

Obtaining Ethical Approval:

A guide for Undergraduate and Postgraduate Students of KGMU

- **The Institutional Ethics Committee (IEC) meeting is held every 2-3 months.**
Information of future meetings may be obtained in the office of Ethics Committee, in 1st floor of research cell building. This building is in front of central library, KGMU.
- **For your document to be considered in an IEC meeting, you must ensure that your complete application is submitted to the ethics committee office 1 month prior.**
Past experience indicates that no concessions are usually made in this regard, especially if the study is multi-centric in nature. For instance, the last date for submission of documents for IEC meeting of 8th February 2019 was 11th January.
- **Results, remarks and comments of the IEC meeting with regards to your proposal will be communicated one month after the meeting.** Please ensure that your proposal has been thoroughly review prior to submission. For instance, often students do not submit sample size calculation which is marked by the IEC and they ask students to re-submit. This may result in a delay of upto 3 months in starting the project depending on when the next meeting is held.
- Therefore, for applying for Clinical Trials Registry of India (CTRI) approval, or for ICMR-STC project work, **please have a margin of upto 3 months to ensure that you obtain ethical approval within time.**
- Following documents will need to prepared for the ethical approval . These have been available in the following document for sample purposes.
 1. **Cover Letter to the Member Secretary , Research Cell**
 - Must be recommended and forwarded by the Head of the Department
 2. **Completed pro-forma of the ethical approval**

- Must be recommended and forwarded by the Head of the Department

3. Consent forms in Hindi and English.

- Please ensure that your Hindi consent form is understandable. It is read in detail by the IEC. Solely using google translate on the English version often will result in you being asked to redraft the informed consent form correctly.
- Both English and Hindi forms need to be signed by all the investigators

4. Signature Page of all investigators (both the student and the faculty mentor)

5. Executive Summary of the proposal/work/study

- Please ensure that it is in the correct format – 1 Inch margins, times new roman, 12-font.
 - Please avoid exceeding 5 pages
-
- **Arrange the documents in the order as given above, after ensuring all signatory requirements have been fulfilled.**
 - **Ensure 3 photo-copies of the entire application and a CD containing the entire filled and scanned application (all documents scanned in colour in original) – This scanning facility is available in Reading room of KGMU.**
 - Submit the entire original application with 3 copies and the CD (with your project details written using CD marker) to the ethics office. The persons working there will check your application and submit it for consideration in the next IEC meeting.

To
Member Secretary
Research Cell
KGMU, Lucknow
25th January, 2019

It may be Ethical Approval of
Intramural Research Project

Subject: Ethical Approval of ICMR STS Study

Respected Sir

With due regards, I, Ahmad Ozair, MBBS Student, Batch of 2016, KGMU wish to submit the following ICMR project for ethical clearance.

I request you to kindly consider the project for review by the Ethical Committee. I shall be highly obliged for the same.

Kindly find attached the required documents regarding the project.

Signature and Stamp.

*Recommended and Forwarded by
Head, Department of xxxxxxxx
King George's Medical University*

Signature

Thank you
Yours Sincerely

Ahmad Ozair

Medical Student, Batch of 2016
King George's Medical University UP Lucknow

Phone No. +91xxxxx xxxxx

ahmadozair1@gmail.com

Required.

K.G. Medical University UP, Lucknow

Check List for submitting Research Proposals for clearance of Ethical Committee

PART I

1. Title of the Project : **Loss of Empathy in Undergraduates of Different Medical Colleges.**
2. Investigator's Name & department:
 - **Teacher Supervisor:** Dr. xxxxx xxxxx, Professor, Department of xxxxxx, KGMU
 - **Student Investigator:** Ahmad Ozair, MBBS 2016, KGMU
3. Source of Funding :
 - **No Funding required**

4. Check List:

S. No.	Particulars		Yes	No	If No (Give Reason)
a.	Executive Summary (Proposal)		✓		-
b.	New Proposal		✓		-
c.	Informed consent form	(a) English	✓		-
		(b) Hindi	✓		-
d.	Budget			✓	(No funding required locally)
e.	Memorandum of Understanding (Industry Sponsored Projects)			✓	Not required
f.	Indemnity Agreement (Industry Sponsored Projects)			✓	Not required

