Protocol Review Number:_____
(Assigned by IRB)

University of the Pacific
Institutional Review Board
Existing Data Research Review Form

Project Information	
Investigator Name:	J. Mark VanNess, Ph.D.
E-Mail:	mvanness@pacific.edu
College/School:	COP
Department:	HESP
If Student, Name of Advisor:	
Advisor Dept:	
Advisor email:	
Other Thesis/Dissertation Committee Members:	
If Student, Expected Graduation Date:	
Project Title:	Collection and Analysis of Clinical Data from Fatigue Clinic Patients
Date CITI training was completed:	Data will be accessed by: Todd Davenport – CITI on file with IRB Lily Chu – CITI cert is attached Christopher Snell – CITI cert is attached Mark VanNess – CITI on file with IRB Christopher Chuang – CITI cert is attached Jared Stevens – CITI cert is attached
Review category & number: See pg. 24 in the IRB Manual* *If your research does not fit Exempt 4 or Expedited 8, stop completing this application and complete the "Human Subjects Activity Review Form"	Exempt 4
When do you plan to begin this study (date/year)?	Maty, 2017
What is the expected duration of the study?	Ongoing
Has this project been reviewed by any other IRB? If yes, stop completing this application and contact the IRB administrator to determine whether a Cooperative Agreement is possible.	No
Project Support	
☐Funded x☐ xUnfunded	If funded, list source:
Does any conflict of interest exist between the funding source and the investigator? ☐ Yes x ☐ xNo (refer to Conflict of Interest Policy)	If yes, describe:
Investigator Status (Check one)	
X Student x☐ xFaculty ☐Administrator ☐Other_____	

Investigator Signature and Certification:
In submitting this proposed project and signing below, I certify that:

1) I have read and understand the Investigator's Manual on Research with Human Subjects;
2) I will conduct the research involving human subjects as presented in the protocol and approved by the unit, faculty supervisor (if a student project), and IRB;
3) I will present any proposed modifications in the research to the IRB for review prior to implementation;
4) All conflicts of interest between myself and any funding agencies have been resolved to the satisfaction of the University of the Pacific Office of Sponsored Programs, and,
5) I will report to the IRB any problems to subjects.

Signed: _____ Date: 5-2-17

Faculty Supervisor Review (if researcher is a student): My signature verifies that:

1) I will supervise this student's research project, and
2) The research complies with federal and University policies regarding protection of human subjects.

Approval: _____ Date: _____

Unit Review: The signature below verifies that the project:

1) Has been reviewed by the unit, and
2) Complies with federal and University regulations for research with human subjects.

Approval: _____ Date: 5/2/17

Name: Courtney Jensen

Unit reviewer may be: department chair, college dean, or a member of the Institutional Review Board (IRB) within the researcher's department. Human Subject Research training is required for all unit reviewers.

INVESTIGATOR: Please provide answers to all of the following questions (attach additional pages as needed).

I. Determining Review Category

A.) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102[d]).

Does your study fit the federal definition of research?

x☐x Yes ☐No

B.) Is the source publicly available? "Publicly available" means that the general public can obtain the data/biological specimens. Sources are not considered "publicly available" if access is limited to researchers.

☐ Yes x☐xNo

C.) How are data/biological specimens identified when they are made available to the investigator/study team?

1. Direct Identifiers (subject name, address, social security number, entire medical record, etc.)	☐ Yes	x☐x No
2. Coded (a key or code exists that can link individuals to the information)	☐ Yes	x☐x No
3. No Identifier (the researcher is unable to individually identify a subject based upon information provided with the data/biological specimens)	x☐ xYes	☐ No

D.) How are data/biological specimens maintained by the investigator/study team?

4. Direct Identifiers (Individuals will be identifiable throughout the study and analysis, but *not* in the reporting of results.)	☐ Yes	x☐x No
5. Coded (the information will be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects)	☐ Yes	x☐x No
6. No Identifier (If a code or key exists which links individuals to data/specimens, the investigator/study team is restricted from obtaining this key.)	x☐x Yes	☐ No

II. Objectives and Data Maintenance

A.) Briefly describe the purpose and objective of the project and attach a copy of the research protocol and any other study related materials (data collection forms, etc.).

Extensive data regarding fatigue in patients with Myalgic Encephalomyelitis (ME) are collected by the Workwell Foundation. The information they collect and the tests they do with the patients are for the purpose of gaining physical capability information for insurance and disability evaluation.

The current objective of this research project is to use the information on these patients to examine the pathophysiology of ME.

All personal information for the patients will be removed from the data before we gain access to it. Only coded identifiers will be used to organize the data once it is received.

None of the investigators will utilize the data until is has been blinded by removing all personal identifying information.

B.) What is (are) the type(s) of data or specimens?

