

AD_____

Award Number: W81XWH-04-C-0083

TITLE: Internet-Based Cervical Cytology Screening System

PRINCIPAL INVESTIGATOR: David C. Wilbur, M.D.
Barbara A. Crothers, D.O.
John H. Eichhorn, M.D.
Min S. Ro, M.D.
Jeffrey A. Gelfand, M.D.

CONTRACTING ORGANIZATION: Massachusetts General Hospital
Boston, Massachusetts 02114

REPORT DATE: April 2007

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-04-2007		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 15 Mar 2006 – 14 Mar 2007	
4. TITLE AND SUBTITLE Internet-Based Cervical Cytology Screening System				5a. CONTRACT NUMBER W81XWH-04-C-0083	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) David C. Wilbur, M.D.; Barbara A. Crothers, D.O.; John H. Eichhorn, M.D., et al. E-Mail: dwilbur@partners.org				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Massachusetts General Hospital Boston, Massachusetts 02114				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This project explores the combination of computerized automated primary screening of cervical cytology specimens in remote sites with interpretation of device-selected images transmitted via the Internet. The project is in 3 phases: 1) hardware/software and interface development and end user training with 200 case pilot study; 2) a 500 case prospective pilot study with hardware/software adjustment, with the development of clinically applicable specimen triage and management guidelines; and 3) a 5000 case prospective clinical trial of the completed system, with report and development of a training and operation manual. During this report period, the Army Office of Research Protection approved the phase 2 protocols for WRAMC (8/3/06) and Massachusetts General Hospital (2/12/2007), and patient accrual has begun at the WRAMC site and will shortly begin at the MGH site. At present no further data analysis, phase 3 preplanning, or further publications development have been initiated. During this study period an assurance for the phase 3 study in Korea has been arranged through Tripler Army Medical Center.					
15. SUBJECT TERMS telecytology, cytopathology, telemedicine, cancer screening, health care information systems, cervical cancer					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	19	19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	5
Key Research Accomplishments.....	8
Reportable Outcomes.....	9
Conclusion.....	10
References.....	None
Appendices.....	11

Introduction

Cervical cancer is theoretically completely preventable by effective screening using cervical cytology methods (the Pap test). The process of preparing and interpreting Pap tests remains one of the last high-volume manual processes in the clinical laboratory. Recent technological advances in specimen preparation and computerized primary screening make automated approaches to cervical cancer screening possible. In addition, advances in information technology have facilitated the Internet transmission and archival storage of digital images and other clinical information. The combination of automated preparation and screening of cervical cytology specimens, with Internet transmission of selected images, and remote interpretation and reporting of results has not been previously attempted.

This project develops a highly automated cervical cytology screening system, a software interface capable of transmitting and presenting images to remote reading stations, with facility for immediate results reporting back to the specimen source. Clinical studies utilizing this developed system will be performed to test accuracy and functionality against the current on-site manual screening process. Primary development of the system has been accomplished at the Massachusetts General Hospital (MGH) site and reading stations have been installed at MGH and at Walter Reed Army Medical Center (WRAMC). A phase 1 pilot study has been completed, data has been analyzed and reported. A phase 2 study of 500 prospectively obtained, consented patients is currently underway following a very lengthy delay due to US Army IRB oversight approval processes (Office of Research Protections) that were pending at the last annual report and have been finally approved during the time of this report (WRAMC – 8/3/06, and MGH – 2/12/07). Patients are being accrued at WRAMC (approximately 100 patients have been enrolled at the time of this report) and the accrual process is planned to begin within the next month at the MGH site. A phase 3 clinical trial is planned and a submission to the US Army Office of Research Protections is currently being prepared as the investigators have received advice from that office that the Phase 3 protocol may be reviewed prior to completion of Phase 2. Planned Phase 3 clinical sites are the 121st Army Hospital in Seoul, Korea and MGH.

