Research Project: Persons with ME/CFS: An Examination of Health Issues and Relationships with Social Institutions in Australia

PARTICIPANT INFORMATION STATEMENT
PHASE III
FIRST CALL FOR EXPRESSIONS OF INTEREST

5 January 2010

Dear Potential Participant

Re: Research Project: Persons with ME/CFS: An Examination of Health Issues and Relationships with Social Institutions in Australia

My name is Geoffrey Hallmann. I am a ME/CFS researcher at the Southern Cross University in Lismore, New South Wales. I am currently recruiting potential participants for Phase III of my research, which is now due to get underway in approximately May/June 2010.

In previous notices the advice was that the study would enter Phase III around December 2009. Phase I and II are now being coded and the questionnaire for Phase III is being constructed.

The following will outline the background of the study, its objectives and interview process, along with your rights and obligations.

Background
This study forms part of a PhD thesis being conducted by Mr. Geoffrey Hallmann under the supervision or Dr. Rosanne Coutts and Dr. Yvonne Hartman has been approved by the Human Research Ethics Committee at Southern Cross University. The approval number is ECN-08-146.

Participation
To participate in this study it is necessary for you to have a current or past diagnosis by a doctor of:

- Chronic Fatigue Syndrome (CFS)
- Myalgic Encephalomyelitis (ME)
- Myalgic Encephalopathy
- Post Viral Syndrome (PVS)
- Post Viral Fatigue Syndrome (PVFS)
- Post Infectious Fatigue Syndrome (PIFS)
- ME/CFS
- Chronic Mononucleosis

In addition to satisfying the above, you will also have the ability to read and speak English and you will satisfy the three major definitions of ME/CFS used here in Australia ***(please refer to the attached appendix)***.

Objectives of the Study

It is envisaged that this research will lead to an improved understanding of the impact of the condition to assist a variety of people and social institutions that have dealings with the ME/CFS here in Australia. The conclusions and findings Phases I and II of this project will be used to construct a questionnaire for Phase III to be distributed to ME/CFS participants throughout Australia and made available via the Website, Survey Monkey (www.surveymonkey.com.au).

Outline of the Research

This phase of the study will be conducted in the mid 2010 via a Participant Questionnaire. The Questionnaire will be constructed from the data collected during interviews in Phase I and II of the research. The participants in these phases were sourced (due to restrictions of cost) from throughout the eastern seaboard of Australia.

In order to get a geographic representation of Australia and verify the research Phase III will include the entire continent – city and country alike.

The Questionnaire will be available in three formats. The first and most preferable will be via a website call Survey Monkey. Once the questionnaire is finalised it will be posted on the site and all participants will be notified and invited to complete. For those who cannot use the site, a second format and third format will be provided. The second format will be the same questionnaire delivered via Email and the third will be delivered by (snail) mail. The latter two are for those participants who want to be a part of the research but simply cannot or do not have access to the Internet, or who are unable to endure the time required on the Internet site.

Given the nature of ME/CFS, particularly with respect to the fatigue, pain, cognitive and memory features that can occur, there will be an appropriate time period allowed to complete the instrument.

A *Consent Form* will be provided in phase III to obtain your agreement to participate in the study. For those using the website, this will appear at the front, whereas those receiving it via Email/Mail will have to fill out a hard copy and return.

The *Consent Form* is your agreement to be involved in the study, however you are free to withdraw at any time if you so desire. All information provided would be treated as anonymous and strictly confidential. Participation in the study will not necessarily benefit you directly.

Possible Discomforts and Risks

Given the nature of the condition, the process of data collection may cause distress or exacerbate the symptoms of your condition. If during any stage of the research you believe that the data collection process is causing you distress or exacerbating the symptoms of the condition, inform me and the process will stop the session immediately.

Conversely, if I believe that you appear to be in distress or the process is exacerbating your symptoms, I will terminate the interview in order to protect your health. If either event occurs, you will be referred to your treating General Practitioner for investigation and treatment if required.

Where an interview is terminated early, we can come back to the session at a later date if you wish to continue.

Time Commitment of Participants

Data Collection: You will be required to participate in a questionnaire that may take around 30 minutes to 90 minutes to complete.

Responsibilities of the Researcher

The security and confidentiality of all data that is collected will be of the highest priority. As data is collected it will be stored securely by Mr. Geoffrey Hallmann at Southern Cross University. Once all the research data has been collected it will be appropriately analysed. The results of the information analysis will be de-identified, documented and used as part of a PhD dissertation and may also be published in appropriate scientific literature. At no stage will your participation in the research be identified in any published material or documentation.

An opportunity for you to provide either a postal or email address in order for you to receive the results of this research immediately follows the consent section of this form. Additionally, if you wish to discuss the results further, access to the researchers will be arranged in order for you to do so.

Freedom of Consent

Participation in this study is voluntary. Non-participation will not result in any adverse consequences. You are free to withdraw consent and discontinue participation in this study at any time without adverse consequence. During the interview, you may refuse to answer any question, stop the questionnaire and withdraw at any time.

Confidentiality

All data, Emails and other notes will be numerically coded and if names are necessary, a pseudonym will be used. Quotations will be attributed to a pseudonym.

Documents and data will be kept at the University in locked cabinets with all identifying information such as name and address removed. Online data will be secured and kept confidential within the website. After completion of the study data files will be securely stored for 7 years. After that time all files will be shredded.

Enquiries/Complaints

The ethical aspects of this study have been approved by the Southern Cross University Human Research Ethics Committee. The approval number is ECN-08-146. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Ethics of your participation in this research, you may contact the Committee through the Ethics Complaint Officer:

Ms. Sue Kelly
Secretary & Ethics Complaints Officer
HREC
Southern Cross University
PO Box 157
Lismore NSW 2480
Telephone (02) 6620 9139
Facsimile (02) 6626 9145
Email: skelly@scu.edu.au).