Cardiopulmonary exercise testing results – oxygen consumption, pulmonary ventilation, heart rate and blood pressure data

Data from open-ended questionnaire (attached)

C.) Were the data/biological specimens originally collected solely for research purposes?

x☐x No
☐ Yes

D.) What is the source of the existing or archived data/biological specimens (be specific: e.g. medical records, specimen bank, etc.)?

Data will come from patients referred to the Workwell Foundation for disability evaluation. The data will be blinded by the technician and provided to me via email. Only blinded data will be used from the patients.

E.) Will any data or biological specimen(s) be collected directly from subjects after submission of this application?

xx☐ No
☐ **Yes***

* Activities requiring direct interaction with subjects require a separate review of data which has yet to be collected. Complete the "Human Subjects Activity Review Form"

F.) Attach the CITI completion report for the protection of human subject research training. Training is required of all personnel involved in data collection/analysis and is valid for three years. Visit https://www.citiprogram.org/ to complete training.

Completion Date 02-Feb-2017
Expiration Date 02-Feb-2018
Record ID 22128153
This is to certify that:
Lily Chu
Has completed the following CITI Program course:
Human Subjects Research - BASIC (Curriculum Group)
Human Subjects Research – Biomedical Basic (Course Learner Group)
1 - Independent Learner (Stage)
Under requirements set by:
Independent Learner
Verify at www.citiprogram.org/verify/?w3a9246b3-ed40-4518-b5e9-6554b39f8962-22128153

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*
* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details.
See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.
• Name: Christopher Snell (ID: 6137750)
• Institution Affiliation: University of the Pacific (ID: 2800)
• Institution Email: csnell@pacific.edu
• Institution Unit: Health, Exercise & Sport Sciences
• Curriculum Group: Biomedical Research - Basic/Refresher
• Course Learner Group: Same as Curriculum Group
• Stage: Stage 1 - Basic Course
• Description: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.
• Record ID: 22214630
• Completion Date: 04-Feb-2017
• Expiration Date: 04-Feb-2020
• Minimum Passing: 80
• Reported Score*: 88
REQUIRED AND ELECTIVE MODULES ONLY DATE
COMPLETED SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080) 03-Feb-2017 3/3
(100%)
Avoiding Group Harms - International Research Perspectives (ID: 14081) 04-Feb-2017 3/3
(100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
(ID: 14777)
04-Feb-2017 5/5
(100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680) 04-Feb-2017 5/5
(100%)
Belmont Report and CITI Course Introduction (ID: 1127) 04-Feb-2017 3/3
(100%)
Cultural Competence in Research (ID: 15166) 04-Feb-2017 5/5
(100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2) 04-Feb-2017 5/5
(100%)
Informed Consent (ID: 3) 04-Feb-2017 4/5 (80%)
History and Ethics of Human Subjects Research (ID: 498) 04-Feb-2017 7/7
(100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4) 04-Feb-2017 4/4

(100%)
Records-Based Research (ID: 5) 04-Feb-2017 2/3 (67%)
Genetic Research in Human Populations (ID: 6) 04-Feb-2017 4/5 (80%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8) 04-Feb-2017 4/4
(100%)
Vulnerable Subjects - Research Involving Children (ID: 9) 04-Feb-2017 2/3 (67%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10) 04-Feb-2017 2/3 (67%)
FDA-Regulated Research (ID: 12) 04-Feb-2017 5/5
(100%)
Research and HIPAA Privacy Protections (ID: 14) 04-Feb-2017 3/5 (60%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483) 04-Feb-2017 4/4
(100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488) 04-Feb-2017 2/5 (40%)
For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.
Verify at: www.citiprogram.org/verify/?kf8757c9c-5547-41e4-a553-9c70f3d587d4-

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*
* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details.
See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

• Name: Christopher Chuang (ID: 6150709)

• Institution Affiliation: University of the Pacific (ID: 2800)
• Institution Email: osp@pacific.edu
• Institution Unit: School of Engineering and Computer Science
• Phone: 2099462285
• Curriculum Group: Biomedical Research - Basic/Refresher
• Course Learner Group: Same as Curriculum Group
• Stage: Stage 1 - Basic Course
• Description: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.
• Record ID: 22260162
• Completion Date: 19-Feb-2017
• Expiration Date: 19-Feb-2020
• Minimum Passing: 80
• Reported Score*: 83

REQUIRED AND ELECTIVE MODULES ONLY DATE
COMPLETED SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080) 08-Feb-2017 3/3
(100%)
Avoiding Group Harms - International Research Perspectives (ID: 14081) 19-Feb-2017 3/3
(100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
(ID: 14777)
19-Feb-2017 5/5
(100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680) 19-Feb-2017 5/5
(100%)
Belmont Report and CITI Course Introduction (ID: 1127) 19-Feb-2017 3/3
(100%)
Cultural Competence in Research (ID: 15166) 19-Feb-2017 5/5
(100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2) 19-Feb-2017 5/5
(100%)
Informed Consent (ID: 3) 19-Feb-2017 5/5
(100%)
History and Ethics of Human Subjects Research (ID: 498) 19-Feb-2017 7/7
(100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4) 19-Feb-2017 4/4
(100%)
Records-Based Research (ID: 5) 19-Feb-2017 3/3
(100%)
Genetic Research in Human Populations (ID: 6) 19-Feb-2017 5/5
(100%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8) 19-Feb-2017 4/4