5. Whether the project involves
 - 5.1. Clinical trial with new drug(s) device(s) approved by DCGI **No**
 - 5.2. Clinical trial with existing drug(s) device(s) approved by DCGI **No**
 - 5.3. Clinical trial with traditional medicines from Ayurvedic/ Unani/ Homeopathy/ Tribal systems **No**
 - 5.4. None of the above – **Yes (it is a survey based study of healthy subjects)**
- CAUTION NO DRUG/DVICE IS TO BE USED UNLESS CONTROLLER OF INDIA*

If answer to 5.1. is yes, kindly furnish evidence of experimental and clinical safety of the drug (Use separate sheets)

True for Survey-based studies, not for investigation-based or interventional.

6. If the human material to be collected is human tissue specify the tissue NO

6.1. It will be obtained by Operation/Biopsy/ Abortion /Autopsy
Other (Specify _____)
_____)

6.2. Whether the procedure required to obtain the tissue is otherwise indicated for the management of the patient N/A

6.3. Whether the project involves normal human tissue N/A

If answer to 6.2 is yes please explain the full procedure and justify collection and use of material (Use separate sheets) N/A

6.4. Will it be collected in amounts in excess of which would otherwise be collected for the management of patient

If answer to 6.4 is yes then specify the excess amount

.....ml at a time
.....ml total

6.4. (a) Will it be collected by extraperipheral venous puncture which would otherwise be required for the management of the patient N/A

If answer to 6.4.(a) is yes then specify the total number of peripheral venous punctures (_____)

6.4. (b) Will it be collected by a method which would otherwise not be required for the management of the patient? N/A

If answer to 6.4.(b) is yes then specify the method (_____)

7. Any other human material NO

If answer to 7 is yes then answer 7.1. and 7.2. below

7.1. Specify the method of collection (_____
_____)

7.2. Specify the amount to be collected (_____)

PART II

(DECLARATION BY THE PRINCIPAL INVESTIGATOR)

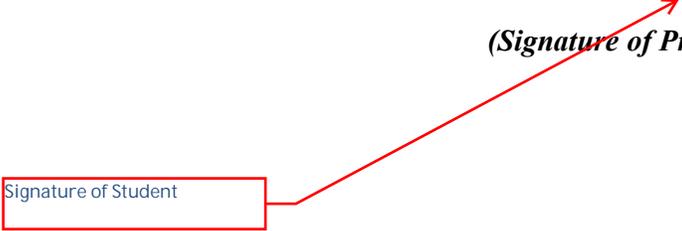
I hereby declare that:

1. Voluntary written consent of the human subject will be obtained.
2. In case of children and mentally handicapped subjects-voluntary written informed consent of the parents/guardians will be obtained.
3. The probable risk involved in the project will be explained in full details to the subjects/parents/guardians.
4. Subjects/parents/guardians will be at liberty to opt out of the project at any time.
5. I will terminate the experiment at any stage, if I have probable cause to believe, in the exercise of the good faith, skill and careful judgement required for me that continuation of the experiment is likely to result in injury, disability or death to the experimental subject.

Date:

(Signature of Principal Investigator)

Signature of Student



PART III

(DECLARATION BY THE PRINCIPAL INVESTIGATOR/HEAD OF THE DEPTT.)

1. Is The Department/University ready to undertake the responsibility of the human subjects in case of injury? **No**
2. Do you think that the experiments are so designed that they would yield meaningful results that could not be obtained by the other method? **Yes**
3. Do you think that the animal experiments carried put support the need for clinical experimentation? **Yes**
4. Do you think that the experiments would be conducted in a manner to avoid all unnecessary physical and mental suffering and injury? **Yes**
5. Do you think the experiments have been planned in a manner so that the degree of risk to be taken would never exceed that determined by the humanitarian importance of the problem to be solved by the experiment? **Yes**
6. Do you think that proper preparations would be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, Disability or death; **Yes**
7. Do you think that safeguards have been taken to see that the experimentation would be conducted only by scientifically qualified persons who possess the requisite competence, experience and qualities to carry out the research? **Yes**
8. Does your project involve cloning and/or transformation experiments, infections and/or expression of genes in eukaryotic or prokaryotic organisms and handling of infectious organisms?' if yes; project needs review by Institutional Biosafety Committee of KGMU (Check on University Web site) **No**

Signature of Student

Signature and Stamp

(Signature of Principal Investigator)

*(Signature of Head of the Department.)
With seal*

Date of Receiving _____

(Signature)

On behalf of Research Cell

To Be filled by research cell -
Leave Alone.

