**Covering letter – Dissertation proposals by MD/MS/M. Ch/DM/MSc/MDS/PhD**

From, Date:
Dr. Sourav Jana
1st Year Junior Resident
Paediatric Surgery

To,
The Member-Secretary,
Institutional Research Committee,
AIIMS Patna.

**Sub: Submission of Research Proposal to Institutional Research Committee – reg.**

Sir,
I am hereby submitting my Research Proposal for approval by the Institutional Research Committee. The details of the proposal are as follows:

| | |
|---|---|
| Title of the proposal | : Outcome analysis of different types of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus |
| Name of the PG Student | : Dr Sourav Jana |
| PG Year [JR/SR] | : JR, 1st year |
| Department | : Paediatric surgery |
| Session/Year of admission | : January 2021 |
| Name of the Guide | : Dr Amit Kumar Sinha |
| Designation of the Guide | : Associate professor |
| Department | : Paediatric surgery |

**Submission checklist:**

| Sr. No. | Formats | Yes/No |
|---|---|---|
| 1. | Institutional Research Committee format | Yes |
| 2. | Funding statement/declaration | Yes |
| 3. | Declaration to conduct the research on ethical principles and guidelines | Yes |

Thanking you,
Yours sincerely,

**Format**

**FOR SUBMITTING PG DISSERTATION PROPOSAL FOR CONSIDERATION BY INSTITUTIONAL RESEARCH COMMITTEE**

**SECTION- 1**

**PART A – GENERAL INFORMATION**

1. Title of the dissertation : Outcome analysis of fixed pressure ventriculo peritoneal shunts on early ventricular drainage of CSF in paediatric congenital hydrocephalus
2. Name of the candidate : Dr Sourav Jana
3. Contact&Email ID : 7003381703, janasourav6393@gmail.com
4. Name of the course studying : MCh, 6yrs (Paediatric surgery)
5. Session/Year of admission : January 2021
6. Month and year of appearing for final examination: December 2023
7. Month and year of submitting dissertation: June 2023
8. Name (s), Designation (s) & Addresses of the guide and co-guide (s) with mobile numbers and email ID:

| Details of Guide | | | | |
|---|---|---|---|---|
| Name | Designation | Office Address | Mobile Number | Email Address |
| Dr Amit Kumar Sinha | Associate Professor | Department Of Paediatric Surgery, AIIMS Patna | +91-9855572734 | dr_amits@yahoo.com |
| Details of Co-guide/s (Co-guide is mandatory, you may..) | | | | |
| Dr Bindey Kumar | Professor | Department Of Paediatric Surgery, AIIMS Patna | +91-9334114626 | bindeyster@gmail.com |
| Prof (Dr) Prem Kumar | Professor | Department Of Radiodiagnosis, | +91-9430212777 | drprempat@gmail.com |

| | | | | |
|---|---|---|---|---|
| | | AIIMS Patna | | |

9. A. State whether it is intradepartmental or interdepartmental: (Encircle one option)

**Interdepartmental**

B. If the study is interdepartmental:

I. State the names of collaborating departments: Department of Radiodiagnosis

II. State whether consent has been obtained from them: Yes

10. Total funds required for the study (in rupees): nil

11. Source of funding: NA

## PART B – TECHNICAL DETAILS

1. Title of the dissertation: Outcome analysis of different types of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus

Introduction:
Hydrocephalus refers to a spectrum of conditions where there is disturbance in cerebrospinal fluid (CSF) dynamics(1) (2). Congenital hydrocephalus is due to obstruction of flow of cerebrospinal fluid at cerebral aqueduct. Pathophysiology of congenital hydrocephalus includes two separate mechanisms - 1. Genetic abnormality 2. Secondary injury mechanisms that occur as a result of expanding ventricles(3). CT is often the initial imaging modality to detect and characterize the type of hydrocephalus, degree and cause of obstruction, and complications from acute obstruction(4). Besides CT scan, USG brain is also very helpful in assessment of brain and ventricles during first few months of life when anterior fontanelle is open(5). Ventriculo-peritoneal (VP) shunts are the generally considered as standard treatment of hydrocephalus(6). The standard fixed pressure valves work depending on the differential pressure across them(7). There are low (0–5 cm of $H_2O$), medium (5–10 cm of $H_2O$) and high pressure (10–15 cm of $H_2O$) shunts for which there are no general guideline(7). In congenital hydrocephalus, generally low or medium pressure shunts are used

A. Problem statement: Hydrocephalus is a common congenital anomaly with large number of VP shunt surgeries being done at hospitals across the country. The incidence of congenital hydrocephalus is about 0.2–0.5/1000 live births(8). Usually medium and low pressure shunts are used as per surgeon's personal choice. There is paucity of information available data suggesting which fixed pressure shunt will help in early drainage of CSF and amelioration of symptoms due to raised intracranial pressure.

