Obtaining Institutional Ethics Committee (IEC) Approval:

A Guide for Undergraduate and Postgraduate Students of King George's Medical University

Version: **2.0**

Date: 16th Nov, 2020

Author: Ahmad Ozair, MBBS Student, Batch of 2016.

- **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-STS project work, **please have a margin of upto 3 months to ensure that you obtain ethical approval within time.**

Documents required for Ethical Approval

- 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. A format is given below
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.**
    - Both English and Hindi forms need to be signed by all the investigators.
    - 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.
4. **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 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 the photocopies 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.

- **Mail the scanned documents to IEC** (copy all the other investigators on the same email) at **ETHICS@KGMCINDIA.EDU**

- **After 1 month of the ethics committee meeting you will receive the decision letter.** This letter will have a reference number (ECM/??????).

Salient Points for Investigators

1. **The reference number is to be given in all research papers**. Do not just write 'study was approved by intitutional ethics committee'.

2. **It is possible to get a provisional letter of approval, which can be issued by the Member Secretary of IEC on special request in cases of urgency**. Talk to your supervisor that they request the IEC to provide the same. This is often required when you are participating in an external study with deadline of data collection

3. **If you are participating in any international clinical study (where you have to share anonymous patient data, you must get ICMR Health Ministry Screening Committee (HMSC) approval.**

    - This rule applies even if the study you are doing is an observational study only. This rule applies even if the study is non-funded.
    - Please contact your National Coordinator for the Study to coordinate getting the HMSC approval.

King George's Medical University, U.P.

Lucknow - 226003 (UP) India

Institutional Ethics Committee

Prof. R.K. Garg
Member Secretary, IEC

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

Sample - Provisional Approval

No. 752 Ethics /2020

Dated: 05-08-2020

To

Dr. Ankur Bajaj,
Associate Professor,
Department of **Neurosurgery,**
K.G's Medical University U.P
Lucknow

Sub.: Expedited review of research proposal entitled "***CovidSurg-Week Study***.

Dear Sir,

Please refer to your letter no. NS-972 dated 23rd July, 2020, the proposal has been reviewed. The comments and decision are given below for your information and necessary action accordingly:

Decision: Provisionally approved

The Ref. Code will be provided to you after EC meeting.

Yours sincerely

RKGOR2

(R.K. Garg)
Member Secretary IEC

Dr. Ankur Bajaj

Head of Neurosurgery Department
K.G's Medical University U.P., Lucknow

King George's Medical University U.P.,
Institutional Ethics Committee
Lucknow - 226003 (UP) India

Prof. R.K. Garg
Member Secretary, IEC

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Sample - Final Approval Letter

To,

Dr. Ankur Bajaj,
Associate Professor,
Department of **Neurosurgery,**
K.G's Medical University, U.P.,
Lucknow

No. 878 **/Ethics/2020**

Dated: 02-09-2020

Dear Sir,

The Institutional Ethics Committee in its meeting held on 18th August, 2020 has reviewed and discussed your application submitted via letter no. NS/749/2020 dated 12th June, 2020 to conduct the research proposal entitled ***"Determining the global outcomes of traumatic brain injury in low-, middle-, and high-income countries: A prospective, international cohort study"*** sponsored by GNS & OHSU Brain Institute ***Ref. code: 102nd ECM IIA/P32***

Following documents were reviewed:-

a) Check List
b) Executive summary
c) English Consent form
d) Hindi consent form
e) Case record form

EC Decision: Approved

Kindly quote the above reference code in all further communications regarding the above subject.

Yours Sincerely

Member Secretary
Institutional Ethics Committee

10/9/2020

Head of Neurosurgery Department
K G's Medical University U.P., Lucknow

Format of Cover Letter

To

Member Secretary

Research Cell

KGMU, Lucknow

16th January 2020

Subject: Ethical Approval of Research Study

Respected Madam

With due regards, I, Ahmad Ozair, MBBS Student, Batch of 2016, KGMU wish to submit the following 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.