ANNEXURE - 1

Sign in front of your details.

All investigators, whose names are listed, must sign.

Title of Project: Loss of Empathy in Undergraduates of Different Medical Colleges.
Investigators : Ahmad Ozair, MBBS Student, KGMU.
Contact details and signature of Principal-Investigator: xxxxxxx xxxxxxxx
Collaborators: None.
Potential funding agency: No local funding.

Patient/Parent/Guardian Consent

PART 1

1. **Purpose of the study:** 1.) To compare the loss of empathy in undergraduates studying in different medical colleges of India (2) To determine the covariates of loss of empathy in Indian medical schools
2. **Study procedures:** This survey questionnaire-based study will be conducted online where students will receive a link to fill out the survey (It will take 10 minutes to complete)
3. **Risk from the study:** No risks since study is survey based.
4. **Benefits from the study:** Comprehensive studies across the world and in India indicate a significant a loss of empathy in medical colleges. However data is lacking regarding comparison of this loss in different medical colleges in India. No studies have been done regarding impact of any regional or cultural forces or local teaching practices on this loss in India. Completion of this study will fulfill all the above requirements. Understanding what regional factors influence the loss of empathy may help us stem the tide. We may be able to identify colleges which have a much lower or slower loss of empathy than others. These colleges may be further studied and the lessons incorporated into medical school curriculum.
5. **Complications:** No complications whatsoever
6. **Compensation:** No financial or material compensation.
7. **Confidentiality:** Identities of all participants will be kept confidential until and unless it is legally required to reveal identity. Even if this study is published, identities will be kept strictly confidential.
8. **Rights of the participants:** Right to not participate.
9. **Alternatives to participation in the study:** Non-participation in survey

Write benefits in detail. Explain in easy language.

Copy and paste the exact same language.

PART 2

Patient/Parent/Guardian Consent

I have had the study explained to me and have read the contents of this form/had the contents of this form read to me. I have been given the opportunity to ask question and have them answered to my satisfaction.

I am willing for my child to be enrolled in the study

Name of subject:

Signature of Patient/Parent/Guardian:

Name of Patient/Parent/Guardian & relationship to subject:

Date:

To be filled at the time of study. Please leave unfilled right now.

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:

Name of the Investigator:

Signature of the Witness:

Date:

Name of the Witness:

To be filled at the time of study. Please leave unfilled right now.

सूचित स्वीकृति प्रपत्र

प्रोजेक्ट का शीर्षक: विभिन्न मेडिकल कॉलेजों के छात्रों में चिकित्सा सहानुभूति में कमी का अध्ययन।

अन्वेषक का नाम एवं सम्बन्ध | अहमद ओज़ेयर, एमबीबीएस छात्र, केजीएमयू।

अन्वेषक का कान्टेक्ट डिटेल्स एवं हस्ताक्षर .xxxxxxxxxxx

कोलेबोरेटर्स— कोई नहीं ।

फनडिंग एजेंसी: कोई स्थानीय वित्त नहीं ।

भाग -1

1. **अध्ययन का उद्देश्य.** हम भारत के विभिन्न मेडिकल कॉलेजों में अध्ययनरत अंडरग्रेजुएट्स में सहानुभूति के नुकसान की तुलना करना चाहते हैं तथा सहानुभूति के नुकसान के निर्धारकों का पता लगाना चाहते हैं ।

2. **अध्ययन की प्रक्रिया** — यह सर्वेक्षण प्रश्नावली-आधारित अध्ययन ऑनलाइन आयोजित किया जाएगा। छात्रों को सर्वेक्षण भरने के लिए एक लिंक प्राप्त होगा (इसे भरने में केवल 10 मिनट का समय लगेगा) ।