Body

The following is a summation of the work completed to the present time based on the project's accepted Statement of Work. Details follow below in an expanded version of the Statement of Work:

Statement of Work

Task 1: Complete hardware, software and network development required for testing of the internet-based cervical cytology screening system

- a) Modify the FocalPoint device to accept, process and analyze ThinPrep specimens - **completed**
- b) Adapt FocalPoint hardware for internet transmission of digital images from ThinPrep and SurePath specimens - **completed**
- c) Adapt commercial software (Wellogic) to permit rapid and secure transmission of digital images to remote review stations - **completed**
- d) Procure and install remote microscopy stations (2) - **completed**
- e) Adapt commercial software/hardware (Wellogic) to allow secure, automated reporting of cervical cancer screening results - **completed**
- f) Adapt commercial software (Wellogic) to integrate screening results reporting with medical decision support system - **Phase 2 pretrial modifications have been made.**
- g) perform initial testing of integrated hardware/software/network - **completed**

Task 2: Develop morphology and terminology for digital images and perform pilot clinical trial

- a) Develop a set of learning cases with known diagnostic outcome - **pilot set of 200 cases completed (100 SurePath, 100 ThinPrep).**
- b) Develop morphologic criteria for accuracy of interpretation - **Phase 1 completed, pending Phase 2 modifications.**

- c) Develop reporting terminology appropriate for case management - **Phase 1 completed, pending Phase 2 modifications.**
- d) Develop medical decision support algorithms - **Phase 1 completed, pending Phase 2 modifications.**
- e) Perform pilot trial using a set of 500 unknown specimens to identify preliminary system performance characteristics - **This is a Phase 2 task. Local IRB approval for Phase 2 was received for MGH on 8/26/2004 (reapproved on 8/16/2005), and tentative approval following second level review for WRAMC on 4/26/2005. US Army oversight IRB (Office of Research Protections) protocol review was submitted on 5/16/2005. Request for revisions from ORP was received on 1/3/2006, and a resubmission was returned on 2/20/2006. WRAMC approval was granted by ORP on 8/3/06 and MGH approval was granted on 2/12/07. Patient accrual is now progressing at WRAMC and will begin by 5/1/07 at MGH.**
- f) Modify procedures/equipment based on pilot trial results - **Phase 2 modifications completed.**
- g) Develop training methods/materials for clinical practice - **Phase 2 modifications completed.**

Task 3: Complete large, prospective clinical trial of the performance of the internet-based system compared to conventional on-site screening.

- a) Develop and receive approval for clinical trial protocol and consent forms -**Phase 3 protocols are being prepared for submission to ORP. Based on advice from that office, the Phase 3 protocols can be submitted prior to completion of Phase 2.**
- b) Install equipment at selected sites - **future**
- c) Train clinical personnel participating at selected sites - **future**
- d) Conduct the clinical trial - **future**
- e) Perform trial data analysis - **future**
- f) Prepare report of trial with implementation recommendation - **future**

Expanded Discussion

A) Phase 1 of the project has been completed. This Phase included:

- 1) development of hardware, software, and interfaces between computerized scanning device and Internet-linked servers and reading stations.
- 2) development of a 200 case test set of slides with known reference diagnosis (100 SurePath and 100 ThinPrep slides)
- 3) analysis of the test set on the prototype system with interpretation by 6 individuals (3 cytotechnologists, 3 pathologists)
- 4) data analysis
- 5) reporting of the data in 3 abstracts presented at the US-Canadian Academy of Pathology Annual meeting (February 2006)
- 6) development of training materials to guide and improve performance
- 7) submission of revisions/improvements to software

Comments: Phase 1 showed a successful first feasibility trial of this system. 191 cases were included in the analysis (SP-101, TP-90; 99-NILM, 4-ASC-US, 3-ASC-H, 4-AGC, 63-LSIL, 18-HSIL). ≥ 3 reviewers agreed on the correct general categorization for unsatisfactory/normal in 87%, and for abnormal in 83%. For specific Bethesda interpretation, ≥ 3 reviewers agreed on the correct categorizations as follows: ASC-US - 75%, ASC-H - 100%, AGC - 25%, LSIL - 83%, HSIL - 94%. These results indicate that correct triage of abnormal cases could be performed at a sensitivity very comparable to the manual screening standard. In addition it was noted during the data analysis/training phase, that a substantial number of the "missed" cases had to do with experience of the observers in identifying clues present in the review station images or with institutional "biases," meaning differences in interpretations that could be traced to practice setting differences between MGH and WRAMC.