Thank you

Yours Sincerely

Recommended and Forwarded by

Head, Department of xxxxxxxx

King George's Medical University

Ahmad Ozair

Medical Student, Batch of 2016

King George's Medical University UP Lucknow

Phone No. +91 xxxxx xxxxx

ahmadozair@kgmcindia.edu

This is a must

Sample - Cover Letter

Department Of Neurosurgery
King George's Medical University,
Lucknow-226 003 (U.P. India)
Phone No. 0522-2257606, E-mail.: neurosurgerykgmu@gmail.com

Dr. B.K. Ojha M.S. M.Ch. Prof. & Head email: bkojha@rediffmail.com (OPD Wednesday)	**Dr. Anil Chandra** M.S. M.Ch. Professor email: anilchandraneuro@kgmc india.edu. (OPD Friday)	**Dr. S. K. Singh** M.S. M.Ch. Professor email: drsksingh2k@gmail.com (OPD Tuesday)	**Dr. Chhitij Srivastava** M.S. M.Ch. Professor email: drchhitij@Yahoo.co.in (OPD Thursday)
Dr. Manish Jaiswal M.S. M.Ch. Associate Professor, manishjaiswal@kgmuindia.edu (OPD Tuesday)	**Dr. Somil Jaiswal** M.S.,M, Ch. Associate Professor dr. somil26@gmail.com (OPD Friday)	**Dr. Ankur Bajaj** (M.S., MCh,) Associate Professor ankur.thehealer@gmail.com (OPD Wednesday)	**Dr. Awdhesh Kumar Yadav** M.S., M.Ch., Assistant Professor awkymail@gmail.com (OPD Monday)

Ref.....

Date 12/6/2020

To

Member Secretary

Research Cell

KGMU, Lucknow

10th June 2020

Subject: Ethical Approval of Observational Study

Respected Sir

With due respect, I, Dr Ankur Bajaj, Associate Professor, Department of Neurosurgery, KGMU wish to submit the following project for ethical clearance – "Global NeuroSurg-1 Study" as the local project lead for this multi-centric observational study being conducted by Oregon Health and Science University (OHSU) of the United States.

I request you to kindly consider the project for review by the Ethical Committee. I shall be highly obliged for the same. Attached herewith are all necessary documents.

Thank you

Yours Sincerely

Dr Ankur Bajaj

Associate Professor, Deptt. Of Neurosurgery
King George's Medical University UP Lucknow
Phone No. 84373 47990 | dr.ankurbajaj@gmail.com

NS/749 dt. 12/6/2020

F & R

Head of Neurosurgery Department
K.G's Medical University U.P., Lucknow

Dr. ANKUR BAJAJ
M.S, M.ch.
Associate Professor
Department of Neurosurgery
K.G's Medical University, Lucknow

Sample - Filled Proforma

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

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

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:

Determining the Global Outcomes of Traumatic Brain Injury in low-, middle-, and high- income countries: A prospective, international cohort study

Short Title:

Global NeuroSurg 1 Study (GNS-1)

	Name, Designation & Qualifications	Departmental Tel No. and email ID	Signature
PI	**Dr Ankur Bajaj**, MBBS, MS, MCh (neurosurgery) Associate Professor, Department of Neurosurgery, KGMU	dr.ankurbajaj@gmail.com +91 522-2258831 (telephone) +91 84373 47990 (cellular)	
Co-PI 1	**Prof B. K. Ojha,** MBBS, MS, MCh (neurosurgery) **Professor and Head,** Department of Neurosurgery, KGMU	drbkojha@gmail.com +91 94151 08077	
Co-PI 2	**Prof. Chhitij Srivastava,** MBBS, MS, MCh (neurosurgery) Professor, Department of Neurosurgery, KGMU	drcsrivastava@gmail.com +91 93352 57029	
Co-PI 3	**Ahmad Ozair** Final Year MBBS Student, Batch of 2016, King George's Medical University	ahmadozair@kgmcindia.edu +91 84399 11101	

Description of Overall/Global PI:

Study is led by a steering committee, details of whose members are provided in the official protocol.

