



# CERTAS: A Researcher Configurable Self-Monitoring System

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## Abbreviated Abstract

The research plan for this Phase II contract extends our work on a researcher configurable electronic self-monitoring system called CERTAS which provides the functionality for researchers to create questionnaires and scheduled alerts which were then synced to Palm device to deliver the self-monitoring protocol to subjects, record responses, and upload the data for analysis. For Phase II, we plan to fully develop the remote capacities of CERTAS by providing for wireless Palm syncing of data and support for wireless digital phones as well. The resulting system will be evaluated by cancer control researchers. Two subsequent trials with monitoring subjects will test the usability and validity of the wireless CERTAS system and compare the recording compliance and cost benefits of local and wireless synced Palm monitoring compared to paper-based monitoring.

## Primary Investigator

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## Research Team & Affiliations

Mr. Jatinder Singh is a Senior Programmer at PICS and was the lead developer for this project. He received a B.S. in Mechanical Engineering from the University of Maryland.

## Total Budget

\$749,314

## Research Objectives

AIMS

- 1) Develop the capabilities to deliver the CERTAS system on wireless PDA's and JAVA-compatible, digital wireless phones.
- 2) Develop the participant management and data management features of the system.
- 3) Develop a website allowing researchers to access public domain standardized assessment tools used by cancer control researchers.
- 4) Evaluate the system by a) obtaining feedback on the CERTAS system from cancer control and prevention researchers; b) assessing usability and concurrent validity in a small trial (n = 51) using the CERTAS



system delivered on cell phones and wireless PDA's; and c) assessing compliance and cost in a trial (n = 206) comparing the CERTAS system delivered on locally synced and wirelessly synced PDA's to a simulated paper condition.

## Theory/Hypothesis

We hypothesized that our evaluation would determine that our system results in a) questionnaire data showing high concurrent validity and high system usability (Trial 1: n = 50), b) greater recording compliance and lower cost compared to a paper based delivery system (Trial 2: n = 200).

## Experimental Design

**Trial 1:** 51 subjects assigned to various cancer risk factor protocols and randomly assigned to the Cell phone or the Treo delivery device condition.

**Trial 2:** 206 subjects randomly assigned to the locally synced PDA, wirelessly synced PDA, or the simulated paper based condition.

## Final Sample Size & Study Demographics

- 1) Cancer Control Researchers (n = 37): 62% Female, 38% Male; 16% Asian, 8% African-American, 76% White; 100% Non-Hispanic.
- 2) Trial (n = 51): 75% Female, 25% Male; Mean Age – 52 years (sd – 14 years); 28% Single, 57% Married, 12% Divorced, 4% Widowed; 61% Employed full or part time, 39% Unemployed or retired; 16% H.S. Degree, 45% Associates or Bachelors Degree, 37% Graduate Degree; 4% Asian, 10% African-American, 86% White; 86% Non-Hispanic, 6% Hispanic, 8% Unreported ethnicity.
- 3) Trial (n = 206): 72% Female, 28% Male; Mean Age – 51 years (sd – 14 years); 64% Single, 22% Married, 10% Divorced, 2% Cohabiting, 2% Widowed; 61% Employed full or part time, 11% Homemaker, 3% Student, 25% Unemployed or retired; 16% H.S. Degree or less, 44% Associates or Bachelors Degree, 39% Graduate Degree; 5% Hispanic, 6% Asian, 10% African-American, 79% White Non-Hispanic.

## Data Collection Methods

**Trial 1:** Subjects completed CERTAS questionnaires administered via cell phones or via Treo devices for 2 weeks. One live phone call to assess concurrent validity of questionnaire responses was completed during the 2 week period. Subject usability was assessed at the 2 week point.

**Trial 2:** Subjects completed CERTAS questionnaires administered via a) locally (condition 1) or b) wirelessly synced (condition 2) devices over a 4 week period. Subjects in condition 3 completed the questionnaire data using a simulated paper diary. Subject usability was assessed at the 4 week point.

## Outcome Measures

**Trial 1:** Recording compliance rates, agreement rates, usability ratings.

**Trial 2:** Recording compliance rates, cost comparisons between conditions.



## Evaluation Methods

Descriptive analyses, ANOVA, Cost computations

## Research Results

**Trial 1:** Subjects in both device conditions provided high usability ratings. Additionally, agreement ratings averaged 85% for all of the protocol conditions when comparing questionnaire responses given using the devices to questionnaire responses given during a live phone interview.

**Trial 2:** Compliance rates were significantly higher for the two CERTAS conditions compared to the paper-based condition and cost analyses computed using the modified cost of the devices indicated that the costs of using the CERTAS program on either a locally synced device or a wirelessly synced device are significantly lower than the costs associated with paper-based recording.

## Barriers & Solutions

N/A

## Product(s) Developed from This Research

CERTAS