B) Initiation of Phase 2 of the project has been significantly delayed

- 1) Local IRB approvals were granted for Phase 2 at MGH and WRAMC
- 2) US Army "oversight" IRB (Office of Research Protections - ORP) required review submitted - 5/17/2005.
- 3) ORP requested revisions - 1/3/2006
- 4) Revisions submitted to ORP - 2/20/2006
- 5) ORP final approval for WRAMC was granted on 8/3/07. (see attached)
- 6) ORP final approval for MGH was granted on 2/12/07. (see attached)
- 7) Wellogic software modification have been made and the system is ready to receive Phase 2 patient inputs.

Comments: This IRB "oversight" process has significantly delayed the project. At the time of ORP submission, the timeline for completion of Phase 2 showed a final date in the Fall of 2005, with Phase 3 initiation before the end of 2005. At present, Phase 2 patient accrual is underway and should be completed by Fall of 2007. At the time of this report, patient accrual at WRAMC is approximately 100 of the 250 total patients anticipated, and patient accrual at MGH is about to begin.

C) Phase 3 changes since the last Annual Report

- 1) Investigators received advice from ORP that a Phase 3 protocol could be submitted for review prior to completion of Phase 2. The Phase 3 protocol is being prepared at the time of this report.
- 2) An assurance was obtained for research to be performed at the 121st Army Hospital in Seoul, Korea via the Tripler Army Medical Center. (See attached email verification)

Key Research Accomplishments

- 1) IRB (Office of Research Protections) submissions approved
- 2) Investigators met at WRAMC to review the criteria for specimen interpretation which was necessary based on the long delay since Phase 1 completion.
- 3) Assurance obtained for Phase 3 oversight at 121st Army Hospital via Tripler.
- 4) Patient accrual has begun at WRAMC.
- 5) Patient accrual will begin within 1 month at MGH.
- 6) Modifications have been completed for the reading station software (Wellogic) based on outcomes of Phase 1.

Reportable Outcomes

1) Final publication of pilot study publication.

Eichhorn JH, Gelfand JA, Brauns TA, Crothers B, Wilbur DC. A Novel Automated Screening and Interpretation Process for Cervical Cytology Using Internet Transmission of Low Resolution Images: A Pilot Study. Cancer (Cancer Cytopathol) 2005;105:199-206

2) Publication in preparation for Phase 1 results.

Conclusions

- 1) System development is has changed only marginally since last report. Modifications to the Wellogic reading station software have been accomplished
- 2) IRB (ORP) issues have significantly delayed progress, but approvals have now been granted for both Phase 2 sites and patient accruals are underway.
- 3) Assurance has been obtained for 121st Army Hospital in Seoul, Korea via Tripler.
- 4) System installation at Phase 3 clinical sites is postponed as per the requirements of ORP.

Attachments

- 1) Memorandum for the Record – Approval of WRAMC Phase 2 Protocol (8/3/06)
- 2) Memorandum for the Record – Approval of MGH Phase 2 Protocol (2/12/07)
- 3) Copy of Email from James Phillips to David Wilbur dated 3/1/2007 indicating IRB services have been applied to Korea Phase 3 work via Tripler Army Medical Center
- 4) Accepted Amendment of Solicitation/Modification of Contract dated 3/12/06 indicating a revised budget and no-cost extension of contract.

3 Aug 2006

MEMORANDUM FOR THE RECORD

SUBJECT: Protocol, "The Internet Based Cervical Cytology Screening Research Program ("Telepaps") – Phase II," Submitted by COL Barbara A. Crothers, MC, Walter Reed Army Medical Center, Washington, D.C., Proposal Log Number PR033199, Award Number W81XWH-04-C-0083, HSRRB Log Number A-12412.2b

1. The final revised protocol, informed consent form, and supportive documents received 29 June 2006, 24 July 2006 and 01 August 2006 for the referenced study to be conducted at the Walter Reed Army Medical Center (WRAMC), Washington, D.C., have been reviewed and found to comply with applicable Federal, DoD, U.S. Army and U.S. Army Medical Research and Materiel Command (USAMRMC) human subjects protection regulations. Documentation of approval by the WRAMC Department of Clinical Investigations (DCI) Human Use Committee (HUC) was received on 29 June 2006.

2. This no greater than minimal risk study is approved for implementation for the enrollment of up to 250 subjects at the WRAMC site. This is a multi-center research study.