Sponsor Information: **No explicit sponsorship or funding, however study is hosted at Oregon Health and Science University**

1. Indian N/A	~~a) Government☐ Central☐ State ☐ Institutional ☐~~ ~~b) Private ☐~~
2. International	a) Government☑ ~~Private☐ UN Agencies☐~~ **GNS is hosted by the Neurological Surgery Department of Oregon Health and Science University and OHSU Brain Institute, the USA.** **No funding is being given to KGMU investigators.**
3. Industry N/A	~~a) National☐ Multinational☐~~
4. Contact address of sponsor	**Department of Neurological Surgery, Oregon Health and Science University** **3181 S.W. Sam Jackson Park Rd.** **Portland, Oregon 97239-3098, United States**
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:

Study is not a clinical trial. It is only observational.

Drug/Vacancies/Device/Herbal Remedies

i. Does the study involve use of : **NO**

~~Drugs ☐ Devices☐ Vaccines☐~~
~~Indian systems of Medicines / or Alternate systems of Medicine ☐Any other☐~~ None☐

ii. Is it approved and marketed

N/A as study is not a clinical trial. It is only observational.

~~In India☐ UK & Europe ☐USA☐~~
~~Other countries, specify~~

iii. Does it involve a change in use, dosage, route of administration?

N/A as study is not a clinical trial. It is only observational. Yes ☐ No ☐

~~if yes, whether DCGI's/Any other Regulatory Authority's permission obtained? Yes ☐ No ☐~~
~~If yes, copy of permission attached. Yes ☐ No ☐~~

iv. Is it an Investigational New Drug?

N/A as study is not a clinical trial. It is only observational.

~~Yes ☐ No ☐ 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 (Sheet attached)

5. Subject selection

i. **Number of subjects:**

All cases in pre-specified two-weeks period (two different such periods) which present to KGMU trauma centre and are eligible for inclusion.

ii. **Duration of** a) Study: 2 weeks period x 2 different times

b) Subject participation: 90 days follow-up after recruitment

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 ☐~~	

Traumatic brain injury (TBI) patients, whom this study aims to assess are typically seriously ill (critically ill) patients. Many of them belong to poor socio-economic strata.

vii. **Special group subjects** ~~Yes ☐~~ No ☑

(Tick the appropriate boxes) N/A

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

6. Privacy and confidentiality

i. Study Involves

- Direct Identifiers ☐
- Indirect Identifiers/Coded ☑
- Completely Anonymised / Delinked ☐

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

7. Use of biological / hazardous materials

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?	N/A	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?	N/A	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 : **N/A**
- Facility not available in India ☐
- Facility in India inaccessible ☐
- Facility available but not being accessed ☐

If so, reasons

b. Has necessary clearance been obtained **N/A** 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	☐
Compensation for participation	☐		
Benefits if any on future commercialization e.g.		Genetic basis for drug development	☐
Compensation for study related injury	☐	Translation of information sheet in local language	☐

ii. If healthy volunteers will be included, information sheet for them attached **N/A** ~~Yes ☐ No ☐~~

iii. Consent form in English ☑ Hindi ☑

iv. Who will obtain consent (PI/Co-PI) ☑ ~~Nurse / Counsellor ☐~~

~~Research Staff ☐~~ ~~Any other ☐~~

* If written consent is not obtained, give reasons: **N/A**

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 ☐~~

The study is an observational study which will only utilize routine parameters and variables collected during management of a patient of traumatic brain injury (TBI).

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 ☑

Not required since study is not a clinical trial. Study will only assess routine practice of neurosurgeons.

ii. Is there a plan for reporting of adverse events? Yes ☐ No ☑

Not required since study is not a clinical trial. Study will only assess routine practice of neurosurgeons.

if yes, reporting will be done to **N/A**

~~Sponsor ☐ IEC ☐ DSMB ☐~~

iii. Is there a plan for interim analysis of data? ~~Yes ☐~~ No ☑

Not required since study is not a clinical trial. Study will only assess routine practice of neurosurgeons.

12. Is there compensation for injury? ~~Yes ☐~~ No ☑

Not required since study is not a clinical trial. Study will only assess routine practice of neurosurgeons. No physical injury is possible from participating in the study.

