

Appendix E

Research Data Forms

This appendix contains copies of the various forms used in our epilepsy infrared thermography project to collect data and perform ethical research. Here is a list of the blank forms that follow:

- *Informed Consent* – This informed consent form was approved by our human subjects research review committee and signed by all participants in the study.
- *Subject Information Form* – All personal information that could identify the participant as an individual was recorded on this form and kept in a separate location from the research data to protect privacy.
- *Background Information* – This form documented relevant background information including conditions that could contribute to anomalous abdominal thermographic features.
- *Epilepsy Signs and Symptoms* – This simple checklist helped us to learn more about premonitions, auras, and autonomic nervous system (ANS) symptoms that may be relevant to Cayce’s model of epilepsy.
- *Constipation Scoring System* – Some Cayce readings indicate that constipation and other large bowel processes can be relevant as a source of nerve reflexes in certain cases of epilepsy. We used this instrument so that we would not miss any relevant data in this area. No significant correlations with seizures or other symptoms were noted.
- *Physician’s Form* – This form was used to obtain diagnostic information about the epilepsy patients.
- *Authorization to Obtain Medical Information* – This is a standard release to obtain medical information. In our study it was used to establish diagnostic criteria.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Thermographic Anomalies in Epilepsy Patients. **SPONSOR:** Meridian Institute, Virginia Beach, VA

INVESTIGATORS: Eric A. Mein, M.D., David McMillin, M.A., Douglas G. Richards, Ph.D., Carl Nelson, D.C.

Abdominal symptoms that are common in epilepsy may be relevant to the cause and treatment of certain forms of the illness. The temperature patterns on the surface of your skin on the abdomen may reflect the activity of the nervous system in the abdomen. These patterns are called thermographic anomalies. We will use an infrared camera (a camera that takes pictures of temperature patterns) to compare temperature patterns on your abdomen with your epilepsy symptoms to determine whether temperature is related to the nervous system activity in epilepsy. You will be asked to provide medical records documenting the type and severity of epilepsy and will allow a picture to be taken of your abdomen with the heat-sensitive infrared camera. The pictures will only be of your abdomen, and you will not be identifiable. Your participation will involve one visit to Meridian Institute for a camera session, which will take approximately one hour. For children, the parent or guardian of the child will be present at all times.

There are no known side-effects associated with this type of thermographic assessment; it is simply a picture taken by a camera.

This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better understanding in the future of the possible role of thermographic anomalies in the cause and treatment of epilepsy.

You will be compensated with \$100.00 for participation in the study.

The results of this research may be presented at meetings or in publications. Your identity will be kept confidential and will not be disclosed in those presentations.

Your participation in this study is voluntary. You may decide to not participate in this study. If you do participate, you may freely withdraw from the study at any time.

Meridian Institute will not pay for medical treatment for any research-related injury or illness.

If you have questions about your rights as a research subject or about the research protocol, you may contact Eric Mein, M.D., whose phone number is 496-2651.

Consent:

I have read this consent form. I understand the information about this study. All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study.

By signing this consent form I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

Subject Name (printed)

Subject Signature

Date

Parent or Legal Guardian (Printed)

Signature of Parent or Legal Guardian

Date

Signature of Person Conducting Informed Consent Discussion

Date

Subject Information Form

Name: _____ Subject Number: _____

Address: _____

Phone: _____ Email: _____

Name of Parent or Guardian (if applicable): _____

Would you like to receive the Meridian Institute newsletter? Y or N

Abdominal Thermography Project

BACKGROUND INFORMATION

Subject Number: _____ Date: _____

Age: _____ Sex: M F

Height _____ Weight _____

Please check any digestive system diseases that you have had:

_____ Irritable Bowel Syndrome

_____ Appendicitis

_____ Ulcerative Colitis

_____ Cancer involving abdominal organs (specify: _____)

_____ Crohn's Disease

Please describe any other digestive system problems or symptoms that you have had:

Have you ever had abdominal or back surgery? _____ If yes, please describe: _____

Please list any other medical conditions that you have? _____

Number of childbirths and date of most recent: _____

EPILEPSY SPECIFIC ITEMS

Neurologist: _____

Have your seizures ever been triggered by eating certain foods or GI tract processes? _____

If yes, please describe: _____

What is the formal medical classification of your epilepsy? _____

Have you had surgery for your epilepsy? _____ If yes, describe: _____

How old were you when your epilepsy began? _____

What medications are you currently taking for epilepsy? _____

How long have you taken antiseizure medication? _____

How often do you experience seizures? _____

To what extent are your seizures controlled by medication?

No control

Some control

Total control

Explain: _____

What is the severity of your seizures?

NA

Mild

Moderate

Severe

Epilepsy Signs and Symptoms Questionnaire

Name: _____ Date: _____

PREMONITIONS

A *premonition* is an early indication that a seizure may occur later in the day, even several hours later. Check any of the following premonitions that you typically experience in advance of a seizure. If you do not currently experience seizures or premonitions due to treatment, check premonitions that you typically had in the past.