3. Please note the following reporting obligations:

a. Any modifications to the subject protocol must be submitted to the Office of Research Protections (ORP), with the WRAMC DCI HUC approval documentation, prior to implementation. Such amendments to the protocol must be granted US Army Medical Research and Materiel Command (USAMRMC) Human Subjects Research Review Board (HSRRB) approval prior to implementation.

b. All unanticipated problems involving risks to subjects or others, serious adverse events related to study participation, and deaths must be reported promptly to the USAMRMC Office of Research Protections (ORP).

c. Any deviation to the subject protocol that affects the safety of the subject and/or integrity of the study data must be reported promptly to the ORP.

d. All modifications, deviations, unanticipated problems, adverse events and deaths must also be reported at the time of continuing review of the protocol.

e. A copy of the continuing review report approved by the WRAMC DCI HUC should be submitted to the ORP as soon as possible after receipt of approval. Records indicate that the referenced study was initially approved with revisions by the Clinical Investigation Committee (CIC) on 5 April 2005 and at the HUC meeting on 26 April 2005. The revised study documents were reviewed and approved by the HUC on 23 May 2006. It appears that the next continuing review will be due in April 2007.

f. In addition, a copy of the current version of the protocol and consent form (if applicable) should be submitted along with the continuing review report and the copy of the WRAMC DCI HUC approval notice for continuation of the protocol.

g. When available, a copy of the final study report submitted to the WRAMC DCI HUC, including a copy of the local IRB letter and any supporting documents, must be submitted to the ORP.

4. Further information regarding the award/grant/cooperative agreement can be obtained by calling the USAMRAA Contract Specialist, Ms. Monica Pileggi at 301-619-2268.

5. Further information regarding technical oversight can be obtained by calling Dr. James Phillips, CDMRP, at 301-619-7522.

6. The ORP point of contact for this study is Melanie Oringer, R.N., Human Subjects Protection Scientist, at 301-619-6766.

CARYN L. DUCHESNEAU, CIP

Vice Chair, Human Subjects

Research Review Board

Note: The official copy of this approval is housed with the protocol file at the Office of Research Protections, 504 Scott Street, Fort Detrick, MD, 21072. Signed copies will be provided upon request.

Note: Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer or Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MD 21702-5012



REPLY TO
ATTENTION OF

MCMR-ZB-P

12 Feb 2007

MEMORANDUM FOR THE RECORD

SUBJECT: Protocol, "Internet-Based Cervical Cytology Screening Program (Phase 2)," in Support of the Proposal, "Internet-Based Cervical Cancer Screening System," Submitted by David C. Wilbur, M.D., Massachusetts General Hospital, Boston, Massachusetts, Proposal Log Number PR033199, Award Number W81XWH-04-C-0083, HRPO Log Number A-12412.2a

1. The final revised protocol, informed consent form, and supportive documents received 1 November 2006 and 1 February 2007 for the referenced study to be conducted at the Massachusetts General Hospital (MGH), Boston, Massachusetts, have been reviewed and found to comply with applicable Federal, DOD, U.S. Army, and U.S. Army Medical Research and Materiel Command (USAMRMC) human subjects protection regulations. Documentation of approval of the amended documents by the PARTNERS Human Research Committee was received on 6 February 2007.
2. This no greater than minimal risk, multi-center research study is approved for implementation for the enrollment of up to 250 subjects at the Massachusetts General Hospital site.
3. Please note the following reporting obligations:
 - a. Major modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the USAMRMC Office of Research Protections (ORP), Human Research Protections Office (HRPO) for approval prior to implementation. All other amendments are to be submitted with the continuing review report to the USAMRMC ORP HRPO for acceptance.
 - b. All unanticipated problems involving risks to subjects or others, serious adverse events, and deaths must be reported promptly to the ORP/HRPO/HSRRB.
 - c. Any deviation to the subject protocol that affects the safety of the subject and/or integrity of the study data must be reported promptly to the ORP/HRPO/HSRRB.
 - d. All modifications, deviations, unanticipated problems, adverse events, and deaths must also be reported at the time of continuing review of the protocol.