B. Rationale: It is always thought by many clinicians that low pressure VP shunt will drain earlier than medium pressure shunt. But there is paucity of information available to say which shunt between low and medium pressure shunt drains more efficiently. This study will help to see early drainage of CSF is associated with low or medium pressure shunts.

C. Novelty: After thorough research there is paucity of information available to see which type of fixed pressure VP shunt is associated with early drainage of CSF in Paediatric congenital hydrocephalus

D. Expected outcome and application: Low pressure VP shunt and medium pressure VP shunt are associated with early drainage of CSF with equal efficiency

Research question(s): What is the clinical effect of different fixed pressure VP shunt in early drainage of CSF in paediatric congenital hydrocephalus patients?

1. Research hypothesis (es), if any: Low pressure VP shunt is associated with early drainage of CSF in paediatric congenital hydrocephalus patients with equal efficiency as compared to medium pressure VP shunt

2. Aim and objectives:

Aim: To evaluate the clinical effect of type of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus patients

Objectives:

I. Primary objective(s): To assess the clinical effect of type of fixed pressure VP shunt on status of anterior fontanel in paediatric congenital hydrocephalus patients

II. Secondary objective(s): To assess the clinical effect of type of fixed pressure VP shunt on ventriculo-hemispheric ratio in paediatric congenital hydrocephalus patients

**Review of literature: (up to 1000 words):**

Hydrocephalus is a disorder of CSF physiology caused by accumulation of CSF inside the brain leading to enlargement of ventricles(2). Non communicating hydrocephalus is due to obstruction of flow of CSF inside ventricular system(4). Diversion of CSF to the peritoneal cavity is the primary treatment option for hydrocephalus. Generally low pressure or medium pressure VP shunts are used for which there is no standard guidelines(7).

Boon et al in his study compared the low pressure shunt and medium pressure shunt in adult with normal pressure hydrocephalus and concluded that low pressure shunt is better than medium pressure shunt(9).

But in the study by Larsson et al. it is shown that reduction in ventricular size in normal pressure hydrocephalus is not associated with shunt opening pressure(10). A retrospective study by Robinson S. · Kaufman B.A was done in neonates and they concluded that valve opening pressure is important component for shunt complication and medium pressure shunts associated with lesser complications(11).

3. **Methodology:**

A. Study design: Randomized control trial

B. Study participants

a. Inclusion criteria:

1. children with congenital hydrocephalus
2. less than 2 yrs of age
3. anterior fontanelle open
4. 1st time shunt being placed

b. Exclusion criteria:

1. Children having severe cardiac or renal anomaly
2. Children in sepsis or shock or organ failure
3. Shunt redo surgery being done
4. Hydrocephalus other than congenital origin
5. Papilledema present

c. Number of groups to be studied, identify groups with definition:

Two groups

1. Group A: children in which low pressure VP shunt will be placed
2. Group B: children in which medium pressure VP shunt will be placed

C. Sampling :

a. Sampling population: Children having congenital hydrocephalus being admitted Paediatric surgery department of AIIMS patna

b. Sample size calculation

Since this is a pilot study, sample size could not be calculated in reference to previous studies. For adequate statistical analysis sample size for each type of operative procedure is taken to be 15. Two groups formed; group A included

patients to be placed low pressure shunt and group B included patients to be placed medium pressure shunt. So total number of patients to be evaluated is 30.

D. Randomization details: Block randomization will be done using random sequence generated by online software. The list so generated will be used to make sequentially numbered opaque sealed envelope which will be kept in our OPD. On the day of the study the parent (or guardian) of the patient will visit the OPD where he/she will be given the top envelope, thus allocating them into either group.

E. Study procedure: Parents of all children admitted to the In-patient Paediatric Surgery ward at AIIMS Patna who are satisfying the Inclusion criteria as specified will be approached by the Primary Researcher for study participation. If willing they will be informed in about the study and consent for participation will be taken (either one of the parents if both are available). That parent will henceforth be considered enrolled.

