-जनसांख्यिकीय चर (उम्र, व्यवसाय, शिक्षा, वैवाहिक स्थिति) और कैंसर स्क्रीनिंग से संबंधित प्रश्नों (स्तन आत्म-परीक्षा, नैदानिक स्तन परीक्षा और मैमोग्राफी) के बारे में एक प्रश्नावली भरने के लिए कहा जाएगा।

7. मुझे क्या करना होगा?

ऊपर जो बताया गया है, उसके अलावा और कुछ नहीं।

8. वह कौन सी दवा या प्रक्रिया है जिसका परीक्षण किया जा रहा है?

लागू नहीं

9. निदान या उपचार के विकल्प क्या हैं?

लागू नहीं

10. भाग लेने के क्या दुष्प्रभाव हैं?

कोई नहीं।

11. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

कोई नहीं।

12. भाग लेने के संभावित लाभ क्या हैं?

कोई नहीं।

13. क्या होगा यदि नई जानकारी उपलब्ध हो जाती है?

लागू नहीं

14. क्या होता है जब शोध अध्ययन बंद हो जाता है?

चूंकि हमारे अध्ययन में कोई दवा/उपचार शामिल नहीं है। ऐसे में सहभागी को कोई फर्क नहीं पड़ेगा।

15. क्या हो यदि कुछ गलत हो जाए?

चूंकि हमारे अध्ययन में कोई दवा/उपचार शामिल नहीं है। ऐसे में सहभागी को कोई फर्क नहीं पड़ेगा।

16. क्या इस अध्ययन में मेरे भाग लेने को गोपनीय रखा जाएगा?

अध्ययन के दौरान आपके बारे में एकत्र की गई सभी जानकारी को पूरी तरह गोपनीय रखा जाएगा।

17. शोध अध्ययन के परिणामों का क्या होगा?

शोध अध्ययन एक जर्नल में प्रकाशित किया जाएगा। हालाँकि, आपका डेटा गोपनीय रखा जाएगा।

18. अनुसंधान का आयोजन और वित्त पोषण कौन कर रहा है?

इसका वित्तपोषण आईसीएमआर, नई दिल्ली द्वारा किया जाता है। यह आईसीएमआर एसटीएस कार्यक्रम, 2022 के तहत है।

19. अध्ययन की समीक्षा किसने की है?

आई.ई.सी. (संस्थागत आचार समिति) ने अध्ययन की समीक्षा की है।

20. अधिक जानकारी के लिए संपर्क करें:

प्रो. विनोद जैन,
प्रोफेसर,
जनरल सर्जरी विभाग,
किंग जॉर्ज मेडिकल यूनिवर्सिटी,
शाहमीना शाह रोड, चौक,
लखनऊ-226003, उत्तर प्रदेश, भारत।

श्री वैभव सिंह,
चिकित्सा विज्ञान संकाय,
किंग जॉर्ज मेडिकल यूनिवर्सिटी,
शाहमीना शाह रोड, चौक,
लखनऊ-226003, उत्तर प्रदेश, भारत।

प्रो. शैली अवस्थी ,
डीन, अनुसंधान और विकास,
किंग जॉर्ज मेडिकल यूनिवर्सिटी,
शाहमीना शाह रोड, चौक,
लखनऊ-226003, उत्तर प्रदेश, भारत।

21. कानूनी रूप से अधिकृत प्रतिनिधि

कानूनी रूप से अधिकृत प्रतिनिधि (एलएआर), लागू कानून या न्यायिक प्राधिकरण के तहत, एक संभावित प्रतिभागी की ओर से सहमति दे सकता है, जो कानूनी या चिकित्सा कारणों से, अनुसंधान में भाग लेने या निदान से गुजरने के लिए खुद को सहमति देने में असमर्थ है, नैतिक समिति द्वारा विधिवत अनुमोदित अनुसंधान प्रोटोकॉल के अनुसार चिकित्सीय या निवारक प्रक्रिया।

दिनांक: 21/05/2022

वैभव सिंह

अन्वेषक के हस्ताक्षर:

EXECUTIVE SUMMARY FOR ETHICAL APPROVAL

1) **TITLE OF PROJECT:** ***"Barriers to Breast Cancer Screening in a Cohort of Urban Indian Women."***

2) **TEACHER INVESTIGATOR:**
PROF. VINOD JAIN, Professor, Department of General Surgery, KGMU, Lucknow, India.