All complaints, in the first instance, should be in writing to the above address. All complaints are investigated fully and according to due to process under the National Statement on Ethical Conduct in Research involving Humans and the University. Any complaint you make will be treated in confidence and you will be informed of the outcome.

We sincerely thank you for your time and greatly appreciate the effort and commitment of in participating in this study. It is only with your efforts and cooperation that valuable research such as this is able to be conducted.

Please contact the writer in the meantime if you wish any clarification of any aspect of this letter.

Yours sincerely

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Appendix A – Criteria

Definition and Criteria

To participate in this research you must satisfy all of the following three criteria:

Criteria 1 - Ramsay defines the clinical identity of Myalgic Encephalomyelitis as:

(1) a unique form of muscle fatigability whereby, even after a minor degree of physical effort, three, four or five days, or longer, elapse before full muscle power is restored;

(2) variability and fluctuation of both symptoms and physical findings in the course of a day; and

(3) an alarming tendency to become chronic (Ramsay 1988).

Criteria 2 - Fukuda *et al.* 1994 define Chronic Fatigue Syndrome as:

In a patient with severe fatigue that persists or relapses for 6 months (Fukuda *et al*. 1994).

Major Criteria - Fatigue is sufficiently severe: of new or definite onset (not lifelong), not substantially alleviated by rest, and results in substantial reduction in previous levels of occupational, educational, social or personal activities; and

Clinically evaluated, unexplained, persistent or relapsing chronic fatigue that is
1) of new or definite onset (has not been lifelong);
2) is not the result of ongoing exertion;
3) is not substantially alleviated by rest; and
4) results in substantial reduction in previous levels of occupational, educational, social, or personal activities;

AND

Minor Criteria: The concurrent occurrence of four or more of the following symptoms, all of which must have persisted or recurred during six or more consecutive months of illness and must not have predated the fatigue:

(1) Self-reported impairment in short-term memory or concentration severe enough to cause substantial reduction in previous levels of occupational, educational, social, or personal activities

(2) Sore throat

(3) Tender cervical or axillary lymph nodes

(4) Muscle pain,

(5) Multijoint pain without joint swelling or redness

(6) Headaches of a new type, pattern, or severity

(7) Unrefreshing sleep

(8) Postexertional malaise lasting more than 24 hours

The Fukuda Definition excludes the following from a diagnosis of Chronic Fatigue Syndrome:

(1) Active medical condition that may explain the chronic fatigue, such as untreated hypothyroidism, sleep apnoea, narcolepsy;

(2) Previously diagnosed medical conditions that have not fully resolved, such as previously treated malignancies or unresolved cases of hepatitis B or C virus infection;

(3) Any past or current major depressive disorder with psychotic or melancholic features, including bipolar affective disorders, schizophrenia, delusional disorders, dementias, anorexia nervosa, or bulimia nervosa;

(4) Alcohol or other substance abuse within two years before the onset of chronic fatigue and at any time afterward. (Komaroff & Buchwald 1998)

Criteria 3 - Carruthers et al, 2003 defines ME/CFS as:

1. Fatigue (physical and mental)
- unexplained
- persistent
- new/definite onset ; or
- recurrent
- results in substantial reduction in previous activity levels
-

AND

2. Post-exertional malaise/fatigue
- inappropriate loss of physical and mental stamina
- rapid muscular and cognitive fatigability
- post exertional malaise; and/or
- pain and a tendency for other associated symptoms to worsen
- recovery period of > 24 hours

AND

3. Sleep dysfunction
- unrefreshing sleep and/or
- sleep quantity or rhythm disturbances
- a small number of people may not suffer sleep dysfunction but CFS/ME is the only diagnosis that fits

AND

4. Pain
- a significant degree of myalgia.
- may be experienced in muscles and/or joints
- may be migratory in nature
- may be significant headaches of new type, pattern or severity

- a small number of people may not suffer pain but CFS/ME is the only diagnosis that fits

AND

5. Two or more of the following neurological/cognitive manifestations:
- confusion
- impairment of concentration and short-term memory consolidation
- disorientation
- difficulty with information processing, categorising and word retrieval
- perceptual and sensory disturbances e.g. spatial instability, disorientation and inability to focus vision
- Ataxia, muscle weakness and fasciculations are common.
- Overload phenomena may occur leading to 'crash' periods and/or anxiety – cognitive, emotional, and/or sensory e.g. photophobia, noise hypersensitivity.

AND

6. At least 1 symptom from 2 of the following categories:

A. Autonomic dysfunction
- Orthostatic intolerance – neurally mediated hypotension, postural orthostatic tachycardia syndrome, delayed postural hypotension
- Light-headedness, extreme pallor
- Nausea and irritable bowel syndrome
- Urinary frequency and bladder dysfunction
- Palpitations with or without cardiac arrhythmias
- Exertional dyspnoea.

B. Neuroendocrine manifestations
- Heat/cold intolerance
- Marked weight change – anorexia or abnormal appetite
- Loss of adaptability and worsening of symptoms with stress.

C. Immune manifestations
- Tender lymph nodes, recurrent sore throat, recurrent flu-like symptoms
- General malaise
- New sensitivities to food, medications and/or chemicals.

AND

7. Chronic duration
- Symptoms persisting for at least 6 months. Preliminary diagnosis may be possible earlier. Three months is appropriate for children. It usually has a distinct onset (although it may be gradual).

AND

8. Exclusion of active disease processes that explain most of the symptoms.

- Idiopathic chronic fatigue: If the patient has unexplained prolonged fatigue (6 months or more), but has insufficient symptoms to meet the criteria for ME/CFS, it should be classified as idiopathic chronic fatigue.