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OFFICE OF INSTITUTIONAL COMPLIANCE
Institutional Review Board

INSTITUTIONAL REVIEW BOARD
NOTICE OF REVIEW DECISION

TO: Professors Kristen Sethares, Elizabeth Chin, & Paul Fortier

FROM: Andrew Karberg, Director of Institutional Compliance

RE: New Study Approval – Expedited Category # 4, 5, 6 ,& 7 – "The Effect of Mobile Self-Monitoring on Self-Care Behaviors in Heart Failure and COPD Patients"

IRB # 14.011

DATE: March 10, 2014

FWA: 00000180

In accordance with Federal Regulations for review of research protocols, the Institutional Review Board has reviewed the above referenced protocol and found that it met approval under an Expedited category for the following period of time: **March 10, 2014 – March 9, 2015**

On March 6, 2014, the full IRB approved the wireless monitor / sensor for oxygen saturation and EKG measurements as a non-significant risk device.

Expedited category of approval:
___**(1)** Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review). (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

___**(2)** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children2, considering

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the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

___**(3)** Prospective collection of biological specimens for research purposes by Non-invasive means. Examples:

(a) hair and nail clippings in a non-disfiguring manner;
(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
(c) permanent teeth if routine patient care indicates a need for extraction;
(d) excreta and external secretions (including sweat);
(e) uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
(f) placenta removed at delivery;
(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the Process is accomplished in accordance with accepted prophylactic techniques;
(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
(j) sputum collected after saline mist nebulization.

_X__**(4)** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples:

(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
(b) weighing or testing sensory acuity;
(c) magnetic resonance imaging;
(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

_X__(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt).

__X_(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

__X_(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt).

_X___ Please use the attached approved informed consent – written consent required.

____You have been granted Waiver of Documentation of Consent
According to 45 CFR 46.117 and/or 21 CFR 56.109(c)(1), an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

___ The research presents no more than minimal risk

AND

___ The research involves procedures that do not require written consent when performed outside of a research setting 45 CFR 46.117, 21 CFR 56.109(c)(1).

<OR>

___ The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research,

AND

___ The consent document is the only record linking the subject with the research

AND

___This study is not FDA regulated (45 CFR 46.117)

AND

___Each participant will be asked whether the participant wishes documentation linking the participant with the research, and the participant's wishes will govern.

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____ You have been granted Waiver of Informed Consent
According to 45 CFR 46.116(d), an IRB may waive or alter some or all of the requirements for Informed consent if:

___ The research presents no more than minimal risk to subjects;
___ The waiver will not adversely affect the rights and welfare of subjects;
___ The research could not practicably be carried out without the waiver; and
___ Whenever appropriate, the subjects will be provided with additional pertinent information they have participated in the study.
___ This study is not FDA regulated (45 CFR 46.117)

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR FOR ONGOING PROTOCOLS:

(1) Report **immediately** to the IRB any unanticipated problems.

(2) Proposed changes in approved research during the period for which IRB approval cannot be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the participant. Changes in approved research initiated without IRB review and approval initiated to eliminate apparent immediate hazards to the participant must be promptly reported to the IRB, and reviewed under the unanticipated problems policy to determine whether the change was consistent with ensuring the participants continued welfare.

(3) Report any significant findings that become known in the course of the research that might affect the willingness of subjects to continue to take part.

(4) Insure that only persons formally approved by the IRB enroll subjects.

(5) Use **only** a currently approved consent form (remember approval periods are for 12 months or less).

(6) **Protect the confidentiality of all persons and personally identifiable data, and train your staff and collaborators on policies and procedures for ensuring the privacy and confidentiality of participants and information.**

(7) Submit for review and approval by the IRB all modifications to the protocol or consent form(s) prior to the implementation of the change.

(8) Submit a Continuing Review Report for continuing review by the IRB. Federal regulations require IRB review of on-going projects no less than once a year. It is the responsibility of the PI to submit the Continuing Review Report before the expiration

period.

(9) Notify the IRB when the study has been completed and complete the Final Report Form.

(10) Please help us help you by including the above protocol number on all future correspondence relating to this protocol.

Thank you for your help in this matter.

Sincerely,

Andrew Karberg
Director, Office of Institutional Compliance & Ethics

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CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

You are being asked to participate in a research study. This form provides you with information about the study. The Principal Investigators (Kristen Sethares or Elizabeth Chin) will provide you with a copy of this form to keep for your reference, and will also describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part. Your participation is entirely voluntary and you can refuse to participate without penalty or loss of benefits to which you are otherwise entitled.