STUDENT INVESTIGATOR:
MR VAIBHAV SINGH, Third Year MBBS Student, Batch of 2019, KGMU

3) **BACKGROUND**

The global cancer burden is expected to be 28.4 million cases in 2040, a 47% increase from the corresponding 19.3 million cases in 2020. Globally, Breast cancer is the most commonly diagnosed cancer and the leading cause of cancer death among females, followed by colorectal and lung cancer for incidence, and vice versa for mortality.[1] Breast cancer has the highest incidence rate (13.5%) and death rate (10.6%) in India.[2]
However, early detection of breast cancer has better chances of survival and also reduces treatment costs.[3] The 5-year survival rate with early detection is approximately 85% whereas it is reduced to 56% with late detection.[4] Unfortunately, over 70% of the women present in advanced stages of breast cancer which is the main cause of high mortality among these patients. Advanced stage presentation of breast cancer occurs mainly due to the non-existent breast cancer screening program, and non-participation of women if any such program does exist.[5]

Breast Cancer Screening is defined as testing women before any evident symptoms appear, to detect and treat cancers or pre-cancers.[6] Breast Self-Examination (BSE), Clinical Breast Examination (CBE) and Mammography are some of the screening techniques used for Breast cancer.[7] In India, Breast cancer screening is part of the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases, and Stroke (NPCDCS).[8] Its guidelines are used for the screening of different cancers in eligible men and women[9] but there is still no existing National Screening Program.[8]

Notably, India's National Family Health Survey-5 (NFHS-5) data reveal that NPCDCS has not taken off in any state. According to NFHS-5 2020-21 data on Breast Cancer Screening, The state with the highest percentage coverage for breast cancer screening was Mizoram, with 2.7% women screened.[9] Only 0.4% of women between the age of 30 and 49 years had ever undergone a breast examination for breast cancer, both in rural and urban areas of Uttar Pradesh.[10]

According to a recent report from National Cancer Registry Programme (NCRP) India, The highest burden of breast cancer has been observed in metropolitan cities.[11] So, it becomes essential to analyse various reasons for women to not avail of existing screening facilities even after being aware of the high mortality associated with advanced stages of breast cancer. Identification of barriers to breast cancer screening can be very helpful in improving morbidity and mortality status.

In a nutshell, lack of awareness has been shown to be one of the biggest barriers to screening and early detection of breast cancers [12] therefore it is crucial to assess existing levels of cancer awareness in urban Indian women. Moreover, currently, there is a significant gap in the literature with respect to the barriers that affect screening practices amongst Indian women. Hence, this study aims to fill in this gap by assessing various factors that affect screening practices amongst urban women in India. And, considering very much lower screening rates for breast cancer in India, in this study, we also aim to identify factors that act as barriers to breast cancer screening in urban Indian women.

4) OBJECTIVES

Primary objectives:

To evaluate breast cancer screening practices in urban Indian women.

To identify barriers of screening for breast cancer in a cohort of urban women.

Secondary objectives:

To assess various factors affecting screening practices.

5) METHODOLOGY

5.1. Type of Study: Observational study

5.2. Study Design: Survey-based, cross-sectional study.

5.3. Study Setting & Population: The Participants for this study will include urban Indian women living in Uttar Pradesh.

The definition of an urban area is as follows [13];

1. All places with a municipality, corporation, cantonment board or notified town area committee, etc.
2. All other places which satisfy the following criteria:
    a) A minimum population of 5,000;
    b) At least 75 per cent of the male main working population engaged in non-agricultural pursuits;
    c) A density of population of at least 400 persons per sq. km

5.4. Inclusion criteria:

I. Indian women living in urban areas.
II. Women consenting for participation in this study.

5.5. Exclusion criteria:

I. Women not consenting for participation in this study.
II. Women not completing the questionnaire (<70%).

5.6. Sample Size: 385 participants (calculated with a 95% confidence level and a 5% margin of error.)

Sample size was calculated using the formula:

