

CIFE/DMC/ICMR No: 5/4-5/127/Neuro/2013-NCD-I

Zone No.	Ward No.	PHC No.	Cluster No.	Household ID No.	Subject No.

Dayanand Medical College & Hospital, Ludhiana-141001

Indian Medical Council & Research, New Delhi-110029

SUBJECT INFORMATION SHEET

Project Title: Towards developing a national epilepsy control program: A pilot, community-based, cluster randomized trial of delivery of care to people with epilepsy.

ICMR No: 5/4-5/127/Neuro/2013-NCD-I

Ethics No: DMCH/DTEC/2013/429

Dear Sir/Madam,

We invite you to take part in this study entitled, “Towards developing a national epilepsy control program: A pilot, community-based, cluster randomized trial of delivery of care to people with epilepsy” conducted under the aegis of Dayanand Medical College (DMC) & Hospital, Ludhiana and the Indian Council of Medical Research, New Delhi. This project has been approved by the Ethics Committees of Dayanand Medical College & Hospital. The study has been designed in order to determine the optimal method of ensuring safe and effective community treatment of epilepsy in India.

Your participation in this study is entirely voluntary and will in no way affect the medical care privileges offered to you by all primary health center or Dayanand Medical College and Hospital.

As a part of the study, a field worker, trained at Dayanand Medical College Hospital, Ludhiana will contact you. He or she will be accompanied by the Accredited social health activists (ASHAs)/ Auxiliary Nurse Midwifery (ANM) who regularly frequents your house. The field worker will administer a questionnaire to you. This would take about 5 minutes of your time. You are free to decline to answer the questionnaire. The questionnaire comprises of a set of 9 questions and is able to determine if you possibly have suffered from epileptic fits in the past. If you are found to screen positive on the basis of this questionnaire, we will then invite you to visit a health center on an appointed day, where you will be examined by a neurologist. If the latter confirms you to be epileptic you will be called to the hospital on an appointed day for an EEG test. EEG involves the application of certain electrodes to the scalp with the help of a paste. It records your brain waves and helps in the diagnosis and treatment of epilepsy. These investigations are essentially harmless and facilitate the treatment of epilepsy. The neurologist will also offer you advice on the nature and treatment of epilepsy. As you are aware, primary center provides essential medications for the treatment of epilepsy. Information obtained by way of this questionnaire will be kept strictly confidential. It will be fed into a stand- alone computer and then analyzed only after anonymisation. The data will be under the possession of Dr. Gagandeep Singh, Department of Neurology, Dayanand Medical College & Hospital, Ludhiana and only members of the study team will have access to this data.

If you are keen to participate in this survey, please indicate so by signing the consent form given below.

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CONSENT FORM

I,.....s/o/d/o..... R/O
 agree to participate in this study
 entitled “Towards developing a national epilepsy control program: A pilot, community-based, cluster
 randomized trial of delivery of care to people with epilepsy” and to fill up the questionnaire. My
 participation is entirely voluntary.

Witness	Signature.....
Signature.....	Full Name.....
Address.....	Address.....
.....
.....
Relationship to subject.....	
Investigator	
Signature.....	
Full Name.....	
Designation.....	

If you have any questions, you may contact any of the following:

Name of the Person (Investigators)	Telephone No	Email id
GNM/ANM		icmrepilepsyproject@gmail.com
SRF-Suman Rani		icmrepilepsyproject@gmail.com
Dr. Jatinder Singh Goraya	9872654466	gorayajs@gmail.com
Dr. Gagandeep Singh	9815500720	gagandeep_si@yahoo.co.uk

Address: Permanent <input type="checkbox"/> Temporary <input type="checkbox"/>
Complete Address:
.....
.....
Permanent Address (If Tenant):
.....
.....

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CASE REPORT FORM

STUDY TITLE

Towards Developing a National Epilepsy Control Program :A Pilot Community-Based of Delivery of Care to People with Epilepsy/ Community Interventions for Epilepsy (CIFE)

Ad Hoc ICMR Epilepsy Project – ICMR No: 5/4-5/127/Neuro/2013-NCD-I

Clinical Trial Site	Dayanand Medical College & Hospital, Ludhiana
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Subject Initials	
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Zone No.	Ward No.	PHC No.	Cluster No.	Household ID No.	Subject No.

1. Has the patient signed written		Informed Consent for this study	
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/>	
2. Date of Informed Consent			
DD MMM		YYY	

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INCLUSION CRITERIA

	Yes	No
A history of more than one epileptic seizures		
Subject willingly given written informed consent		

EXCLUSION CRITERIA

	Yes	No
Subject having inactive epilepsy		
Subject having only febrile seizures		
Subject having non-epileptic seizure		
Pregnancy as determined by the urine pregnancy test		
Medical Contraindication to MRI(pace-maker, implant)		
No History of progressive neurological deficit		
Unwillingness to provide informed consent/Assent		

Zone No.	Ward No.	PHC No.	Cluster No.	Household ID No.	Subject No.

Enrollment Visit

Demographic Information

1. **Date of Birth:**

DD MMM YYYY

2. **Age:** Years

3. **Gender:** Male Female

4. **Religion:** Sikh Christian Hindu Muslim Buddhist

Jain Parsee Jews Bahais others

5. **Weight:** kg

6. **Height:** cm

7. **Place of Birth:**.....