SUBJECT: Amendment and Continuing Review for the Protocol, "Understanding Breast Cancer Risk Assessment and Screening Behavior Among the Underserved," Project 1 of Consortium Proposal, "Tailored Communication to Enhance Adaptation Across the Breast Cancer Spectrum," Submitted by Suzanne M. Miller, Ph.D., Fox Chase Cancer Center, Proposal Log Number BC004061, Award Number DAMD17-01-1-0238, HRPO Log Number A-10788.1

MCMR-ZB-P

SUBJECT: Protocol, "Internet-Based Cervical Cytology Screening Program (Phase 2)," in Support of the Proposal, "Internet-Based Cervical Cancer Screening System," Submitted by David C. Wilbur, M.D., Massachusetts General Hospital, Boston, Massachusetts, Proposal Log Number PR033199, Award Number W81XWH-04-C-0083, HRPO Log Number A-12412.2a

- e. A copy of the next continuing review report approved by the PARTNERS Human Research Committee should be submitted to the HRPO within 30 days after receipt of approval. It appears that the next continuing review for this study is due no later than 21 August 2007. In addition, a copy of the current version of the protocol and consent form should be submitted along with the continuing review report and the copy of the PARTNERS Human Research Committee approval documentation for continuation of the protocol.
- f. When available, the final study report a copy of the final study report submitted to the PARTNERS Human Research Committee, including a copy of the local IRB letter and any supporting documents, must be submitted to the HRPO.
4. Further information regarding the award/grant/cooperative agreement can be obtained by calling the U.S. Army Medical Research Acquisition Activity (USAMRAA) Contract Specialist, Ms. Monica Pileggi at 301-619-2268.
5. Further information regarding technical oversight can be obtained by calling Dr. James Phillips, Congressionally Directed Medical Research Program (CDMRP), at 301-619-7522.
6. The ORP point of contact for this study is Melanie Oringer, R.N., Human Subjects Protection Scientist, at 301-619-6766.
7. NOTE: Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer or Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.

E-Signed by LAURA R. BROSCH
EDIRV authentication with approval

LAURA R. BROSCH, Ph.D.
Colonel, Army Nurse Corps
Deputy, Office of Research Protections
U.S. Army Medical Research and Materiel
Command

Wilbur, David C., M.D.

From: Phillips, James B Dr USAMRMC [james.phillips19@us.army.mil]
Sent: Thursday, March 01, 2007 8:36 AM
To: Wilbur, David C., M.D.
Cc: Stanley, Amber L Ms AZIMUTH
Subject: RE: Human Subject Recruitment PR033199 Tripler 10K

Dr. Wilbur,

Thanks for your response. Also, we sent the \$10,000 to Tripler Army Medical Center (TAMC) for IRB services to cover the work in Korea (MIPR no. MIPR7EDATM7061). You might want to contact the group in Korea and let them know.

Best regards,

Jb Phillips

-----Original Message-----

From: Wilbur, David C., M.D. [mailto:DWILBUR@PARTNERS.ORG]
Sent: Thursday, March 01, 2007 7:50 AM
To: Stanley, Amber L Ms AZIMUTH
Subject: RE: Human Subject Recruitment PR033199

see answers below. D. Wilbur

-----Original Message-----

From: Stanley, Amber L Ms AZIMUTH [mailto:Amber.Stanley@amedd.army.mil]
Sent: Thursday, March 01, 2007 7:26 AM
To: Wilbur, David C., M.D.; mlsmith@partners.org
Cc: Phillips, James B Dr USAMRMC
Subject: Human Subject Recruitment PR033199

Dr Wilbur,

I am working with Dr. Jay Phillips, the grants/contract manager for PRMRP. This email requires a response concerning recruitment efforts on your Human Subjects Study. Please supply the following information as soon as possible:

- 1) The total number of your projected enrollment - 250 at Mass General, 250 at Walter Reed (phase 2); 5000 total (phase 3)
- 2) Your recruitment numbers to date - 100 (all at Walter Reed), 0 at Mass General
- 3) A description of any barriers you are encountering that is harboring recruitment efforts - it has taken over 1 year to get ORP approval for phase 2 - which was finally granted at Walter Reed last Nov, and just granted 2 weeks ago at Mass General. The enrollment process is underway at Walter Reed and we are beginning the enrollment process at present at Mass General
- 4) If you are encountering recruitment difficulties, what solutions are you using to overcome them - as above
- 5) Confirm in what phase (I or II for example) is your clinical trial.
- phase
2

Your quick response is most appreciated. Deadline for this information will be at close of business March 5, 2007.