Sample Size = $N * [Z^2 \times p \times (1-p)/e^2] / [N - 1 + (Z^2 \times p \times (1-p)/e^2]$

where N = Population size,

Z = Critical value of the normal distribution at the required confidence level,

p = Sample proportion,

e = Margin of error

5.7. DATA COLLECTION

Data shall be collected by administering a comprehensive self-designed and validated, structured questionnaire via online as well as offline medium. A consent form will also be included with the questionnaire. After explaining the study's purpose and its benefits for women's health, participant's written and verbal consent will be obtained. Questionnaire has been prepared by using the information on breast cancer and screening from the literature. Questionnaire includes the socio-demographic variables (age, occupation, education, marital status) of the participants, and Cancer screening related questions (about Breast Self-Examination, Clinical Breast Examination and Mammography).

5.8. STATISTICAL ANALYSIS

After data collection, the collected data will be first organized and tabulated in Microsoft excel. The data obtained will be analysed with the help of IBM SPSS (Statistical Package for the Social Sciences) Software Version 24 for which institutional access is available. Chi-square test will be used to correlate various parameters affecting breast cancer screening practices.

6) **Time Frame:** This study will be conducted over a period of 2 months, after approval.

7) **Risks to Participants & Ethical Considerations:** The study does not involve any kind of health risks to the participants. It will be conducted only after approval by the Institutional ethics committee, KGMU. A consent form will also be included with the questionnaire. All data will be stored and handled in a strictly confidential manner.

8) **ETHICAL CONSIDERATIONS**

We have submitted the proposal for ethical clearance to the Institution's Ethics Committee and it will be attached at the time of report submission. Participation in this study will be voluntary. Data will be collected only after obtaining participants' consent and data will be kept confidential.

9) **IMPLICATIONS**

1. This study will help us enhance awareness about screening programmes among women.
2. This study may help us in the development and implementation of well-organized screening programmes in India as well as in strengthening existing screening facilities.
3. Identifying barriers is crucial in improving women participation in breast cancer screening programs which would ultimately result in detecting early-stage cases and lowering the treatment cost.
4. Identification of barriers to breast cancer screening in a cohort of urban Indian women would be very helpful in reducing morbidity and mortality as well as disease burden.
5. This study can provide better insight on how to eliminate various barriers to improve cancer screening rates in India.

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KING GEORGE'S MEDICAL UNIVERSITY
LUCKNOW, UP

TITLE OF PROJECT:
"Barriers to Breast Cancer Screening in a Cohort of Urban Indian Women."

PRINICIPAL INVESTIGATOR (PI):
MR VAIBHAV SINGH, Third Year MBBS Student, Batch of 2019, KGMU

GUIDE:
PROF. VINOD JAIN, Professor, Department of General Surgery, KGMU, Lucknow, India.

QUESTIONNAIRE

NAME:		**DATE:**
ADDRESS(CITY):		
AGE (YEARS):	**OCCUPATION:** EMPLOYED / UNEMPLOYED / STUDENT	
MARITAL STATUS: SINGLE / MARRIED / OTHER		**HEALTH INSURANCE:** YES / NO
HIGHEST LEVEL OF EDUCATION: 1. No formal education 2. Primary education 3. Secondary education 4. Higher secondary education 5. Graduation or higher studies		

1. **Have you heard of breast cancer?** Yes / No
2. **Have you heard of breast cancer screening?** Yes / No

Breast Self-Examination (BSE)

- Have you heard of Breast Self-Examination (BSE)? Yes / No
- Do you believe that BSE is a useful tool for the early detection of breast cancer? Yes/No
- Do you know how to do BSE? Yes / No
- Do you practice BSE? Yes / No
- If the answer to the question above is yes, how often?
  a) Weekly
  b) Monthly
  c) Occasionally
  d) Rarely
- If the answer is no, why not?
  (Agree or Disagree, Participant can choose more than one option.)
  - I don't know how to perform BSE.
  - I don't have any symptoms of breast cancer.