Demographic details will be collected using a physical proforma. The parent/attendant will subsequently visit the Out Patient Clinic Office of the Department where he/she will be given the top envelope from a pile of Sequentially Numbered Opaque Sealed Envelope (SNOSE) randomised as per Block Randomisation Protocol.
After the surgery, data will be collected using a physical proforma on daily basis and on 5$^{th}$ POD one USG cranium will be done to see the Ventriculohemispheric ratio (VHR)

F. Data collection methods including settings and periodicity:
Data will be collected using physical proforma. Then data will be put onto 'Microsoft Excel' software. Data collection will be done only during the hospital stay when the child's surgery happens. On post operative day 5 VHR will be determined by USG cranium and the reports entered into a physical proforma.

G. If the clinical trial, whether registration with CTRI will be done: Yes

H. Are the drugs/devices to be used approved for these indications by Drug Controller General of India (DCG-I)? (Enclose the approval letter for the drug/device from DCG-I for trial on humans or give undertaking to get the approval from DCGI; For all drugs and devices submit documents showing DCGI approval for the proposed indication of the study): Yes

I. List of variables and their measurement methods with standardization techniques:

a. Independent variables
   -Child's Gender
   -Age
   -Body weight

b. Outcome variables
   -Anterior Fontanelle status- Flat/bulging/ depressed
   -VHR (by USG)- on 5th POD

c. **Confounding and interacting variables**

J. Statistical analysis plan:
The Demographic data will be collected using the physical proforma
Anterior frontanelle status to be recorded on daily basis in a physical proforma
VHR on 5th POD will be recorded on a physical proforma

All the data collected via these forms will be stored onto Microsoft Excel from where it will be analyzed by SPSS software.

K. Limitations of Study:
Long term outcome of both the fixed pressure shunts is not being taken into consideration for this study

4. List risks and benefits of the study:

Risk: Risk and complications associated with shunt surgery
Benefit: Early drainage of CSF with low and medium pressure VP shunt can be seen

5. Plagiarism Check:
<10% plagiarism as checked via www.smallseotools.com/plagiarism-checker/

6. Budget [Justification of budget to be provided]
No funds will be required

7. Relevant references for the project:


1. Oi S. Hydrocephalus Research Update. Neurol Med Chir (Tokyo). 2010;50(9):859–69.

2. Toma AK. Hydrocephalus. Surg Oxf. 2015 Aug;33(8):384–9.

3. McAllister JP. Pathophysiology of congenital and neonatal hydrocephalus. Semin Fetal Neonatal Med. 2012 Oct;17(5):285–94.

4. Maller VV, Gray RI. Noncommunicating Hydrocephalus. Semin Ultrasound CT MRI. 2016 Apr;37(2):109–19.

5. Krishnan P, Raybaud C, Palasamudram S, Shroff M. Neuroimaging in Pediatric Hydrocephalus. Indian J Pediatr. 2019 Oct;86(10):952–60.

6. Kahle KT, Kulkarni AV, Limbrick DD, Warf BC. Hydrocephalus in children. Lancet Lond Engl. 2016 Feb 20;387(10020):788–99.

7. Pediatric hydrocephalus: Does the shunt device pressure selection affect the outcome? - Abstract - Europe PMC [Internet]. [cited 2021 Jul 20]. Available from: https://europepmc.org/article/PMC/3326822

8. Venkataramana NK. Hydrocephalus Indian scenario – A review. J Pediatr Neurosci. 2011 Oct;6(Suppl1):S11–22.

9. Boon AJ, Tans JT, Delwel EJ, Egeler-Peerdeman SM, Hanlo PW, Wurzer JA, et al. Dutch normal pressure hydrocephalus study: baseline characteristics with emphasis on clinical findings. Eur J Neurol. 1997 Jan;4(1):39–47.

10. Larsson A, Jensen C, Bilting M, Ekholm S, Stephensen H, Wikkelsö C. Does the shunt opening pressure influence the effect of shunt surgery in normal pressure hydrocephalus? Acta Neurochir (Wien). 1992;117(1–2):15–22.

11. Robinson S, Kaufman BA, Park TS. Outcome Analysis of Initial Neonatal Shunts: Does the Valve Make a Difference? Pediatr Neurosurg. 2002;37(6):287–94.

