AIIMS/JDH/PED/2021/246

Date- 29/7/21

To,

The Member Secretary
Institutional Ethical Committee
AIIMS, Jodhpur

Subject: Submission of intramural (Non Funded) project for ethical clearance
Dear Sir,

I am submitting a survey based study entitled "**Post COVID neurological complications in children**" for ethical clearance in 1 copy.
Kindly do needful.
Thanking you,

Yours Sincerely,

Dr. Lokesh Saini
Assistant Professor
Department of Pediatrics
AIIMS, Jodhpur

F&T

डॉ. कुलदीप सिंह
Dr. Kuldeep Singh
आचार्य व विभागाध्यक्ष, शिशु चिकित्सा
Professor & HOD, Pediatrics
एम्स, जोधपुर (राज.)
AIIMS, Jodhpur (Raj.)

All India Institute of Medical Sciences
Jodhpur, Rajasthan

Format of submission of Research Project to Institution Ethics Committee (HR)

Note: Fill all columns neatly. Use additional sheets, if required

S.No.		
1.	Title of the Research Project	**Post COVID neurological complications in children.**
2.	Name, designation & address of Principal Investigator/Supervisor **Dr. Lokesh Saini** Assistant Professor Department of Pediatrics, AIIMS, Jodhpur	Signature of Principal Investigator/Supervisor डॉ. लोकेश सैनी Dr. Lokesh Saini सहायक आचार्य Assistant Professor शिशु चिकित्सा विभाग Department of Pediatrics अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर All India Institute of Medical Sciences, Jodh
3.	Name, Designation & address of Co-investigators (AIIMS) a. **Dr. Kuldeep Singh**, Professor and Head, Department of Pediatrics b. **Dr. Daisy Khera**, Additional professor, Department of Pediatrics c. **Dr Jagdish Prasad Goyal, Professor,** Department of Pediatrics d. **Dr Prawin Kumar**, Associate professor, Department of Pediatrics e. **Dr Ashwini Agarwal,** Additional Professor, Department of Microbiology. f. **Dr Sarbesh Tiwari**, Assistant professor, Department of diagnostic and interventional radiology.	Signature of Co-Investigators डॉ. कुलदीप सिंह Dr. Kuldeep Singh आचार्य व विभागाध्यक्ष, शिशु चिकित्सा Professor & HOD, Pediatrics एम्स, जोधपुर (राज.) AIIMS, Jodhpur (Raj.) डॉ. डेजी खेरा Dr. Daisy Khera अतिरिक्त आचार्या Additional Professor शिशु चिकित्सा विभाग Department of Pediatrics अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर All India Institute of Medical Sciences, Jodhpur डॉ. जगदीश प्रसाद गोयल Dr. Jagdish Prasad Goyal आचार्य Professor शिशु चिकित्सा विभाग Department of Pediatrics अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर All India Institute of Medical Sciences, Jodhpur डॉ. अश्विनी अग्रवाल Dr. Ashwini Agarwal अतिरिक्त आचार्य Additional Professor सूक्ष्म जीव विज्ञान विभाग Department of Microbiology अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर All India Institute of Medical Sciences, Jodhpur डॉ. सर्बेश तिवारी Dr. Sarbesh Tiwari सहायक आचार्य Assistant Professor डायग्नोस्टिक एवं इंटरवेन्शिअनल रेडियोलोजी विभाग Department of Diagnostic & Interventional Radiology अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर All India Institute of Medical Sciences, Jodhpur
4.	Name of the department(s) where research/study will be carried out	Department of Paediatrics
5.	Name of the institutions (Other than AIIMS) collaborating in the study (MoU duly signed by the Principal Investigator & Head of the Institution should also be submitted)	**NA**
6.	Details of the centres involved in multicentre study (applicable to multicentric studies only).	**NA**
7.	Name & address of Funding Agency	**None**
8.	Does the project involve :	