- I know that I can never have breast cancer.
- I am scared of being diagnosed with breast cancer.
- Doing BSE makes me worry about breast cancer
- Doing BSE is embarrassing to me
- I don't have enough privacy to do BSE.
- I don't believe in the efficacy of this test.
- I don't think I should touch my body like that.
- BSE takes too much time.
- BSE is unpleasant/ painful.
- I don't think BSE is important.

- If you have been practising BSE, have you ever discovered any abnormality in your breast? (1)Yes (2)No (3)I have not done BSE before
- If the answer to the question above is yes, what did you do?
  (1)Consulted a doctor (2)Did nothing (3)Others (specify)

Clinical Breast Examination (CBE)

- Have you heard of Clinical Breast Examination (CBE)? Yes / No
- Do you believe that CBE is a useful tool for the detection of breast cancer? Yes / No
- Has a health care provider ever examined your breasts? Yes / No
- Have you undergone CBE recently? Yes / No

MAMMOGRAPHY

- Have you heard of mammography? Yes / No
- Do you believe that a mammography is a useful tool for the early detection of breast cancer? Yes / No
- Have you ever undergone mammography? Yes / No
- Have you undergone mammography recently? Yes / No

3. What centre would you like to visit for Breast screening?

a) Primary Health Centre (PHC)
b) Community Health Centre (CHC)
c) Any Government Hospital
d) Any Private Hospital
e) Anywhere (No Preference)

4. Which doctor would you prefer for Breast screening?

a) General Physician
b) Breast surgeon
c) Gynaecologist
d) Anyone (No Preference)

5. **Did you ever undergo breast screening at a hospital or clinic?** Yes / No

6. **How do you feel about undergoing breast screening?**
   - It is better for early detection.
   - It should be done only when the need arises.
   - It is culturally unacceptable.
   - I have religious issues in doing so.

7. **Gender preference of health care provider if undergoing breast screening:**
   Male / Female / Anyone (No Preference)

8. **Comfort level during consultation about breast cancer with a physician:**
   a. Yes, I am comfortable in discussing this with a physician.
   b. I am not comfortable discussing this with a physician.

9. **Do you feel embarrassed talking about breast cancer in society?** Yes / No

10. **In your opinion what is the main barrier in undergoing breast screening?**
    (Participant can choose more than one option)
    a. Culture/traditions of the family
    b. Ignorance
    c. Fatalism
    d. Traditional healers' consultation
    e. Shyness, Hesitant or Embarrassment / Reluctance to discuss such issues
    f. No screening facilities
    g. No female doctor/ do not want to be examined by a male doctor
    h. Inadequate knowledge regarding breast cancer & screening
    i. Lack of access:
       Financial Problems
       Lack of time or long waiting time for appointments
       Geographic & Transportation Problem
    j. Conservative society
    k. Fear of diagnosis
    l. Fear of pain
    m. Negative past experiences
       (due to pain, inappropriate services, bad behaviour or any other reason)
    n. Language barrier
    o. Others, Please specify

Thank you very much for your time and effort. It is very well appreciated.

ANNEXURE: 9-RV-1/2019 (SOP-IEC-KGMU)

KING GEORGE'S MEDICAL UNIVERSITY, LUCKNOW, UP

INFORMED CONSENT FORM

Study Title: ***"Barriers to Breast Cancer Screening in a Cohort of Urban Indian Women."***

Study Number: _____

Contact details of Principal-Investigator: **MR. VAIBHAV SINGH, MBBS 2019, KGMU**
MOB: 8429367353 / Email: vaibhav1816.19@kgmcindia.edu

Subject's Full Name: _____

Date of Birth/Age: _____

Address: _____

PART 1

1. **Purpose of the study:**
   - To evaluate breast cancer screening practices in urban Indian women.
   - To identify barriers of screening for breast cancer in a cohort of urban women.
   - To assess various factors affecting screening practices.

2. **Study procedures:**
   Eligible participants for this study will be selected as per inclusion & exclusion criteria. Data shall be collected by administering a comprehensive self-designed and validated, structured questionnaire via online as well as offline medium. A consent form will also be included with the questionnaire. After explaining the study's purpose and its benefits for women's health, participants' written and verbal consent will be obtained. Questionnaire has been prepared by using the information on breast cancer and screening from the literature. Questionnaire includes the socio-demographic variables (age, occupation, education, marital status) of the participants, and Cancer screening related questions (about Breast Self-Examination, Clinical Breast Examination and Mammography).