8. Enclosures:
    A. **Data collection proforma**
    B. **Questionnaires**
    C. **Consent form (English and Hindi version)**
    D. **Other relevant papers**

9. Undertaking for DCGI approval: (When?)

10. Declarations by guide: **(Type content of declaration)**

| | |
|---|---|
| Signature of the candidate<br>(Name & Designation) | |
| Signature of the Guide<br>(Name & Designation) | |
| Signature (s) of the Co-guide from the Department<br>(Name & Designation) | |
| Signature of Head of the Department<br>(Name & Designation) | |
| Signature (s) of the Co-guide from the Collaborative Department(s)<br>(Name & Designation) | |
| Signature (s) of the Head from the Collaborative Department(s)<br>(Name & Designation) | |

## Demographic details

NAME: AGE: SEX: BODY WEIGHT:

CR NO:

ADDRESS:

## Pre op evaluation

CLINICAL PRESENTATION:

HEAD CICUMFERENCE (HC):

STATUS OF ANTERIOR FRONTANELLE (AF):

VENTRICULOHEMISPHERIC RATIO (VHR):

**DAY OF SURGERY:**

**POST OP EVALUATION**

AF IN 1ST FIVE POST OPERATIVE DAYS-

| | DAY 1 | DAY 2 | DAY 3 | DAY 4 | DAY 5 |
|---|---|---|---|---|---|
| AF | | | | | |

VHR AT DAY 5:

**PATIENT INFORMATION SHEET**

**Title: Outcome analysis of different types of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus**

By- Dr Sourav Jana
Post Graduate, 1st year
Paediatric Surgery, AIIMS Patna
Guide- Dr Amit Kumar Sinha, Associate Professor, Department of Paediatric Surgery
CO Guide- 1. Dr Bindey Kumar, Professor and HOD, Department of Paediatric Surgery
2. Dr Prem Kumar, Professor and HOD, Department of Radiodiagnosis
Contact Details: 7003381703
Address: Department of Paediatric Surgery, AIIMS Patna, Pincode-801507

**Introduction:** You are invited to voluntarily take part in a research study titled "**Outcome analysis of different types of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus** ". Before agreeing to participate in this study, it is important that you read and understand this form. It describes the purpose and procedure of the study. If you participate, you will receive a copy of the consent form to keep for your records.

**Purpose:** There is paucity of information available to say which shunt between low and medium pressure shunt drains more efficiently. This study will help to see early drainage of CSF is associated with low or medium pressure shunts.

**Participation in the study:** Your participation in the study is entirely voluntary. You may refuse to take part in the study or withdraw from the study and this will not affect your treatment. To become part of the study and to authorize use and disclosure of your personal health information, you or your legal representative must sign and date the consent form.

**Procedure**: In this study, the participants will receive consent information as per study protocol. They will then be evaluated for surgery and according to the sequentially numbered opaque sealed envelope they will be enrolled in a group. Demographic details and pre operative evaluation results will be entered into physical proforma and after the surgery assessment results will be entered into physical proforma. Then all the data will be put in MS EXCEL software and will be analysed using SPSS software

**Confidentiality:** The identity of the subjects will be maintained with confidentiality both during the study and while publishing the results of the study.

**Signature**……. **Date…….**

**PATIENT CONSENT FORM**

**Outcome analysis of different types of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus**

Name of the participant:

Name of the Principal Investigator: Dr. Sourav Jana

Designation: 1st Year, Junior Resident

Contact Number: 7003381703

Email ID- drsouravjana@aiimspatna.edu.in

Name of the Institution: AIIMS Patna

1. The contents of the information sheet dated_____ that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents.
1. The nature and purpose of the study and other relevant details of the study have been explained to me in detail. I consent to photography and recording of the Images, which may be viewed for academic purpose only subject to the identity being adequately protected. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.
2. I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS. I give permission for these individuals to have access to my records.
3. I hereby authorize the doctor/person designated to take medical information and sample from me for the above-mentioned study.
4. I agree to take part in the above study.

**Name of the subject**

**Signature of the subject** **Thumb impression of the subject**

**Name of Witness 1**

**Signature of Witness 1** **Thumb impression of Witness Address:**

# UNDERTAKING

Annexure – 1A

IEC-AIIMS-Patna Serial No and Date: ……..…….

**Title of the Proposal: Outcome analysis of different types of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus**

I,

Dr Amit Kumar Sinha, Associate Professor
Department of Paediatric Surgery

Do hereby solemnly state and affirm that the above mentioned project shall be done in accordance with the guidelines of ICMR and GCP.

…… ……

(Signature of the Guide) Date

# UNDERTAKING

Annexure – 1B

IEC-AIIMS-Patna Serial No and Date: ……..…….

**Title of the Proposal - Outcome analysis of different types of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus**

I,
Dr Amit Kumar Sinha, Associate Professor
Department of Paediatric Surgery

do hereby solemnly state and affirm as under.

The above mentioned project shall be done in accordance with ICMR and GCP Guidelines …… …… (Name and Address of the Institute/Sponsor/Individual) will be responsible in case of any adverse event caused due to deviation in above mentioned guidelines.