If yes, by N/A

~~Sponsor ☐ Investigator ☐~~

~~Insurance Company ☐ Any other ☐~~

13. Do you have conflict of interest? ~~Yes ☐~~ No ☑

(Financial / Non-financial)

Check list for attached documents:

Project proposal – 03 copies

~~Curriculum Vitae of non KGMU Investigators~~ ☐

Brief description of proposal/summary ☑

Copy of the Protocol / Project and questionnaire (provided by GNS group) ☑

~~Investigator's Brochure~~ ☐

~~Copy of Patient information sheet in local language~~ ☐

Copy of Patient 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 ☑

Signature of PI with stamp

Dr. ANKUR BAJAJ
M.S, M.ch.
Associate Professor
Department of Neurosurgery
K.G's Medical University, Lucknow

Date 10th June 2020

Signature of HOD with stamp

Head of Neurosurgery Department
K.G's Medical University U.P., Lucknow

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

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

1 **NAME OF THE PROJECT :**

Determining the Global Outcomes of Traumatic Brain Injury in low-, middle-, and high- income countries: A prospective, international cohort study [Global Neurosurg 1 Study]

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

Dr Ankur Bajaj, MBBS, MS, MCh (neurosurgery) | Associate Professor, Department of Neurosurgery, King George's Medical University

3 **OTHER MEMBERS OF THE RESEARCH TEAM**

Co-PI 1: Prof B. K. Ojha, MBBS, MS, MCh (neurosurgery), Professor and Head, Department of Neurosurgery, KGMU

Co-PI 2: Prof. Chhitij Srivastava, MBBS, MS, MCh (neurosurgery) | Professor, Department of Neurosurgery, KGMU

Co-PI 3: Ahmad Ozair, Final Year MBBS Student, Batch of 2016, King George's Medical University

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

This ethics committee submission pertains only to KGMU. No part of the study with regards to local PI will be done at other institution.

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

I am PI for 2 projects currently.

Declaration:

- 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.

Signature of Principal Investigator **Date 10th June 2020**

Dr Ankur Bajaj, MBBS, MS, MCh (Neurosurgery)
Associate Professor, Department of Neurosurgery, KGMU

Dr. ANKUR BAJAJ
M.S, M.ch.
Associate Professor
Department of Neurosurgery
K.G's Medical University, Lucknow

Sample - Consent Form

ANNEXURE: 8-RV-1/2019 (SOP-IEC-KGMU)

किंग जार्ज चिकित्सा विश्वविद्यालय, उ0प्र0, लखनऊ

सूचित सहमति पत्र

अध्ययन का शीर्षक निम्न, मध्यम, और उच्च आय वाले देशों में दर्दनाक मस्तिष्क चोट के वैश्विक परिणामों का निर्धारण: एक अंतरराष्ट्रीय अध्ययन

अध्ययन का नम्बर

अन्वेषक का सम्पर्क विवरण डॉ अंकुर बजाज, सहयोगी प्रोफेसर, न्यूरोसर्जरी विभाग, के जी एम यू।

+91 84373 47990 | dr.ankurbajaj@gmail.com

सहभागी का पूरा नाम_____

उम्र_____ **मोबाइल फोन नंबर** _____

पता _____

भाग–1

अध्ययन का उद्देश्य:– उच्च और निम्न विकास वाले देशों के बीच दर्दनाक मस्तिष्क की चोट के लिए आपातकालीन शल्य चिकित्सा के परिणामों की तुलना करना।

अध्ययन की प्रक्रियाएं:– यह अध्ययन मस्तिष्क की चोट के लिए वर्तमान आपातकालीन शल्य चिकित्सा को केवल माप देगा और साधारण स्वास्थ्य देखभाल में कोई बदलाव नहीं किया जाएगा।

अध्ययन से जोखिम:– साधारण चिकित्सीय देखभाल की तुलना में कोई अतिरिक्त जोखिम नहीं है।

अध्ययन से लाभ:– वैज्ञानिक ज्ञान में योगदान।

दुनिया भर में 5 अरब लोगों को शल्य चिकित्सा देखभाल तक पहुंच नहीं है और यह घाटा विशेष रूप से न्यूरोसर्जरी जैसे विशेषज्ञ क्षेत्रों में स्पष्ट है। यह अध्ययन दिमाग की चोट के लिए आपातकालीन शल्य चिकित्सा देखभाल में पूरी दुनिया में मौजूदा अभ्यास और परिणामों में अंतर निर्धारित करना चाहता है। यह विभिन्न देशों के बीच मस्तिष्क की चोट के परिणामों की तुलना करेगा।