	a. Clinical trial with new drug(s)/device(s) approved by DCGI. b. Clinical trial with existing drug(s)/device(s) approved by DCGI. c. Traditional medicine(s) (Ayurvedic/Unani/Homeopathic/Tribal System). d. Animals will be used. (if YES, refer to IEC-A) e. None of the above. (if "a" is yes, kindly provide details/evidence of experimental & clinical safety of the drug(s)/device(s))	**NO** **NO** **NO** **NO** **NO**
9.	Permission from DGFT if applicable:	**Not required**
10.	Will human material be collected: a. If "yes" please specify the tissue b. Mode of collection of tissue (operation / biopsy / autopsy / abortion/others) specify. c. Is the procedure to obtain the tissue indicated for the management of the patient. (Give details of the procedure with justification if the answer of "c" is yes. d. Will the tissue be collected by a method otherwise not required for the management of the patient. (If "yes", specify the method with justification) e. Please also see S.No 6.	**No** NO NO
11.	Are there any anticipated risk(s) during the course of the study (procedural/adverse drug reaction or any other). (If"yes", please provide details along with management/compensation of the risk factors).	No
12.	Details of fees/honorarium payable to investigators/collaborator/volunteers/ patients, if any.	None
13.	Is clearance required from any other agency. (If "yes", kindly furnish the details)	NO
14.	Is there any provision to compensate the volunteers/patients in case of mishap? (If "yes", please provide details.	NO
15.	Conflict of interest of any investigator (If "yes", please furnish details.	NO

Please attach the complete Research Project along with this form and statement of budget (If applicable).

Date: ..... **Signature of Principal Investigator/Supervisor**

Dr. Kuldeep Singh
आचार्य व विभागाध्यक्ष, शिशु चिकित्सा
Professor & HOD, Pediatrics
एम्स, जोधपुर (राज.)
AIIMS, Jodhpur (Raj.)

Date: ..... **Signature of Head of concerned Department**

All India Institute of Medical Sciences
Jodhpur, Rajasthan

Check List for submitting research proposals to Institute Ethical Committee

1. Title of the project : **Post COVID neurological complications in children.**
2. Name, Designation : **Dr. Lokesh Saini**, Assistant Professor,
   Address of Principal : Department of Pediatrics, AIIMS Jodhpur
   Investigator :

S.No.	Particulars	Yes	No	If No, Give reasons
1.	Research project	Yes		
2.	Performa for IEC (duly filled)	Yes		
3.	Informed consent form a. English b. Hindi/Vernacular		No	Not required Retrospective study [CHART Review
4.	Patient Information Sheet a. English b. Hindi/Vernacular		No	Not required Retrospective Study [CHART Review]
5.	Declaration by Principal Investigator	Yes		
6.	Case record form	Yes		
7.	Any other document for consideration by IEC		No	
8.	Permission to use copyrighted questionnaire and proforma		No	
9.	Brief CV of Principal Investigator	Yes		

Date: Signature of Principal Investigator

डॉ. लोकेश सैनी
Dr. Lokesh Saini
सहायक आचार्य
Assistant Professor
शिशु चिकित्सा विभाग
Department of Pediatrics
अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences

For office use only

Date of receiving : ----------

Office No. : ----------

Signature
(On behalf of IEC)

All India Institute of Medical Sciences
Jodhpur, Rajasthan

Declaration by the Principal Investigator

I hereby declare that:

1. The study will be done as per ICMR/ GCP guidelines.
2. The study has not been initiated and shall be initiated only after ethical clearance
3. Voluntary written consent of the volunteers/patients will be obtained.
4. In case of children and mentally handicapped volunteers/patients, voluntary written informed consent of the parents/guardians will be obtained.
5. The probable risks involved in the study will be explained in full to the subjects/parents/guardians in their own language.
6. Volunteers/patients/parents/guardians will be at liberty to opt out of the study at any time without assigning reason.
7. I will terminate the study 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 study/experiment is likely to result in injury/disability/death to the volunteers/subject.

Date: _____

Department _____

(Signature of Principal Investigator)

डॉ. लोकेश सैनी
Dr. Lokesh Saini
सहायक आचार्य
Assistant Professor
शिशु चिकित्सा विभाग
Department of Pediatrics
अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur

Protocol

Title : Post COVID neurological complications in children.

Introduction:

The first case of COVID 19 was reported in December 2019 in Wuhan, China (1), Since then we have already had 2 waves of OCIVD 19. Even though the child appears to be immune or less affected during the acute infection, post covid complications in children like MIS-C, neurological complications, immune-mediated conditions, etc., proved to be a nightmare for the treating physician.

As we all know COVID 19 infection is caused by the SARS-CoV-2 virus which belongs to the coronavirus family and is transmitted by aerosols.

