OFFICE OF RESEARCH SUPPORT

THE UNIVERSITY OF TEXAS AT AUSTIN

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FWA # 00002030

Date: **04/15/10**

PI(s): **Christine L Julien**
Seth M Holloway

Department & Mail Code: **Cockrell School of Engineering**
ELECT & COMPUTER ENGR

Title: **Testing the Usability of the SEAP Pervasive Computing Middleware**

IRB APPROVAL – IRB Protocol # **2010-02-0052**

Dear: **Christine L Julien Seth M Holloway**

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: **03/11/2010 - 03/10/2011** . *(expires 12am [midnight] of this date.)*

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 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.

☐ **(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.

☐ **(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).

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

☒ **(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).

☒ **Please use the attached approved informed consent**

☐ **You have been granted Waiver of Documentation of Consent**
According to 45 CFR 46.117, 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
<**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 participants wishes will govern.

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** (a Continuing Review Report form and a reminder letter will be sent to you 2 months before your expiration date). Please note however, that if you do not receive a reminder from this office about your upcoming continuing review, it is the primary responsibility of the PI not to exceed the expiration date in collection of any information. Finally, 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.

Sincerely,

Jody L. Jensen, Ph.D.
Professor
Chair, Institutional Review Board