सम्भावित जटिलताएं:– साधारण स्वास्थ्य देखभाल की तुलना में कोई अतिरिक्त जोखिम नहीं है।

क्षतिपूर्ति:– कुछ भी नहीं।

गोपनियता:– सभी रोगी 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।

प्रतिभागी के अधिकार:– अध्ययन में भाग न लेने का अधिकार है। अध्ययन से किसी भी समय दूर जाने का अधिकार।

अध्ययन में भागीदारी के विकल्प:– गैर-भागीदारी से स्वास्थ्य देखभाल में कोई फर्क नहीं रखा जाएगा।

भाग–2

1. मुझे अध्ययन अन्वेषक ने विस्तार से सब तथ्यों को समझा दिया है तथा मुझे प्रश्न पूछने का अवसर प्रदान किया।
2. मैंने समझ लिया है कि इस अध्ययन में मेरी प्रतिभागिता स्वैच्छिक है, तथा यह कि मै बिना कोई कारण बताए किसी भी समय अपनी चिकित्सीय देखभाल या कानूनी अधिकारों पर प्रभाव पड़े बिना हट जाने के लिए स्वतंत्र हूं।
3. मैंने समझ लिया है कि चिकित्सीय प्रायोजक की ओर से काम करने वाले अन्य, नैतिकता समिति तथा विनियामक प्राधिकारियों का चालू अध्ययन तथा इससे सम्बन्धित हो सकने वाले किसी अनुसंधान से सम्बन्धित मेर स्वार्सयें अभिलेखों को देखने के लिए मेरी अनुमति की आवश्यकता नही होगी, भले ही मैं इस परीक्षण से हट ही क्यों न जाऊं। तथापि मैंने समझ लिया है कि तृतीय पक्ष को दी गई या प्रकाशित की गई किसी जानकारी में मेरी पहचान को उजागर नही किया जाएगा।
4. इस अध्ययन में प्राप्त किन्ही आकडों या परीक्षणों के प्रयोग पर पाबंदी न लगाने के लिये मै सहमत हूं बशर्ते कि ऐसे प्रयोग मात्र वैज्ञानिक प्रयोजन/नों के लिये ही हों।
5. उपर्युक्त अध्ययन में भाग लेने के लिये मैं सहमत हूं।

सहभागी के हस्ताक्षर या अगूंठे का निशान/कानूनी रूप से स्वीकार्य प्रतिनिधि———————

हस्ताक्षर करने वाले का नाम——————— दिनांक———

सहभागी से सम्बन्ध ———————

मोबाइल फोन नंबर ———————

मैं, अधोहस्ताक्षरी ने सहभागी/कानूनी रूप से स्वीकार्य प्रतिनिधि को सरल, उनको समझ में आने वाली भाषा में, अध्ययन में पालन होने वाली प्रक्रियायें और जोखिम एवं लाभों से अवगत करा दिया है।

अध्ययन अन्वेषक के हस्ताक्षर——————— दिनांक———

अध्ययन अन्वेषक का नाम———————

गवाह के हस्ताक्षर ——————— दिनांक———

गवाह **का नाम** ———————

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

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

INFORMED CONSENT FORM

Study Title: Determining the Global Outcomes of Traumatic Brain Injury in low-, middle-, and high-income countries: A prospective, international cohort study [Global Neurosurg-1 Study]

Study Number_____

Contact details of Principal-Investigator: Dr Ankur Bajaj, MBBS, MS, MCh (Neurosurgery), Associate Professor, Department of Neurosurgery, KGMU | +91 84373 47990 | dr.ankurbajaj@gmail.com