SARS CoV2 invades via ACE2 receptor and transmembrane serine protease 2 (TMPRSS2) both the receptors are present in the CNS. This triggers the pro-inflammatory and pro coagulable cascade and causes symptoms either by direct invasion of the virus or by inducing vasculitis (2–4).

However neurological manifestations in the post COVID period is attributed to the immune-mediated (cytokine storm) phenomena similar to MIS-C, in both the condition cytokine levels like interleukin-1β (IL-1β), IL-6, IL-8, IL-10, IL-17, IFN-γ are found to be elevated and also elevated acute phase reactants (5).

These cytokines cause blood-brain barrier disruption, activate glial cells, and initiate neuroinflammation leading to manifestations like seizure, fatigue, encephalopathy, etc.,

Also, molecular mimicry between coronavirus with gangliosides and myelin basic protein can cause demyelination and can present as GBS (6,7).

Review of literature:

There are only few articles published till date regarding the neurological manifestations associated with COVID 19 infection.

Author,	Demographics	Study	Conclusion
Ray et al., Prospective cohort study 2021 (8)	Children & adolescent <18years, H/o COVID 19 infection , presenting with neurological symptoms.	Neurological manifestations of SARS-CoV-2 infection in hospitalised children and adolescents in the UK: a prospective national cohort study	Compared with patients with a primary neurological disorder, more patients with PIMS-TS needed intensive care, but outcomes were similar overall.
Siracusa et al., Systematic review (9)	Systematic review which included 59 patients from 44 article.	Neurological complications in pediatric patients with SARS-CoV-2 infection: a systematic review of the literature	Nervous system involvement could be isolated, developing during COVID-19 or after its recovery, or arise in the context of a MIS-C.
Lindan et al., (10)	38 children with neurological disease related to SARS CoV2 infection were identified.	Neuroimaging manifestations in children with SARS-CoV-2 infection: a multinational, multi-centre collaborative study	Acute-phase and delayed-phase SARS-CoV-2-related CNS abnormalities are seen in children. Recurring patterns of disease and atypical neuroimaging manifestations can be found and should be recognized being as potentially due to SARS-CoV-2 infection as an underlying etiological factor.

Aims and Objectives:

- To know the possible association of COVID 19 and neurological manifestations in children.
- To know the spectrum of neurological manifestations in children with COVID 19.

Materials and Methods

Study Design: Retrospective study

Study period: January 2020 – August 2021

Study Site: Department of Pediatrics, All India Institute of Medical Sciences, Jodhpur.

Study Population: Retrospective data of all children aged 1month to 18years who were admitted in AIIMS with neurological manifestations and either h/o COVID / COVID contact or positive COVID serology collected.

Sample size: Time dependent

Study Participants:

Inclusion Criteria

1. Children 1 month to 18years of age
2. Children with neurological manifestations like seizure, encephalopathy/encephalitis, neurovascular manifestations and immune mediated neurological conditions etc., with prior h/o COVID 19 infection / contact.
3. Children with neurological manifestations like seizure, encephalopathy/encephalitis, neurovascular manifestations and immune mediated neurological conditions etc., with positive serology.

Methodology:

A retrospective data will be collected from the period of Jan 2021 to July 2021, including all children aged from 1month to 18 years of age who presented to our pediatric emergency or OPD with the neurological manifestation with h/o COVID 19 infection or positive COVID serology.

The details of the cases will be recorded (as mentioned in the case record form), which includes demographics, presentation, evidence of SARS-CoV-2 infection, investigations, treatment and outcome.

The neurological manifestations were further categorized into seizures, headache/meningism, cerebrovascular event (stroke ischemic or hemorrhagic and CSVT), encephalopathy/encephalitis, demyelinating pathology, peripheral nervous system involvement, neuropsychiatric manifestations or movement disorder.

Investigations of the patients including acute phase reactants, CSF examination (if done), neuroimaging and other investigations will be noted down.

Also, the course during the hospital stay like whether the child required PICU admission, ionotropic support and immunomodulatory therapy will also be entered in the case record form.

Ethics and disseminations:

- Research ethics approval: The study would be undertaken after the ethical clearance from institute`s ethical committee.

- Confidentiality: The confidentiality of information obtained will be maintained and revealed only to doctor/auditor involved in study and if required to regulatory authorities.