……. ……
(Signature of the Guide) (Date)

Name and Mobile No. of the person to be contacted in case of adverse event.

1. .Dr. Sourav Jana, 7003381703
1. .
2. .
3. .
4. .
5.

## सहभागी सूचित सहमति प्रपत्र

इस जाचं के लिए सहभागी पहचान नमबर_____

अनुसन्धान शीर्षक_____

मुख्य अन्वेषक का नाम _____ फोन नंबर: _____

मैंने दिनांक_____ के सूचना पत्र में दिये गए सभी तथ्यो को पड़ लिया हैं| मुझे समझ आने वालीं भाषा में विस्तारपूर्वक बत्ता दिया है और मैनें तथ्यो को भली भांति समझ लिया है| मैं पुष्टि करता हूँ कि मुझे प्रशन पुछने का अवसर दिया गया है|

मुझे अध्ययन की प्रकृति, उद्देश्य और इसके सम्भावित लाभ/जोखिमों और अध्ययन की सम्भावित अवधि अन्य प्रासंगिक जानकारी के बारे में विस्तार पुर्वक समझा दिया गया है | मैं समझाता हूँ कि इस अध्ययन में मेरी भागिधारी स्वेछिक है और इस अध्ययन से किसी भी समय बिना कोई कारण बताए, बिना मेरी चिकित्सा देखभाल या कानूनी अधिकारों के प्रभावित हए अपना नाम वापिस ले सकता/सकती हूँ |

मैं समझता हूँ कि इस अनुसन्धान में मेरी सहभागिता से मेरे बारे में एकत्र जानकारी और चिकित्सीय नोटों को एम्स अस्पताल के जिम्मेदार लोगो द्वारा देखा जायेगा| मैं इन व्यक्तियों को अपने रिकोर्ड देखने कि अनुमति प्रदान करता/करती हूँ |

मैं उपयुर्क्त अध्यन में भाग लेने के लिए अपनी सहमति प्रदान करता /करती हूँ |

सहभागी के हस्ताक्षर / बाएं अंगूठे का निशान दिनांक स्थान

सहभागी का नाम

पिता/पति का नाम

पूरा पता

यह प्रमाणित किया जाता हे कि उपयुर्क्त सहमति मेरी उपस्थिति में ली गई हैं |

मुख्य अन्वेषक के हस्ताक्षर दिनाक: स्थान:

१) गवाह के हस्ताक्षर
नाम
पता

२) गवाह के हस्ताक्षर
नाम
पता

# रोगी सूचना पत्र

## शीर्षक: बाल चिकित्सा जन्मजात जलशीर्ष में सीएसएफ के प्रारंभिक निकासी पर विभिन्न प्रकार के निश्चित दबाव वीपी शंट का परिणाम विश्लेषण

By - डॉ। सौरव जाना , पोस्ट ग्रेजुएट, प्रथम वर्ष, पीडियाट्रिक सर्जरी, एम्स पटना
गाइड- डॉ। अमित कुमार सिन्हा, एसोसिएट प्रोफेसर, बाल चिकित्सा सर्जरी
सीओ गाइड- डॉ बिंदी कुमार, प्रोफेसर और एचओडी, बाल चिकित्सा सर्जरी
संपर्क विवरण: 7003381703
पता: डिपार्टमेंट ऑफ पीडियाट्रिक सर्जरी, एम्स पटना, पिनकोड-801507

**परिचय:** आपको स्वैच्छिक रूप से एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया गया है, जिसका शीर्षक है " बाल चिकित्सा जन्मजात जलशीर्ष में सीएसएफ के प्रारंभिक निकासी पर विभिन्न प्रकार के निश्चित दबाव वीपी शंट का परिणाम विश्लेषण"। इस अध्ययन में भाग लेने के लिए सहमत होने से पहले, यह महत्वपूर्ण है कि आप इस फॉर्म को पढ़ें और समझें। यह अध्ययन के उद्देश्य और प्रक्रिया का वर्णन करता है। यदि आप भाग लेते हैं, तो आपको अपने रिकॉर्ड के लिए सहमति पत्र की एक प्रति प्राप्त होगी।

**उद्देश्य: यह कहने के लिए जानकारी उपलब्ध नहीं है कि निम्न और मध्यम दबाव वाले शंट के बीच कौन सा शंट अधिक कुशलता से बहता है। इस अध्ययन से यह देखने में मदद मिलेगी कि सीएसएफ का प्रारंभिक निकासी कम या मध्यम दबाव के शंट से जुड़ा हुआ है**