Subject's Full Name: _____ Ajay

Date of Birth/Age_____ **Mobile Phone No**: _____

Address: _____

PART 1

1. **Purpose of the study**: To compare outcomes for traumatic brain injury (TBI) between high, middle and low income countries.
2. **Study procedures**: This study will measure current practice and no changes to standard patient management will be introduced.
3. **Risk from the study**: No additional risks compared to standard management protocol.
4. **Benefits from the study**: Contribution to scientific knowledge.
   5 billion people worldwide lack access to surgical care and this deficit is particularly pronounced in specialist areas such as neurosurgery. This study seeks to determine differences in current practice and outcomes in emergency surgery for TBI globally.
5. **Complications**: No additional risks compared to standard management protocol
6. **Compensation**: No compensation will be provided for participating in study.
7. **Confidentiality**: Patient identities will be kept confidential by use of coded database. The anonymized patient data will be fed into a confidential, password-protected data platform called as REDCap.
8. **Rights of the participants**: Right to not participate in the study. Right to withdraw at any time from the study.
9. **Alternatives to participation in the study**: Non-participation will not make any difference to management protocol of patients. Patients are free to not participate without any repercussions.

PART 2

Consent

1 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 OR his/her Legally Acceptable Representative (LAR): _____

Signatory's Name: _____

Date: _____

Relationship with subject: _____

Mobile Phone No of LAR : _____

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: ***Date:***

Name of the Investigator:

Signature of the Witness: ***Date:***

Name of the Witness:

Sample - Research Project Summary

Executive Summary for Ethical Approval

1. Title of Project

Determining the Global Outcomes of Traumatic Brain Injury in low-, middle-, and high- income countries: A prospective, international cohort study [Global NeuroSurg 1 Study (GNS-1)]

2. Principal Investigator: Dr. Ankur Bajaj, MBBS, MS, MCh (neurosurgery), Associate Professor, Department of Neurosurgery, King George's Medical University (KGMU), Lucknow, India

3. Co-Principal Investigators (Co-PI)

1. Dr. B. K. Ojha, MS, MCh, Professor and Head, Department of Neurosurgery, KGMU
2. Dr. Chhitij Srivastava, MS, MCh. Professor, Department of Neurosurgery, KGMU
3. Ahmad Ozair, Final Year MBBS Student, Batch of 2016, KGMU

4. Funding Agency: No funding required.

5. Background & Rationale:

Every year, there are about sixty-nine million new cases of TBI worldwide, causing a significant economic burden, even to developed countries. [1,2] However, there are wide variations in the management of TBI across low-, middle-, and high-income countries which affect TBI outcomes worldwide, and even within countries themselves.[1,3-5]

These variations in management protocol have led to heterogeneity in patient outcomes. Mortality rates of TBI are higher in low-and-middle-income countries (LMICs) compared to high-income countries (HICs). For instance, the international CENTER-TBI study looked at 68 sites and found significant differences in decision making by neurosurgeons in different countries.[6,7] Similarly, the CRASH trial was a randomized controlled trial of corticosteroid after significant head injury performed in 239 hospitals in 49 countries [8]. A secondary analysis from the CRASH trial showed that TBI patients in LMICs have twice the odds of dying following severe TBI compared to patients in HICs (OR 2.23, 95% CI 1.51-3.30).

The considerable gap in TBI outcomes between HICs and LMICs could be explained by the variations in management as well as the lack of patient access to proper surgery and the delays in providing the proper care in some LMICs regions. Data from four urban trauma centers in India showed that a third delay (> 10 minutes) was significantly associated with early mortality in TBI patients.[9]

Because resource-limited settings are now gaining access to diagnostic modalities such as computed tomography (CT) head, the outcomes of TBI are expected to have changed in recent years in low and low-middle income countries, of which India is a part. Therefore, the Global NeuroSurg-1 Study (GNS-1) aims to provide updated, high-quality data in order to get a comprehensive global picture of the current management and outcomes of TBI in high-, middle-, and low-income countries.

6. Primary Study Objectives

1. To determine the mortality rates after Traumatic Brain Injury (TBI) in low-, middle-, and high-income countries (LMIC and HIC)
2. To determine the functional outcomes after TBI in low-, middle-, and high-income countries

7. Secondary Study Objectives

1. To compare the mortality rates of TBI in HICs vs. LMICs
2. To compare the functional outcomes of TBI in HICs vs. LMICs
3. To determine the factors associated with mortality following TBI
4. To determine the pattern of TBI management in low-, middle-, and high-income countries
5. To determine TBI associated complications
6. To form an international network of neurosurgery researchers to facilitate future research.