Case Record Form:

S. N.	Patient	Result
1.	Name	
2.	Age	
3.	Sex	
4.	Registration number (UHID)	
5.	Diagnosis	
6.	Underlying comorbidity	
7.	Clinical features: Systemic features Respiratory involvement Encephalopathy Seizures Headache / meningism PNS involvement Focal CNS involvement Behavioural change Cerebrovascular disease Demyelination	

	Movement disorder **Neuropsychiatric manifestation**	
8.	**Investigations:** **SARS-CoV-2 PCR +ve** **COVID serology positive** **Hs CRP** **IL-6** **Ferritin** **CSF (if done)** **Neuroimaging** **Other:**	
9.	**Treatment:** **ICU admission** **Immunomodulation** **Ionotropic support**	
10.	**Outcome:** **Discharged without disability**	

	Disability **Death**	
11.	**Follow up**	

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Name:	Dr. Lokesh saini
Designation:	Assistant Professor
Department:	Department of pediatrics
Institttute:	AIIMS, Jodhpur
Date Of Birth:	16/07/1982
Sex:	Male
SC/ST:	No

II) Education Details:

Sno.	Institution Place	Degree Awarded	Year	Field of Study
1	PGIMER Chandigarh	MD	2012	Pediatrics
2	AIIMS, New Delhi	DM	2016	Pediatric Neurology

III) Employment Details:

Sno.	Institution Place	Position	From (Date)	To (date)
1	PGIMER Chandigarh	Assistant Professor	06/04/2017	30/06/2020
2	PGIMER Chandigarh	Associate professor Professor	01/07/2020	14/04/2021

IV) Honors/Awards:

Sno.	Reader	No.	Description
1.	International		International scholarship award 2020 by American academy of Neurology
2.	National		

V) Publications: 97

Sno.	total	No. 125
1.	International	85

2.	National	40

Uploaded additional information Not uploaded

Publication Details:

Uploaded list of Publication in the peer review Journal of impact factor 1 and above

1. Dayal D, Saini L, Attri SV, Singh B, Bhalla AK. Daily versus alternate day thyroxine therapy to maintain euthyroidismin children with congenital hypothyroidism: Int J Endocrinol Metab. 2013 Oct 1;11(4):e9499
2. Gulati S, Chakrabarty B, Kumar A, Jain P, Patel H, Saini L.Acquired demyelinating disorders of central nervous system: A pediatric cohort.Ann Indian Acad Neurol. 2015 Sep;18(Suppl 1):S48-55
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17. Bhattacharya D, Sharawat IK, Saini L. Intraventricular haemorrhage and obstructive hydrocephalus in a term neonate: an uncommon presentation of haemophilia B. BMJ case reports. 2018;2018.
18. 18.Dhawan SR, Gupta S, Saini L. Unexplained Transaminitis and Hyperactivity: Do Not Forget the Musculoskeletal Examination. The Indian Journal of Pediatrics. 2018;85(8):682–3.
19. Jauhari P, Saini L, Chakrabarty B, Kumar A, Gulati S. Juvenile Canavan Disease: A Leukodystrophy without White Matter Changes. Neuropediatrics. 2018;49(06):420–1.
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VI) Project(s) submitted/being pursued/carried out by Investigator:

Title of the project	Role (Principal Investigator or Co-Investigator	Funding Agency/No funding Agency	Amount of the project	Duration of the project (specify period)
Organ low cost biomechatronic rehabilitative solutions for children with congenital hemiparesis	CO-INVESTIGATOR	DST	44.80LAKH	24 months
Evaluation and efficacy of virtual reality in improving visual perception and Hand-eye coordination in children with hemiplegic cerebral palsy: randomized open label controlled trial	CO-INVESTIGATOR	DST	41.36 LAKH	18 months
Analysis of neural networksunderlying west syndrome using functional MRI	CO-INVESTIGATOR	CSIR	Salary of senior research officer per month as per rules	36 MONTHS
West syndrome – EAST Trial	Co -Investugator	ICMR		24 Months

VII) Professional Experience and Training relevant to the Project:

1. Dr. Lokesh Saini has received second Certification for advanced training in the field of "General Movements" 21st November 2019
2. Received certification for DASII "DEVELOPMENTAL ASSESSMENT SCALE FOR INDIAN INFANTS" certification. 19th October 2019