- A jerk of the body experienced in a drowsy state or when falling asleep (hypnic jerk)
- a feeling of depression or apathy
- irritability
- exultation or ecstasy
- headache
- intestinal upset (such as diarrhoea or constipation)
- Other (specify) _____

AURAS

An *aura* is can be thought of as a mini-seizure that precedes the full seizure, usually by only a few seconds. Whereas *premonitions* may last for a long time and occur well in advance of a seizure, *auras* are usually very brief and occur just as the seizure begins. Check any of the following *aura* phenomena that you experience. If you do not currently experience auras, try to remember typical auras that you have had in the past. Check all that apply.

- A feeling of fear or apprehension
- Nausea (feeling sick)
- Strong recollection of some event or place or even a formed image of some scene
- An sense of having experienced something before which is really being experienced for the first time ('déjà vu')
- A conviction that something static is moving
- Change in temperature (feeling of heat or cold)
- Feeling of tension
- Strange or powerful taste
- Powerful or peculiar odor
- Visual changes such as bright lights, zigzag lines, slowly spreading spots, or dark spots
- Hearing voices or sounds (auditory hallucinations)
- Feelings of numbness or tingling
- Feeling separated from one's body
- Feeling of extreme happiness or ecstasy
- Headache
- Irritability

- Restlessness
- Feeling of lethargy (sluggishness)
- Feeling of apathy
- Feeling of electricity running through the body
- Other _____

AUTONOMIC SIGNS AND SYMPTOMS DURING TYPICAL SEIZURE

Check any of the autonomic nervous symptoms that you experience during a typical seizure. If you do not currently experience seizures, try to remember typical seizures that you have had in the past. Check all that apply.

- Stomach pain
- Lower abdominal discomfort
- Rumbling sounds of gas moving in the intestines (borborygmi)
- Flatulence (intestinal gas)
- Nausea
- Feeling or sensation rising into the throat (epigastric rising)
- Belching
- Vomiting
- Pallor (lack of color, paleness)
- Flushing (skin becomes red due to increased circulation)
- Sweating
- Hair standing on end (piloerection)
- Dilation of the pupils
- Alterations in heart rate and respiration
- Urination
- Bowel movement
- Sexual arousal

Constipation Scoring System
(Agachan et al., 1996)

Subject Number: _____

Date: _____

Frequency of bowel movements

- 0 1-2 times per 1-2 days
- 1 2 times per week
- 2 Once per week
- 3 Less than once per week
- 4 Less than once per month

Difficulty: painful evacuation effort

- 0 Never
- 1 Rarely
- 2 Sometimes
- 3 Usually
- 4 Always

Completeness: feeling incomplete evacuation

- 0 Never
- 1 Rarely
- 2 Sometimes
- 3 Usually
- 4 Always

Pain: abdominal pain

- 0 Never
- 1 Rarely
- 2 Sometimes
- 3 Usually
- 4 Always

Time: minutes in lavatory per attempt

- 0 Less than 5
- 1 5-10
- 2 10-20
- 3 20-30
- 4 More than 30

Assistance: type of assistance

- 0 Without assistance
- 1 Stimulative laxatives
- 2 Digital assistance or enema

Failure: unsuccessful attempts for evacuation per 24 hours

- 0 Never
- 1 1-3
- 2 3-6
- 3 6-9
- 4 More than 9

History: duration of constipation (years)

- 1 0
- 2 1-5
- 3 5-10
- 4 10-20
- 5 More than 20

TOTAL SCORE: _____

(Minimum Score, 0; Maximum Score, 30)



Meridian Institute

Patient Name _____

Date _____

This patient is being considered for participation in a study exploring the usefulness of thermographic (temperature) imaging in the understanding of neurological conditions. The study does not involve any diagnosis, treatment, medication, or other intervention; it consists only of external temperature measurement with a thermographic camera.

We need some information to determine whether this patient meets our inclusion/exclusion criteria. Our study focuses on epilepsy of unknown causation (idiopathic). We will not be able to include participants with a history of head injury or other brain injury, or brain tumors. We would appreciate your answers to the following questions:

What is the medical classification of the condition (type of epilepsy) (check all that apply)?

Partial-onset seizures _____

simple partial seizures _____

complex partial seizures _____

secondarily generalized tonic-clonic seizures _____

Focal origin of the seizures (if known) _____

Generalized-onset seizures _____

absence seizures _____

tonic seizures _____

clonic seizures _____

myoclonic seizures _____

primary generalized tonic-clonic seizures _____

atonic seizures. _____

Other (describe) _____

Is there a history of head injury, brain injury, brain tumor, or other organic cause? _____

Other information (e.g., idiopathic with age-related onset, juvenile absence epilepsy, etc.)

If you would like a copy of the protocol for this study or have any questions,
call Eric Mein, M.D., at (757) 496-2651.

Physician's name (printed): _____

Signature _____ Medical specialty _____

Practice name, address, and phone _____

Authorization to Obtain Medical Information

Print patient's full name

Birth date (Mo/Day/Yr)

Street Address

Social Security number

City, state, zip code

Phone (home) include area code

I, _____, authorize _____

to release medical records relating to my **epilepsy diagnosis**.

Information released to: Eric Mein, M.D.
Meridian Institute
1853 Old Donation Parkway
Virginia Beach, VA 23454

Purpose of disclosure: Epilepsy Research Project

I _____ authorize disclosure of health information on the above named patient. This authorization is valid for 6 months from the date signed. I understand I can revoke this authorization with written notification, but that it will not affect any information previously released prior to the notice of cancellation.

Signature of individual or guardian

Date

Expiration date, not to exceed 6 months