3. **अध्ययन में भाग लेने के जोखिम** — मानक प्रबंधन की तुलना में कोई अतिरिक्त जोखिम नहीं है ।

4. **अध्ययन से लाभ** — दुनिया भर में और भारत में व्यापक अध्ययन से मेडिकल कॉलेजों में सहानुभूति की कमी का संकेत मिलता है। हालाँकि भारत के विभिन्न मेडिकल कॉलेजों में इस नुकसान की तुलना में अध्ययन के लाभ के बारे में कोई अध्ययन नहीं किया गया है। इस अध्ययन को पूरा करने से उपरोक्त सभी आवश्यकताएं पूरी होंगी। कौन से क्षेत्रीय कारक सहानुभूति की हानि को प्रभावित करते हैं, यह समझने से हमें नुकसान को कम करने में मदद मिल सकती है। हम उन कॉलेजों की पहचान करने में सक्षम हो सकते हैं, जिनमें दूसरों की तुलना में सहानुभूति की बहुत कम या धीमी हानि होती है। इन कॉलेजों का और अध्ययन किया जा सकता है और मेडिकल स्कूल के पाठ्यक्रम में शामिल पाठों को सीखा जा सकता है।

5. **जटिलता** — कोई जटिलता नहीं है ।

6. **क्षतिपूर्ति** — कुछ भी नहीं ।

7. **गोपनीयता** — सभी प्रतिभागियों की पहचान तब तक गोपनीय रखी जाएगी जब तक कि पहचान को प्रकट करने के लिए कानूनी रूप से आवश्यक न हो। यहां तक कि अगर यह अध्ययन प्रकाशित किया जाता है तो भी पहचान को सख्ती से गोपनीय रखा जाएगा।

8. **अध्ययन में भाग लेने वालों का अधिकार** — लेखापरीक्षा में भाग लेने का अधिकार नहीं है ।

9. **अध्ययन में भाग लेने वालों का विकल्प** — कोई नहीं ।

भाग -2

रोगी की स्वीकृति

मुझे अध्ययन के विषय में समझा दिया गया है और मैंने इस प्रपत्र को भली प्रकार/प्रपत्र सुना दिया गया है। मुझे प्रश्न के अवसर दिये गये और मेरी संतुष्टि के अनुसार उत्तर दिये गये। मैं इस अध्ययन में सम्मिलित होने हेतु इच्छुक हूँ।

अध्ययन में भाग लेने वाले का नाम एवं पता.....

हस्ताक्षर..... दिनांक.....

जांचकर्ता का कथन

मैं, निम्न हस्ताक्षरकर्ता ने रोगी को उसके द्वारा समझी जा सकने वाली भाषा में , अध्ययन के तौर तरीके, जोखिम और के विषय में समझा दिया है।

जांचकर्ता के हस्ताक्षर

दिनांक.....

जांचकर्ता का नाम.....

साक्षी के नाम हस्ताक्षर

Project for Ethical Approval

Teacher Supervisor

Dr xxxxx xxxxx, Professor, Department of xxxxxxxx
KGMU, Lucknow

—

Student Investigator

Ahmad Ozair, MBBS student, Batch of 2016, KGMU, Lucknow
Phone No : +91 xxxxx xxxxx

Signatures.



Executive Summary for Ethical Approval

Title of Project

Orientation of Medical Students in India Towards Lifelong Learning.

Student Investigator

Ahmad Ozair, MBBS 2016, KGMU (+91 xxxxx xxxxx)

Teacher Supervisor

Dr. xxxxx xxxxx, Professor, Department of xxxxx, KGMU

Funding Agency – None

No funding required.

Use Endnotes feature in Microsoft word to ensure that references are exactly matched.