8. **Ethnic origin:** Punjabi Migrant Others

9. **Education:** Professional Honors Post-graduate Graduate

Post High School Dip (A level) High School Certificate (O level)

Middle School Certificate Primary School Certificate

Illiterate Others: _____

10. **Occupation**

(Self): Professional Self-employed (Business) Semi-professional Clerical

Skilled worker Semi-skilled worker Unskilled worker Unemployed

11. **Occupation of the Head of Fam**:

Professional Semi- professional Clerical/ shop owner Skilled worker

Semi- skilled worker Unskilled worker Unemployed

12. **Education of the Head of Family:**

Professional / Honors Graduate or post graduate

Intermediate or post high school High school certificate

Primary School Certificate Middle School Certificate Illiterate

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13. Family Income / Month:

- \geq Rs 36017
 Rs 18000-36016
 Rs 13495-17999
 Rs 8989-13494
 Rs 5387-8988
 Rs 1803-5386
 \leq Rs 1802
 Don't Know

14. Socioeconomic Class:

- Upper
 Upper Middle
 Lower Middle
 Upper Lower
 Lower
 Not Sure

15. Marital Status:

- Single
 Married (Monogamous)
 Married (Polygamous)
 Divorce
 Living with a partner
 Widow/widower

16. Patient's cell phone:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

17. Patient's e-mail address:**18. If married, is it consanguineous (married to a blood-relation):**

- Yes
 No
 Unknown

19. Sleeping area:

- Sleeps alone
 Share a bedroom, but sleeps on separate beds
 Share a bed with someone
 Share a dwelling but have separate bedrooms
 Stays alone in a different residence

20. Living area:

- Rural
 Semi-urban
 Urban

21. Average distance from place of residence to the health facility (if attending a facility for epilepsy (Kilometer)**22. Means of transportation.....****23. Average cost of transportation (Rupees)****24. Does any family member have a history of seizures or epilepsy?**

- Yes
 No
 Unknown

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25. Water source:

Tap/pump Well Stream/river Pond Others

26. Waste management:

Water closet Pit latrine Bush nearby Bush farther away Others

27. Are you on health insurance:

Yes No Unknown

If female of reproductive age (Add the following information)

28. Age of Menarche _____

29. Last menstrual period ____/____/_____

30. Number of Pregnancy (ies) _____

31. Number of Miscarriage(s) _____

32. Number of live-birth(s) _____

33. History of Major Birth defects:

Yes No Not sure

34. Any child with epilepsy:

Yes No Unknown

If a Child/Minor (Add the following information)

35. Name of next of kin: _____

36. Relationship of next of kin completing questionnaire: _____

37. Primary Caretaker Cell Phone: _____

38. Consanguineous parents?

Yes No Unknown

39. Any other affected siblings with seizures?

Yes No Unknown

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40. Healthy siblings?

Yes No Unknown

If no, specify ill health _____

41. Birth history: Full-term Premature Post-term

42. Birth weight: Normal Low High Unknown

43. Was a Caesarian section done?

Yes No Unknown

44. Birth complications:

Yes No Unknown

If Yes (specify) _____

45. Is the child in school?

Yes No Unknown

If not in school give reason(s).....

46. What academic level is the child?

47. Are there any learning difficulties?

Yes No Unknown

48. Any other disability(ies)?

Yes No Unknown

If Yes (specify) _____

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Epilepsy Information

A. Natural history of the seizure disorder

1. Has the subject had any seizure in the last 5 years?

Yes No Unknown

2. Current Seizure Frequency:

Daily Weekly Monthly Biannual Annual Sporadic

Precipitating factors:

3. **Emotions?** Yes No Unknown

4. **Alcohol?** Yes No Unknown

5. **Sleep?** Yes No Unknown

6. **Lack of sleep?** Yes No Unknown

7. **Flashing lights?** Yes No Unknown

8. **Hyperventilation?** Yes No Unknown

9. **Menstruation?** Yes No Unknown

10. **Stopping the antiepileptic drugs?** Yes No Unknown

11. **Pregnancy?** Yes No Unknown

12. **Specify other precipitating factor(s) not listed.....**

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Blood Pressure: mmHg **Pulse:** beats/min

B. History of Seizures:

1. Duration of Seizures : Days Month Year

2. Type of Seizure

- Focal without impairment of consciousness
- Focal without impairment of consciousness
- Secondarily Generalized
- Generalized Tonic Clonic
- Other
- Unspecified
- Absence
- Myoclonic

3. Frequency of Seizures : _____

C. Any History of Fever/ Headache/ Other/ Focal Neurological deficit (Weakness of one side/ Numbness of one side/ Vision loss in one side:

D. Antecedent history

H/o febrile seizures in childhood: _____

Birth History: _____

Head Injury: _____

CNS Infections : _____

Family history of epilepsy: _____

E. Concomitant medication Yes No

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PREVIOUS MEDICAL HISTORY							
Is there any relevant medical history in the following systems?							
Code	System	*Yes	No	Code	System	*Yes	No
1	Cardiovascular			9	Neoplasia		
2	Respiratory			10	Neurological		
3	Hepato-biliary			11	Psychological		
4	Gastro-intestinal			12	Immunological		
5	Genito-urinary			13	Dermatological		
6	Endocrine			14	Allergies		
7	Haematological			15	Eyes, ear, nose, throat		
8	Musculo-skeletal			00	Other		

Screening Investigations

1. EEG

2. MRI Brain

3. CT Scan:

4. Neuropsychology

5. Other Investigations

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Final Diagnosis [To be filled by PI/Co PI (Neurologist)]

Seizure types:

1. _____
2. _____
3. _____
4. _____

Syndrome: _____

Aetiological Diagnosis: _____

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Previous Medications

Drug	Start date	Stop date	Maximum dose	Adverse effect	Seizure control

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End of Visit Checklist: to be completed by PI/Co-Investigator

		Yes		No
1	Does the subject satisfy the inclusion and exclusion criteria to date?			
2	Have all screening procedures been completed?			
3	Has the concomitant medication page been completed?			
4	Is the subject willing to proceed?			

Signatures	Full Name	Signature	Date
PI/Co-PI			
SRF			
Field worker			