8. Materials and Methods

8.1 Study Setting: The study will be conducted in the registered centers where TBI cases are presented for management and follow up. Any worldwide center where TBI cases are managed is eligible for participation. For KGMU, this will be the Trauma Centre and the Department of Neurosurgery, where this study would be undertaken.

8.2 Study Design: Multi-center international prospective cohort study

8.3 Inclusion Criteria

1. TBI defined as WHO ICD-11 codes from NA07.0 to NA07.9
2. Patients with mild, moderate, or severe TBI
3. Patients with mild, moderate, or severe TBI
4. Patients with mild, moderate, or severe TBI

8.4 Exclusion Criteria

1. Patients of acute brain injury not secondary to trauma
2. Patients not giving written informed consent

8.5 Sample size:

The sample size was calculated by the GNS-1 steering committee, in which KGMU investigators were not involved. A minimum sample size of 1153 patients will allow for detecting a mortality rate of 25% with a 5% wide 95% confidence interval. To achieve this, each collaborating center, including KGMU, will recruit all TBI patients in two-week periods.

8.5 Data Collection & Follow-up

GNS-1 global recruitment period is June 2019 to December 31st, 2020. Local recruitment period is two weeks. Local sites, including KGMU, will collect the data of all consecutive TBI cases attending in

their center and follow them for 90 days. The study protocol allows for multiple such 2-week periods by different teams at one center which Department of Neurosurgery, KGMU will be doing. Each recruited patient will be followed up for 90 days.

8.6 Data Entry:

The Research Electronic Data Capture (Redcap) system provides a secure environment for research teams to collect and store sensitive participant data securely. GNS-1 data will be collected in the Redcap system of Oregon Health & Sciences University, (US), to which KGMU will have access.

8.7 Study Outcomes:

Primary Outcomes: (i) 24-hour and 30-day mortality rate. (ii) 24-hour and 30-day score on Glasgow Outcomes Scale (GOS)

Secondary Outcomes: (i) 90-day mortality rate. (ii) 90-day score on GOS. (iii) Injury severity score. (iv) Duration of hospital stay. (v) Patient disposition. (vi) Radiological findings of CT/MRI. (vii) Pattern of medical management. (viii) Pattern of surgical management (ix) Need for further intervention or "reoperation." (x) The frequency of shunt dependency (xi) Incidence of complications

8.8 Data Analysis:

Participating centers will be classified into three tertiles according to their rank on the human development index (HDI) published by the United Nations. GNS-1 will test the differences between HDI tertiles using the Pearson chi-square test for categorical variables and Kruskal–Wallis test for continuous variables. Binary logistic regression analysis will be conducted to evaluate the predictors of 30-day mortality. Odds ratios (OR) and corresponding 95% confidence intervals will be calculated for each variable. Variables from univariate analysis with $P<0.05$ will be selected for inclusion in the multivariate model. Then variables that are independently contributing to the mortality will be selected and examined. All analyses will be conducted by the GNS-1 data analysis team. KGMU will not be doing the analysis.

8.9 Time Frame:

Timeline for local site (KGMU): 2 weeks for patient recruitment (to be decided after the grant of ethical approval) and 3 months of follow-up of recruited patients

Timeline for the overall GNS-1 study: Total recruitment period from June 2019 till 31st December 2020.

9. Risk to Patients & Ethical Considerations

The study will be conducted only after approval by the institutional ethics committee, KGMU. A written consent form will be used. Patient data that is entered into REDCap will be de-identified and linked to a coded system kept at the local site (KGMU). The use of REDCap will allow all responses to be stored confidentially. Secondly, because the study is purely observational in nature, no additional risk is expected to occur from this study than the standard management protocol.

10. Benefits, Implications & Significance of Study

Current guidelines of the Brain Trauma Foundation (BTF) are limited by the lack of class one evidence from well-designed randomized controlled trials. Most of the current recommendations are based on data from retrospective analyses of existing databases because conducting randomized controlled trials in TBI has been challenged by several methodological and ethical limitations. Recently, the need for comparative effectiveness research (CER) approaches in TBI has been pronounced. Observational studies are powerful tools for CER since they allow evaluation of the treatment strategies using real-world data from the usual care. Given the considerable variation in the TBI management in different clinical settings and the significant gap in mortality following TBI in HICs compared to LMICs, detecting the variations in TBI management and the impact of these variations on TBI outcomes is of great importance. This study will help determine the same.