Use Vancouver style (number) referencing. Put number after the fullstop/period

Background and Review of Literature

Empathy is referred as the ability to understand, imagine and appreciate the feelings of other person.^{1,2} Empathy is often differentiated from sympathy which is referred as experiencing the others emotions and feeling concern for them without involving shared emotions.³ It is very important for the doctors to have empathy for their patients. The patients report the more accurate information about their disease if their doctor shows empathy.⁴ Empathetic doctors have been found to be more trusted by patients⁵ resulting in greater compliance to the treatment.⁶ These all outcomes due to good doctor-patient communication lead to more accurate diagnosis by the doctor.⁷ Being violent at the clinical workplace, whether triggered due to the miscommunication or over-strained health care system, can have a vital impact on the clinical competence of the doctor.⁸ Empathic communications may prevent the rising violence against both the doctor and patient.⁹ There is a significant gap of interpersonal communication between the patients and the doctors. It has been estimated that 80% of the malpractice claims are due to the problem arising from the bad interpersonal relationship between the doctor and patient.¹⁰ Some earlier studies have reported the continued loss of empathy among the Indian doctors.¹¹ All these points indicates that the empathetic doctors have become a societal need. The empathy of medical students has been found to be high at the time of entry in medical college and then decline with the years of medical education with an exception of a few semesters.¹² However, data is lacking regarding comparison of this decline in different medical colleges. In India no earlier studies have been done regarding impact of any regional or cultural forces or local teaching practices on the loss of empathy.

The most commonly used tools which have been be utilised for assessing empathy include the student version of Jefferson Scale of Empathy (JSE-S) and Davies' Interpersonal Reactivity Index (IRI). JSE-S is especially designed instrument for assessing empathy among the medical students.¹³ It consists of 20 items which are answered on a 7 point Likert type scale ranging from “strongly disagree” to “strongly agree”. Interpersonal reactivity index (IRI) is a self-reported instrument used for multidimensional assessment of empathy. It consists of 28 items

which are answered on 5 point Likert scale ranging from “does not describe me very well” to “describes me very well”. JSE-S has been more widely used and validated than IRI, the latter not having been used in India till date (as reported in a PubMed indexed journal, last searched in January 2019)

Thus, the aim of the present study is to investigate the variations in empathy in different medical colleges and the factors responsible for this variation using JSE-S

Study Objectives

Don't provide a long list here. If required, split into primary and secondary.

1. To determine whether there exists a difference in empathy in undergraduates of different medical colleges by using Jefferson Scale of Empathy- student version.
2. To determine the most reliable predictors for the variation in empathy, if any.

Should provide research hypothesis

Research Hypothesis

There exists a difference between empathy of students of different medical colleges in different years, as measured by the Jefferson Scale of Empathy-Student version

MATERIALS & METHODS

Study Setting: Study will be conducted online amongst healthy medical students on a voluntary, community basis.

Study Type: Epidemiological survey-based investigation

Study Design: Cross-sectional study on healthy volunteers.

Inclusion Criteria

- MBBS students, from the first to the final year of the course.
- Students providing informed consent to use their responses for research purposes.

Exclusion Criteria

- Failure to respond to the questionnaire or to provide informed consent.
- Submission of incomplete (<70%) questionnaire.
- Participant's age more than 30 years.

Sample size:

Since the study is the first such comparative investigation in India, specifically using a validated questionnaire, hence it has been planned as an exploratory investigation, which will generate informed hypotheses for future research. Therefore, a sample size requirement

calculation has not been performed. Based on empirical observations of number of personal medical student contacts of both the student investigators which amount to over 600 and the response rate estimated to be 50%, the expected number of participants would be 300.

Instruments for Data Collection

You must state what instruments are going to be used separately

The following instruments will be used to capture participants preferences:

- a questionnaire of the general profile of the respondent, assessing what sociodemographic, cultural or academic factors, which may or may not be found to be strong co-variates, and
- a questionnaire of Jefferson Scale of Empathy Student version.

Data Collection:

Data would be collected from students online using a web-based form ([surveymonkey.com](https://www.surveymonkey.com)). The link to this form will be circulated through email and WhatsApp groups.

Data Management and Analysis:

From the [surveymonkey.com](https://www.surveymonkey.com) website, data will be exported in Excel 2013 (Microsoft, Richmond, Virginia). Using GraphPad Prism 7, statistical analysis would be done. For categorical variables, chi-square tests would be applied. While for continuous variables, Student's t-test and analysis of variance (ANOVA) will be used.