Sincerely

Amber Stanley

Azimuth Inc, Contractor
Grants Coordinator
Congressionally Directed Medical Research Programs US Army Medical
Research and Materiel Command
1077 Patchel Street
Fort Detrick, Maryland 21702
Fax: 301-619-7796

The information transmitted in this electronic communication is intended only for the person or entity to whom it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of or taking of any action in reliance upon this information by persons or entities other than the intended recipient is prohibited. If you received this information in error, please contact the Compliance Helpline at 800-856-1983 and properly dispose of this information.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE S		PAGE OF PAGES 1 2	
2. AMENDMENT/MODIFICATION NO.		3. EFFECTIVE DATE		4. REQUISITION/PURCHASE REQ. NO.		5. PROJECT NO. (If applicable)	
P00002		12-Mar-2006					
6. ISSUED BY CODE		W81XWH		7. ADMINISTERED BY (If other than item 6) CODE		W81XWH	
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014		USA MED RESEARCH ACQ ACTIVITY ATTN: MONICA PILEGGI 301-619-2268 MONICA.PILEGGI FORT DETRICK MD 21702					
8. (State and Zip Code)				9A. AMENDMENT OF SOLICITATION NO.			
THE GENERAL HOSPITAL CORPORATION MARCIA L SMITH DBA MASS GENERAL HOSPITAL RESEARCH MANAGEMENT 50 STANIFORD ST, 10TH FLOOR S50-10 BOSTON MA 02114				9B. DATED (SEE ITEM 11)			
				10A. MOD. OF CONTRACT/ORDER NO. W81XWH-04-C-0083			
				10B. DATED (SEE ITEM 13)			
				15-Mar-2004			
CODE OULU5		FACILITY CODE		11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS			
The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer is extended. is not extended. ☐ Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: ☐ (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.							
12. ACCOUNTING AND APPROPRIATION DATA (If required)							
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.							
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.							
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.							
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).							
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:							
☒ D. OTHER (Specify type of modification and authority) Mutual Agreement and request dtd 2/9/2007							
E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return ☐ copies to the issuing office.							
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: pileggim072699							
Title: Internet-Based Cervical Cancer Screening System Period of Performance: 15 March 2004 through 14 May 2008 (Research ends 14 December 2007). This modification is issued to incorporate a revised budget (personnel) and no-cost extension, per request via letters dated 2 November 2006 and 9 February 2007 and approved by the GOR on 26 February 2007.							
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A as amended, terms and conditions of the contract, and the contract.							
15A. NAME AND TITLE OF SIGNER (Type or print)				16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)			
				PAMELA L. FISHER / CONTRACTING OFFICER			
				TEL: 301-619-2805 EMAIL: pamelal.fisher@us.army.mil			
15B. CONTRACTOR/OFFEROR		15C. DATE SIGNED		16B. UNITED STATES OF AMERICA		16C. DATE SIGNED	
(Signature of person authorized to sign)				BY 		12-Mar-2007	

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
PART 48 OF 52 243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The CLIN extended description has changed from:

Research Title: Internet-Based Cervical Cancer Screening System

Period of Performance: 15 March 2004 through 14 August 2007 (Research ends 14 March 2007)

To:

Research Title: Internet-Based Cervical Cancer Screening System

Period of Performance: 15 March 2004 through 14 December 2007 (Research ends 14 May 2008).

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
POP 15-MAR-2004 TO 14-AUG-2007	N/A	USA MED RESEARCH AND MATERIEL COM JUDY PAWLUS COMMANDER USAMRMC ATTN: MCMR-RMI-S BLDG 504XX FORT DETRICK MD 21702 FOB: Destination	FORM9

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
POP 15-MAR-2004 TO 14-MAY-2008	N/A	USA MED RESEARCH AND MATERIEL COM JUDY PAWLUS COMMANDER USAMRMC ATTN: MCMR-RMI-S BLDG 504XX FORT DETRICK MD 21702 FOB: Destination	FORM9

(End of Summary of Changes)