3. **Risk from the study:** NONE

4. **Benefits from the study:**
   - This study will help us enhance awareness about screening programmes among women.
   - This study may help us in the development and implementation of well-organized screening programmes in India as well as in strengthening existing screening facilities.
   - Identifying barriers is crucial in improving women participation in breast cancer screening programs which would ultimately result in detecting early-stage cases and lowering the treatment cost.
   - Identification of barriers to breast cancer screening in a cohort of urban Indian women would be very helpful in reducing morbidity and mortality as well as disease burden.
   - This study can provide better insight on how to eliminate various barriers to improve cancer screening rates in India.

5. **Complications:** NONE
6. **Compensation:** NONE
7. **Confidentiality:** Personal identifiers will be kept confidential throughout the study.
8. **Rights of the participants:** Right to not participate in the study
9. **Alternatives to participation in the study:** NONE

PART 2
Consent

1) I confirm that I have read and understood the information sheet dated _____for the above study and have had the opportunity to ask questions.

OR

I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3) I understand that the sponsor of the clinical trial/project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)

5) I agree to take part in the above study.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

_____

Signatory's Name: _____ **Date:** __/__/ 20

Relationship with subject: _____

Investigator's statement: -

I, the undersigned have explained to the parent/guardian in a language she/he understands the procedures to be followed in the study and risks and benefits.

Signature of the Investigator: Vaibhav Singh ***Date:*** __/__/ 20__

Name of the Investigator: Mr. Vaibhav Singh, MBBS 2019

Signature of the Witness: ***Date:*** __/__/ 20__

Name of the Witness: _____

एनेक्सचर: 9-आरवी-1/2019 (एसओपी-आईईसी-केजीएमयू)

किंग जॉर्ज मेडिकल यूनिवर्सिटी, लखनऊ, उत्तर प्रदेश

सूचित सहमति पत्र

अध्ययन का शीर्षक: "*शहरी भारतीय महिलाओं के एक समूह में स्तन कैंसर स्क्रीनिंग के लिए बाधाएं।*"

अध्ययन संख्या: _____

अन्वेषक का संपर्क विवरण: *श्री वैभव सिंह, एमबीबीएस 2019, केजीएमयू*

मोबाइल नंबर: 8429367353 / *ईमेल:* vaibhav1816.19@kgmcindia.edu

सहभागी का पूरा नाम: _____

जन्म तिथि/आयु: _____

पता: _____

भाग- 1

1. **अध्ययन का उद्देश्य:**
   - शहरी भारतीय महिलाओं में स्तन कैंसर स्क्रीनिंग प्रथाओं का मूल्यांकन करने के लिए।
   - शहरी महिलाओं के एक समूह में स्तन कैंसर के लिए स्क्रीनिंग की बाधाओं की पहचान करना।
   - स्क्रीनिंग प्रथाओं को प्रभावित करने वाले विभिन्न कारकों का आकलन करना।

2. **अध्ययन प्रक्रियाएं:**
   इस अध्ययन के लिए पात्र प्रतिभागियों को समावेशन और बहिष्करण मानदंडों के अनुसार चुना जाएगा। डेटा को ऑनलाइन और ऑफलाइन माध्यम से एक व्यापक स्व-डिज़ाइन और मान्य, संरचित प्रश्नावली द्वारा एकत्र किया जाएगा। प्रश्नावली के साथ एक सहमति पत्र भी शामिल किया जाएगा। अध्ययन के उद्देश्य और महिलाओं के स्वास्थ्य के लिए इसके लाभों को समझाने के बाद, प्रतिभागियों की लिखित और मौखिक सहमति प्राप्त की जाएगी। प्रश्नावली में प्रतिभागियों के सामाजिक-जनसांख्यिकीय चर (आयु, व्यवसाय, शिक्षा, वैवाहिक स्थिति) और कैंसर स्क्रीनिंग से संबंधित प्रश्न (स्तन आत्म-परीक्षा, नैदानिक स्तन परीक्षा और मैमोग्राफी) शामिल हैं।