(100%)
Vulnerable Subjects - Research Involving Children (ID: 9) 19-Feb-2017 3/3
(100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10) 19-Feb-2017 3/3
(100%)
FDA-Regulated Research (ID: 12) 19-Feb-2017 2/5 (40%)
Research and HIPAA Privacy Protections (ID: 14) 19-Feb-2017 0/5 (0%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483) 19-Feb-2017 2/4 (50%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488) 19-Feb-2017 1/5 (20%)
For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.
Verify at: www.citiprogram.org/verify/?k69404435-8766-47ab-a968-6f7431557b93-22260162
Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*
* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details.
See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

• Name: Jared Stevens (ID: 5280660)

• Email: jstevens12@une.edu
• Institution Affiliation: University of New England (ID: 824)
• Institution Unit: MPH online
• Curriculum Group: Human Research
• Course Learner Group: Social & Behavioral Research Investigators
• Stage: Stage 1 - Basic Course
• Report ID: 18309677
• Completion Date: 27-Jan-2016
• Expiration Date: 26-Jan-2020
• Minimum Passing: 80
• Reported Score*: 86

REQUIRED AND ELECTIVE MODULES ONLY DATE COMPLETED SCORE
Belmont Report and CITI Course Introduction (ID: 1127) 09-Jan-2016 3/3 (100%)
History and Ethical Principles - SBE (ID: 490) 09-Jan-2016 5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491) 09-Jan-2016 4/5 (80%)
The Federal Regulations - SBE (ID: 502) 10-Jan-2016 5/5 (100%)
Assessing Risk - SBE (ID: 503) 24-Jan-2016 4/5 (80%)
Informed Consent - SBE (ID: 504) 24-Jan-2016 4/5 (80%)
Privacy and Confidentiality - SBE (ID: 505) 25-Jan-2016 5/5 (100%)
Research with Prisoners - SBE (ID: 506) 25-Jan-2016 4/5 (80%)
Research with Children - SBE (ID: 507) 26-Jan-2016 4/5 (80%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508) 26-Jan-2016 4/5 (80%)
International Research - SBE (ID: 509) 26-Jan-2016 4/5 (80%)
Internet-Based Research - SBE (ID: 510) 26-Jan-2016 4/5 (80%)
Research and HIPAA Privacy Protections (ID: 14) 27-Jan-2016 4/5 (80%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483) 27-Jan-2016 4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488) 27-Jan-2016 4/5 (80%)
University of New England (ID: 1542) 27-Jan-2016 No Quiz
For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.
Verify at: https://www.citiprogram.org/verify/?80224d25-136e-413a-84c0-689f99341d2d
CITI Program
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

Exercise Recovery Questions

NAME:_____ Date of Exercise Test:_____

_____

1. How did you feel following the exercise test?

_____

_____

_____

2. Describe how you felt the next day.

_____

_____

_____

3. How long did it take you to recover from the exercise test?

One day or less 1 to 2 days 2 to 3 days 3 to 5 days

longer than 5 days

Comments:_____

_____

4. Describe symptoms, if any, experienced after the exercise test.

_____

_____

_____

Please return to Dr. VanNess' office on **Visit 5**, 7 days after the exercise challenge

Existing Data Research

Determining if research involves human subjects:

1. Is information individually identifiable (the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?
   x☐x No ☐ Yes

   If yes, is information private (information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, for example, a medical record)?
   ☐Yes*☐No **

*IRB review and approval is needed, complete this form
** This research does not include "human subjects" according to the federal definition. Do not complete this form.

What this category includes:

- Research involving **existing** data of human subjects ("existing" means existing before the research is proposed to your advisor or the IRB to determine whether the research is exempt.)

- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
  - Example of research invovling materials to be collected for nonresearch purposes: routine patient information recorded for treatment which will simultaneously be included in research data collection for a specific research question.

What this category excludes:

- Data that has yet to be collected from human subjects through direct interaction (i.e. surveys, interviews, interventions). This research must use the *Human Subject Activity Review Form* for IRB review available on the Human Subjects website.

To-Do prior to application submission:

☐ Human subject research training is required. Go to CITI's online course to complete and attach the certificate to the application. Training is required every three years.

☐Obtain all signatures
- a Unit Reviewer is required. This must be a Chair, Dean or IRB member in your department. Unit reviews must also have Human Subjects Research training.
- Advisors signature is required if the research is a student

It is preferred that applications be signed, scanned as PDF documents, and submitted by e-mail to the IRB Administrator.

Questions: email Office of Research and Sponsored Programs at, osp@pacific.edu or call 209-946-7716.