**अध्ययन में भागीदारी**: अध्ययन में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। आप अध्ययन में भाग लेने या अध्ययन से हटने से इनकार कर सकते हैं और इससे आपके उपचार पर कोई असर नहीं पड़ेगा। अध्ययन का हिस्सा बनने के लिए और अपनी व्यक्तिगत स्वास्थ्य जानकारी के उपयोग और प्रकटीकरण को अधिकृत करने के लिए, आपको या आपके कानूनी प्रतिनिधि को सहमति पत्र पर हस्ताक्षर और तारीख करनी होगी।

**प्रक्रिया**: इस अध्ययन में, प्रतिभागियों को अध्ययन प्रोटोकॉल के अनुसार सहमति जानकारी प्राप्त होगी। फिर उन्हें चिंता, ज्ञान और संतुष्टि पर डेटा एकत्र करने के लिए 3 प्रश्नावली दी जाएंगी। इसके बाद परिणामों पर पहुंचने के लिए विश्लेषण किया जाएगा।

**गोपनीयता:** विषयों की पहचान को अध्ययन के दौरान और अध्ययन के परिणामों को प्रकाशित करते समय गोपनीयता के साथ बनाए रखा जाएगा।

..... .....

(हस्ताक्षर) (दिनांक)

# आंशिक सूचित सहमति फॉर्म (PICF)

परियोजना का शीर्षक: बाल चिकित्सा जन्मजात जलशीर्ष में सीएसएफ के प्रारंभिक निकासी पर विभिन्न प्रकार के निश्चित दबाव वीपी शंट का परिणाम विश्लेषण

प्रतिभागी का नाम:

प्रधान अन्वेषक का नाम: डॉ। सौरव जाना

पद: जूनियर रेजिडेंट (अकादमिक)

विभाग: बाल चिकित्सा सर्जरी

संपर्क नंबर: 7003381703

ईमेल-आईडी - drsouravjana@aiimspatna.edu.in

1. सूचना पत्र की सामग्री दिनांकित _____ जो मेरे द्वारा प्रदान की गई थी, मुझे ध्यान से पढ़ी गई / मेरे बारे में विस्तार से बताई गई, उस भाषा में जिसे मैं समझती हूं, और मैंने सामग्री को पूरी तरह से समझ लिया है।

2. अध्ययन की प्रकृति और उद्देश्य और अध्ययन के अन्य प्रासंगिक विवरणों के बारे में मुझे विस्तार से बताया गया है। मैं छवियों की फोटोग्राफी और रिकॉर्डिंग के लिए सहमति देता हूं, जिसे केवल शैक्षणिक उद्देश्य के लिए देखा जा सकता है, जो पहचान के लिए पर्याप्त रूप से संरक्षित है। मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और मैं बिना किसी कारण के किसी भी समय वापस लेने के लिए स्वतंत्र हूं, बिना मेरी चिकित्सा देखभाल या कानूनी अधिकार प्रभावित हुए बिना।

3. मैं समझता हूं कि इस शोध में मेरी भागीदारी से मेरे बारे में एकत्र की गई जानकारी और मेरे किसी भी मेडिकल नोट के वर्गों को एम्स के जिम्मेदार व्यक्तियों द्वारा देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं।

4. मैं उपर्युक्त अध्ययन के लिए चिकित्सक / व्यक्ति से चिकित्सा संबंधी जानकारी और नमूना लेने के लिए अधिकृत करता हूं।

5. मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं।

मरीज़ का नाम: मरीज़ का हस्ताक्षर विषय का अंगूठे का निशान

गवाह का नाम: गवाह का हस्ताक्षर / गवाह का अंगूठे का निशान

पता:

| | |
|---|---|
| Signature of the candidate<br>Dr. Sourav Jana,<br>1st Year Junior Resident<br>Paediatric Surgery | |
| Signature of the Guide<br>Dr. Amit Kumar Sinha<br>Associate Professor<br>Paediatric Surgery | |
| Signature of the Co-guide from the Department<br>Dr. Bindey Kumar<br>Professor and HOD<br>Paediatric Surgery | |
| Signature of Department Head<br>Dr. Bindey Kumar<br>Professor and HOD<br>Paediatric Surgery | |
| Signature of the Co-guide from the Collaborative Department(s)<br>Dr Prem Kumar<br>Professor and HOD<br>Radiodiagnosis | |