Title: **The effect of mobile self-monitoring on self-care behaviors in heart failure and COPD patients**

Principal Investigator: Kristen Sethares PhD, RN, CNE
Co-Investigators: Paul Fortier PhD, Elizabeth Chin PhD, RN

Funding source: University of Massachusetts Dartmouth Provost seed Funding Grant

Invitation
You are invited to take part in a research study. We are asking you to take part because you are aged 50-95 and have a medical history of heart failure or COPD.

Purpose of Research
The purpose of this study is to study ways to improve symptom recognition and self care management in people with heart failure or COPD. Improving these skills will help patients stay well and avoid hospitalizations.

Your Rights
It is important for you to know that taking part in the study is voluntary.
You may decide not to take part or decide to quit the study at any time.
This will not change the quality of the care you receive.

Procedures
If you agree to be in this study it will involve filling out questionnaires by cell phone about your activity level and symptoms three times a week for one-month. You will also be asked to complete a memory test and depression scale once at the beginning of the study, and a self-care behavior questionnaire at the beginning and end of the study. Some participants will be asked to wear a sensor device that will transfer data about their heart rate, blood pressure, oxygenation status and activity level to a cell phone device and central data console so that the patients and the researchers can monitor any changes in your health status.

RISKS
There is minimal risk to you if you do take part. There is the chance that you may have a skin reaction to the sensor adhesive. If a reaction does occur from the sensor adhesive during the study you will be advised to remove the sensor and call your health care provider. Electronic data cannot be fully secured. However we have taken reasonable measures to ensure the security of your data. When transmitted, your data will be encrypted. The encrypted data will be stored on university secured servers. It will be password protected. The servers are secured and maintained according to university computing policies

BENEFITS
There is a possible benefit that being in this study may improve your knowledge and confidence in performing self care management of your heart failure or COPD.

ALTERNATIVES
The alternative is not to take part in the study. This will not affect your care.

COMPENSATION
You will be given a $25.00 gift card for taking part in the study.

CONFIDENTIALITY
Your privacy is important to us. Your confidentiality will be maintained to the degree permitted by the technology used. All data will be stored in a password protected electronic format. You will be assigned a code number when you enter the study and your name will not appear on any data forms. Only the principal investigator, Kristen Sethares, will have a list of participants and code numbers on a sheet kept in a locked file cabinet in a locked office. Any data collected in this study and the master list of participants will also be kept in a locked file cabinet in a locked office, and destroyed after 3 years. Code names will be used in any transcribed documents. Information from this study will only be used for research purposes, including publication in professional journals, research presentations and consultation with other members of the research team. Future analysis of this research data might be done at a later time. If in the unlikely event it becomes necessary for the University of Massachusetts Dartmouth Institutional Review Board to review your research records, then The University of Massachusetts Dartmouth will protect the confidentiality of those records to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate you with it, or with your participation in any study. If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

An exception to sharing information will be made only in cases when the researcher believes your physical or mental health is at risk. In this circumstance the Cardiac Rehabilitation Director, Joyce Grusmark, will be notified and she will follow up with the appropriate person.

QUESTIONS

Before you sign this consent form, please ask any questions you have about the study or your rights as a research subject. If you have questions later, you can call Kristen Sethares, the primary researcher. Tele: 508-999-9148.

If at any time you would like to discuss the study or your research rights with someone who is not part of the research study, you may contact Andrew Karlberg Director of Research Compliance ATMC 151 Marine Street Fall River, MA 508-910-9880.

You will be given a copy of this form to keep for your records.

CONSENT TO PARTICIPATE IN THE RESEARCH PROJECT

Subject's Name:_____

I understand the purpose and procedures of this research project. I also understand the risks, and benefits that might result from participation in the study. I have been told that unexpected events may occur. I had a chance to discuss the risks and benefits of this research with the researcher. All of my questions have been answered. I agree to take part as a volunteer in this research project. I understand that I may quit at any time. I have been given a copy of this consent form.

_____ Date: _____

Subject's signature

STATEMENT OF PERSON OBTAINING CONSENT

I, the undersigned, have fully explained the details of this clinical study as described in the consent form to the subject named above.

_____ Date: _____

Signature of person obtaining consent

INVESTIGATOR'S DECLARATION

As the principal investigator or co-investigator on this project, I attest to the following:

- the nature and purpose of the project and project procedures, as well as the foreseeable risks, discomforts and benefits have been explained to the above-named subject
- the participant has been given the opportunity to ask questions and to have those questions answered by knowledgeable research staff
- the participant meets the inclusion/exclusion criteria for this project

_____ _____

PI Signature Date