3. **अध्ययन से जोखिम:** कोई नहीं

4. **अध्ययन से लाभ:**
   - यह अध्ययन हमें महिलाओं के बीच स्क्रीनिंग प्रथाओं के बारे में जागरूकता बढ़ाने में मदद करेगा।
   - यह अध्ययन हमें भारत में अच्छी तरह से संगठित स्क्रीनिंग कार्यक्रमों के विकास और कार्यान्वयन के साथ-साथ मौजूदा स्क्रीनिंग सुविधाओं को मजबूत करने में मदद कर सकता है।
   - स्तन कैंसर स्क्रीनिंग कार्यक्रमों में महिलाओं की भागीदारी में सुधार करने के लिए, बाधाओं की पहचान करना महत्वपूर्ण है जिसके परिणामस्वरूप अंततः प्रारंभिक चरण के मामलों का पता लगाया जाएगा और उपचार की लागत कम हो जाएगी।
   - शहरी भारतीय महिलाओं के एक समूह में स्तन कैंसर की जांच के लिए बाधाओं की पहचान रुग्णता और मृत्यु दर के साथ-साथ बीमारी के बोझ को कम करने में बहुत सहायक होगी।
   - यह अध्ययन भारत में कैंसर स्क्रीनिंग दरों में सुधार के लिए विभिन्न बाधाओं को खत्म करने के तरीके पर बेहतर अंतर्दृष्टि प्रदान कर सकता है।

5. **जटिलताएं:** कोई नहीं
6. **मुआवजा:** कोई नहीं
7. **गोपनीयता:** व्यक्तिगत पहचानकर्ताओं को पूरे अध्ययन में गोपनीय रखा जाएगा।
8. **प्रतिभागियों के अधिकार:** अध्ययन में भाग नहीं लेने का अधिकार
9. **अध्ययन में भागीदारी के लिए विकल्प:** कोई नहीं

भाग - 2

अनुमति

1) मैं इस बात की पुष्टि करता हूं कि मैंने उपरोक्त अध्ययन के लिए सूचना पत्र पढ़ा और समझा है और मुझे प्रश्न पूछने का अवसर मिला है । **अथवा**
   मुझे अन्वेषक द्वारा अध्ययन के तथ्यों को समझाया गया है और सवाल पूछने का अवसर मिला है ।
2) मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं किसी भी समय, किसी भी कारण से अध्ययन में भाग नहीं लेने के लिए स्वतंत्र हूं, बिना मेरी चिकित्सा देखभाल या कानूनी अधिकारों के प्रभावित हुए ।
3) मैं समझता हूं कि चिकित्सीय प्रायोजक/परियोजना, प्रायोजक की ओर से काम कर रहे अन्य, आचार समिति और नियामक प्राधिकरणों को वर्तमान अध्ययन और इसके संबंध में किए जा सकने वाले किसी भी और अनुसंधान दोनों के संबंध में मेरे स्वास्थ्य अभिलेखों को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी, भले ही मैं परीक्षण से हट जाऊं । हालांकि, मैं समझता हूं कि मेरी पहचान किसी भी तीसरे पक्ष या प्रकाशित करने के लिए जारी की जानकारी में उजागर नहीं होगी ।
4) मैं इस अध्ययन से प्राप्त होने वाले किसी भी आंकड़ो या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्य के लिए हो ।
5) मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं ।

सहभागी के हस्ताक्षर या अंगूठे का निशान / कानूनी रूप से स्वीकार्य प्रतिनिधि:

_____

हस्ताक्षरकर्ता का नाम: _____ दिनांक: __ /__ / 20__

सहभागी के साथ संबंध: _____

अन्वेषक का बयान:-

मैं, अधोहस्ताक्षरी ने सहभागी / कानूनी रूप से स्वीकार्य प्रतिनिधि को अध्ययन की प्रक्रियाओं और जोखिम और लाभ को उसकी भाषा में समझाया है ।

अन्वेषक के हस्ताक्षर: वैभव सिंह दिनांक: __ /__ / 20__

अन्वेषक का नाम: ***श्री वैभव सिंह, एमबीबीएस 2019***

गवाह के हस्ताक्षर: दिनांक: __ /__ / 20__

गवाह का नाम: _____