## DECLARATION OF ETHICAL CONDUCT IN RESEARCH

**Title of the Study:** Outcome analysis of different types of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus

**Name of the Student: Dr Sourav Jana**

**Name of the Department: Paediatric Surgery**

**Name of the Guide: Dr Amit Kumar Sinha**

**Name of the Co-Guide/s: Dr (Prof) Bindey Kumar**

**Departments of the Co-Guide/s: Paediatric surgery**

**I (We) hereby declare that, t**he proposed research study shall be conducted as per the ethical principles and guidelines laid down by ICMR, WHO and ICH-GCP. The identity and the medical and non-medical information of the deceased obtained during the study will be kept confidential and will not be shared in any manner to others except the regulatory authorities like members of IEC (Institutional Ethics Committee) etc. The research shall be conducted for academic purpose only. The result (s) of the research may be presented or published in a scientific conference or journal without disclosing the identity of the subject participants.

| | |
|---|---|
| Signature of the PG student | |
| Signature of the PG Guide | |
| Signature of the PG Co - Guide | 1.<br>2. |

| | |
|---|---|
| | |

Date:

Place:

| | | | |
|---|---|---|---|
| **Sponsor Information** :<br>1. Indian a) Government ☐<br>b) Private ☐ | Central ☐ | State ☐ | Institutional ☐ |
| 2. International Government ☐ | Private ☐ | | UN agencies ☐ |
| 3. Industry National ☐ | Multinational ☐ | | |

**Contact Address of Sponsor:**

**Total Budget:**

| | | | |
|---|---|---|---|
| Who'll bear cost of investigation/implants/drugs? | 1.Patient | 2.Project | 3. Exempted |
| | 4. Other Agencies | | |
| **1.Type of Study :** Cross sectional Case Control Cohort (Clinical Trial) Review<br>Participating Centre : (Single centre) Multi-centric Others (Specify) | | | |
| **2. Status of Review:** New ☐ Revised ☐ | | | |
| Clinical Trials:<br>**Drug /Vaccines/Device/Herbal Remedies:**<br>Does the study involve use of:<br>Drug ☐ Devices ☐ | | | |

Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐

Is it approved and marketed?

In India ◯ UK&Europe ☐ USA ☐

Other countries, specify ☐

| | | |
|---|---|---|
| **iii.** Does it involve a change in use, dosage, route of administration? | Yes | No |
| **If yes**, DCGI's or other Regulatory authority's Permission obtained? | Yes | No |
| **If yes,** Date of permission : | | |
| **iv.** Is it an Investigational New Drug? | Yes | No |
| **If yes,** IND No: | | |
| a). Investigator's Brochure submitted | Yes | No |
| b). *In vitro* studies data | Yes | No |
| c). Preclinical Studies done | Yes | No |
| d). Clinical Study is : Phase I Phase II Phase III Phase IV | | |
| e). Are you aware if this study/similar study is being done else-where? | Yes | No |
| **If Yes**, attach details | | |

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

**5. Subject selection:**

| | | | |
|---|---|---|---|
| ii. | Duration of study : | 1.5y r | |
| iii. | Will subjects from both sexes be recruited | Yes | No |
| iv. | Inclusion / exclusion criteria given | Yes | No |
| v. | Type of subjects | Patients | Volunteers |
| vi. | Vulnerable subjects | Yes | No |

(Tick the appropriate boxes)

| | | | | | |
|---|---|---|---|---|---|
| Pregnant women | ☐ | Children | ☐ | Elderly | ☐ |
| Foetus | ☐ | Illiterate | ☐ | Handicapped | ☐ |
| Mental | | Terminally ill | | Seriously ill | |

i. Special group subjects Yes ☐ No ☐

(Tick the appropriate boxes)

| | | | |
|---|---|---|---|
| captives | ☐ | Institutionalized | employees |
| students | ☐ | nurses/dependent | Armed |
| any other | ☐ | Staff | Forces |

**6. Privacy and confidentiality**

i. Study involves - Direct Identifiers ☐

Indirect Identifiers/coded ☐

Completely anonymised ☐

| | | | |
|---|---|---|---|
| ii. | Confidential handling of data by staff | Yes | No |
| **7. Use of biological/ hazardous materials** | | Yes | No |
| ii. | Use of organs or body fluids | Yes | No |
| iii. | Use of recombinant/gene therapy | Yes | No |
| **If yes,** has Department of Biotechnology (DBT) 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 Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained? | | Yes | No |
| vii. | Use of Infectious/bio hazardous specimens | Yes | No |
| viii. | Proper disposal of material | Yes | No |
| ix. | Will any samples collected from the patients be sent abroad? | Yes | No |
| **IfYes, justify with details of collaborators** | | | |
| a) | Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? | Yes | No |

b) Sample will be sent abroad because (Tick appropriate box):

| | |
|---|---|
| Facility not available in India | ☐ |
| Facility in India inaccessible | ☐ |
| Facility available but not being accessed.<br>If so, reasons… | ☐ |

| **8. Consent :** *Written ☐ | Oral ☐ | Audio-visual ☐ |
|---|---|---|
| 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 biological material | |
| Compensation for participation | Benefits if any On future commercialization | |
| Compensation for study related injury | | |