The study will also contribute to generating high-quality data for LMIC. This will allow adequate resource allocation to tackling neuro-trauma in LMIC. It will also provide data from those countries, where a considerable focus needs to be there to improve their high morbidity and mortality rates following TBI.

References

1. Zammit C, Knight WA (2013) Severe traumatic brain injury in adults. Emerg Med Pract 15:1–28
2. Seifert J (2007) Incidence and economic burden of injuries in the United States. J Epidemiol & Community Health. 61:926–926. doi: 10.1136/jech.2007.059717
3. Centers for Disease Control and Prevention (2019) Surveillance Report of Traumatic Brain Injury-related Emergency Department Visits, Hospitalizations, and Deaths—United States, 2014
4. De Silva MJ, Roberts I, Perel P, et al (2009) Patient outcome after traumatic brain injury in high-, middle- and low-income countries: analysis of data on 8927 patients in 46 countries. Int J Epidemiol 38:452–8. doi: 10.1093/ije/dyn189
5. Jayaraman S, Ozgediz D, Miyamoto J, et al (2011) Disparities in injury mortality between Uganda and the United States: comparative analysis of a neglected disease. World J Surg 35:505–11. doi: 10.1007/s00268-010-0871-z
6. Maas AIR, Menon DK, Steyerberg EW, et al (2015) Collaborative European NeuroTrauma Effectiveness Research in Traumatic Brain Injury (CENTER-TBI): a prospective longitudinal observational study. Neurosurgery 76:67–80. doi: 10.1227/NEU.0000000000000575
7. van Essen TA, den Boogert HF, Cnossen MC, et al (2019) Variation in neurosurgical management of traumatic brain injury: a survey in 68 centers participating in the CENTER-TBI study. Acta Neurochir (Wien) 161:435–449. doi: 10.1007/s00701-018-3761-z
8. Roberts I, Yates D, Sandercock P, et al (2004) Effect of intravenous corticosteroids on death within 14 days in 10008 adults with clinically significant head injury (MRC CRASH trial): randomised placebo-controlled trial. Lancet (London, England) 364:1321–8. doi: 10.1016/S0140-6736(04)17188-2
9. Gupta S, Khajanchi M, Kumar V, et al (2019) Third delay in traumatic brain injury: time to management as a predictor of mortality. J Neurosurg 1–7. doi: 10.3171/2018.8.JNS182182

Sample - Mailing the scanned documents to the IEC, KGMU

Gmail **Ahmad Ozair <ahmadozair1@gmail.com>**

Ethical Submission | Global NeuroSurg 1 Study (GNS-1)

1 message

Ahmad Ozair <ahmadozair1@gmail.com> Thu, Jul 9, 2020 at 6:20 PM
To: ethics@kgmcindia.edu
Cc: Dr Ankur Bajaj Neurosurgery <dr.ankurbajaj@gmail.com>

Note Email

Dear Ethics Committee Team

Kindly find attached the relevant files for the project:

Determining the Global Outcomes of Traumatic Brain Injury in low-, middle-, and high- income countries: A prospective, international cohort study [Global NeuroSurg 1 Study (GNS-1)]

These files have been uploaded on the CD as well.

Warm Regards
Ahmad Ozair
4th-Year Medical Student
King George's Medical University (KGMU), Lucknow, India
https://in.linkedin.com/in/ahmadozair

8 attachments

- **Cover Letter To IEC.pdf** 358K
- **GNS Consent Form.pdf** 1133K
- **GNS 1 Filled Proforma.pdf** 2436K
- **GNS - 1 Executive Summary.pdf** 540K
- **1. About the GNS Collaborative.pdf** 288K
- **4. GNS-I Data Collection Form.pdf** 203K
- **6. GNS-I Data Collection Form Dictionary.pdf** 219K
- **GNS Protocol version 3.0 final.pdf** 4199K