Scale scores will be summed up as an average of constituent items. ANOVA, Chi-square test, Pearson correlations, and Spearman rank-order correlations will be computed to determine the relationships, if any, between student's orientation toward lifelong learning and their demographic characteristics.

Ethical Considerations

Please provide a detailed account as given here.

The study will be conducted only after approval by the institutional ethics committee, KGMU. A consent form will be provided along with the questionnaire and details of the sample population will be concealed. Additionally, an ID will be generated by the digital form, so that participants are not identified by name and hence confidentiality would be ensured in data management and analysis. All responses will be stored and kept in a strictly confidential manner.

Time Frame: Total 3 months

- 1 month for data collection
- 1 month for data analysis
- 1 month for the writing of the manuscript.

Implications of Study

The quantitative result of assessment of the empathy would reveal whether there is need for further improvement in the cultivation of empathy in medical students during their training. We will compare the empathy scores of students of different medical colleges to observe differences in their scoring.

Furthermore, if a significant difference in the scoring is detected it may be related with the region, teaching practices and other parameters of the college. We may be able to find those colleges which have lower or slower loss of empathy. These colleges may be further studied and the lessons learnt can be incorporated into the medical school curriculum.

We will also correlate the empathy scores of with several variables like age, gender and future career choices to find those variables which significantly affect the empathy. These covariates may be explored in future studies. The present study will thus act to provide the initial platform upon which rigorous multi-centric studies may be conducted in the future.

References

Use Endnotes feature.

- ¹ Post SG, Ng LE, Fischel JE, et al. Routine, empathic and compassionate patient care: definitions, development, obstacles, education and beneficiaries. *J Eval Clin Pract* 2014; 20: 872-880.
- ² Soanes C and Stevenson A. Sympathy. In: Stevenson A (ed.) *Oxford English dictionary of English*. 3rd ed. New York: Oxford University Press, 2010.
- ³ Burton N. Empathy Vs Sympathy. *Psychology today*, 2015 May 27.
- ⁴ Derksen F, Bensing J, Lagro-Janssen. Effectiveness of empathy in general practice: a systemic review. *Br J Gen Pract*. 2013;63(606):e76-e84.
- ⁵ Thom DH. Physician behaviors that predict patient trust. *J Fam Pract*. 2001;50:323-8.
- ⁶ Biswas B, Haldar A, Dasgupta A, Mallick N, Karmakar A. An Epidemiological Study on Empathy and its Correlates: A Cross-sectional assessment among Medical students of a Government Medical college of India. *Indian J Psychol Med*. 2018 Jul-Aug; 40(4); 364-369.
- ⁷ Dorr Gould S, Lipkin M. The Doctor-patient relationship: challenges, opportunities, and strategies. *J Gen Intern Med* 1999;14(Suppl 1(MI)):S26-S33.
- ⁸ M Hojat, F S Gonnella, S Mangione, T F Nasca, F F Veloski, F B Erdmann, C A Callahan, M Magee. Empathy in medical students as related to academic performance, clinical competence and gender. *Medical Education* 2002;36:522-527.
- ⁹ Mishra S. Violence against Doctors: The Class Wars. *Indian Heart Journal* 67(2015) 289-292.
- ¹⁰ Avery JK. Lawyers tell what turns some patients litigious. *Med Malpractice Rev* 1985; 2:35-7.
- ¹¹ Shashikumar R, Chaudhary R, Ryali VSSR, Bhat PS, Srivastava K, Prakash J, Basannar D. Cross Sectional assessment of empathy among undergraduates from a medical college. *Med J Armed forces India*: 2014 Apr; 70(2): 179-185.
- ¹² Chatterjee A, Ravikumar R, Singh S, Chauhan PS, Goel M. Clinical empathy in medical students in india measured using Jefferson scale of empathy-student version. *J Educ Eval Health Prof*, 2017 Dec 27.
- ¹³ Hojat M, Mangione S, Nasca TJ, Cohen MJM, Gonella JS, Erdmann JB, Veloski JJ, Magee M. The Jefferson Scale of Physician Empathy; Development and preliminary psychometrics. *Educational Psychol Measurement* 2001;61:349-65.