*if written consent is not obtained, give reasons.

| ii. Who will obtain consent? PG/GUIDE/Co-guide | Nurse/Counsellor |
|---|---|
| Research staff | Any other |

| **9. Will any advertising be done for recruitment of Subjects?** (posters, flyers, brochure, websites – if so kindly 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<br>More than minimum risk<br>High risk | | |

| Is there a benefit to the subject? YES<br>Benefit to society? YES | | |
|---|---|---|
| **11. Data Monitoring** | Yes | No |

| | | |
|---|---|---|
| i. Is there a data&safety monitoring committee/ Board (DSMB)? | | |
| ii. Is there a plan for reporting of adverse events?<br>**If Yes,** reporting is done to :<br>Sponsor Ethics Committee DSMB | Yes | No |
| iii. Is there a plan for interim analysis of data? | Yes | No |
| vi. Are there plans for storage and maintenance of all trial database?<br>**If Yes,** for how long? Till Publication | Yes | No |
| **12. Is there compensation for participation?**<br>**If Yes,** Monetary In kind | Yes | No |
| **13. Is there compensation for injury?**<br>**If Yes,** by Sponsor | Yes | No |
| **14. Do you have conflict of interest?**<br>**(financial/nonfinancial) If Yes, specify :** | Yes | No |
| Conflict of interest for any other investigator(s) (if yes, please explain in brief | 1_____ Yes<br>No 2_____ Yes | |
| 15. Participant Information Sheet<br>*(mark √ if yes)* | Attached English Version √<br>Attached Hindi version √ | |
| 16. **Participant Informed Consent Form**<br>*(mark √ if yes)* | Attached English Version √<br>Attached Hindi version √ | |
| 17. Whether any work on this project has started or not? | *(mark √ if yes, X if no) (Please Separate certificate to this effect).* | |
| 18. In case of clinical trials CTRI status | Will be applied after IEC Approval | |

FORM TO BE FILLED BY THE Junior Resident (Academic)
FOR SUBMISSION TO INSTITUTIONAL ETHICS COMMITTEE (IEC),
AIIMS-PATNA
(FOR ATTACHMENT TO EACH COPY OF THE PROPOSAL)

Serial No of IEC Management Office:

TITLE OF THE PROJECT: - Outcome analysis of different types of fixed pressure VP shunt on early drainage of CSF in paediatric congenital hydrocephalus

| | **Name Designation& Department** | **Tel No. Email Id** | **Signature** |
|---|---|---|---|
| **Junior Resident (Academic)** | Dr. Sourav Jana,<br>1st Year Junior Resident<br>Paediatric Surgery | 7003381703<br>janasourav6393@@gmail.com | |
| **Guide** | Dr. Amit Kumar Sinha<br>Associate Professor<br>Paediatric Surgery | 9855572734<br>dr_amits@yahoo.com | |
| **Co-Guide** | 1. Dr. Bindey Kumar<br>Professor and Head<br>Paediatric Surgery<br>2. Dr Prem Kumar<br>Professor and Head<br>Radiodiagnosis | 1) 9334114626<br>bindeyster@gmail.com<br>2) 9430212777<br>drprempat@gmail.com | |

## CHECKLIST FOR ATTACHED DOCUMENTS

1. Covering letter, through proper channel
2. Project proposal – 01 Copy
3. Curriculum Vitae of Investigator
4. Brief description of proposal
5. Patient information sheet
6. Informed Consent form
7. Investigator's brochure
8. Copy of advertisements/Information brochures
9. Copy of clinical trial protocol and/or questionnaire
10. HMSC/DCGI/DBT/BARC clearance if required
11. Undertaking that the study shall be done in accordance with ICMR and GCP guidelines
12. In case of multi-centric study, IEC clearance of other centres must be provided
13. Definite undertaking as to who will bear the expenditure of injury related to the project
14. If an insurance cover is intended
15. Insurance certificate must be provided (as per ICMR guidelines)

16. Permission to use copyrighted Questionnaire/Performa
17. Investigator should provide undertaking what they will do with the leftover sample tissue
18. Certificate/undertaking as mentioned in column 17
19. Others