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TITLE: Integrative Cardiac Health Project (ICHP)

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14. ABSTRACT
The Integrative Cardiac Health Project (ICHP) aims to lead the way in Cardiovascular Disease (CVD) Prevention by conducting novel research utilizing a Systems Biology / personalized medicine design to discover and develop practical, effective and preemptive integrative approaches in order to detect and combat CVD earlier before it affects the quality of life. ICHP's ultimate goal is to translate our evidenced-based research findings for application into clinical practice. A translational research approach will provide the ability to find novel disease markers, optimal prevention and holistic treatment approaches, and a unique venue for future research as the "virtual laboratory" for optimal comprehensive health prevention in the military beneficiary population. This research method also allows us to further hypothesize and define relationships between CVD, other cardio metabolic disease states and maladaptive behavior patterns unique to service members such as pre-diabetes, stress, overweight and sleep disorders with the aim of targeting these disorders in a pre-clinical phase. Using an integrative, interdisciplinary preventive health approach, ICHP has shown that an individual's cluster of CV risk factors can be effectively targeted and improved.

15. SUBJECT TERMS
Lifestyle; Cardiovascular Disease (CVD); Prevention; Behavior Modification; Genomics; Metabolic Syndrome; PreDiabetes; Diabetes; Obesity; Stress; Sleep; CVD Risk Reduction

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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The Integrative Cardiac Health Project (ICHP) is congressionally mandated and recognized by the Joint Capabilities Board (JROCM 047-17) supporting the Cardiovascular Care Initial Capabilities Document for Cardiovascular Care on 26 May 2017. Its mission is to "*Develop a multicomponent and personalized lifestyle management model for comprehensive and optimal cardiovascular and overall health, specific for military and applicable to the general population" and to "Identify precise strategies for early detection, monitoring and reduction of preclinical/clinical disease" to improve Force Health and optimize delivery of the Quadruple Aim"*

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Cardiovascular (CV) disease; lifestyle medicine; prevention; CV risk; pre-clinical disease; precision medicine; nutrition, activity, stress, sleep; prediabetes; behavior modification; metabolic syndrome, coronary heart disease

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

Study 1A, 1B and 1C: Cardiovascular Health Program (CHP), a lifestyle management intervention (LMI) specifically designed for the military population (1A/1C – new effort; 1B continuing effort):

Specific Aims:

1) To evaluate and enhance the benefits of patient-centric tools for comprehensive CVD risk assessment and reduction in the context of longitudinal outcomes.
2) To evaluate and enhance the ICHP CHP LMIs to improve patient-centric CVD risk reduction in the context of longitudinal outcomes.
3) To analyze self-management behaviors (nutrition, exercise, stress and sleep) that make the military population more vulnerable to CVD due to hazardous occupational exposure.
4) To improve traditional and nontraditional measures of cardiovascular health utilizing the ICHP CHP lifestyle management intervention in subpopulations (i.e. Caucasians vs. Non-Caucasians)
5) To capture patient generated data, including data (motivation, joys, barriers and self-efficacy) not routinely captured in MTF electronic health records to facilitate patient and family engagement to optimize outcomes.

Study 1A: Cardiovascular Health Program (CHP) Study ***(addresses Specific Aims 1, 2, & 4)*** *– This is the Companion Protocol to CHP Registry (Study 1B) per PACM Audit/WRNMMC IO recommendations.*

Study Milestone	Timeline (Months)	% Completed
Submission of protocol to WRNMMC IRB.	20	100%
WRNMMC IRB approval of protocol.	20	100%

HRPO acknowledgement of protocol.	21	0%
CRADA signed.	20	50%
Other necessary agreements as appropriate completed (i.e. DSA).	24-30	25%
Met enrollment predictions of 55 subjects per treatment group per quarter.	20-36	0%
Program Milestones (prior to new protocol submission)		
Patients maintain active participation in the ICHP CHP Registry after enrollment (% = # active patients/# total enrolled during report period of performance)	1-36	100%
100% pre-clinical states identified at ICHP appointments reported to patient's PCP for tracking and follow-up	12-36	100%
Administrative and Clinical ICHP portals in RIMS connected with interfacing capability	6-12	100%
Quality Assurance process in place for trans clinical team review and chart documentation	12-36	100%
ICHP translational research successfully incorporated family history into prediction tools and identified patients at" high risk" for heart attack and stroke who were otherwise told they were" low risk"	12-36	100%
100% dissemination of comprehensive CV health report to providers at baseline, 6 months and 1 year	1-60	100%
Distribute Healthy Living Toolkits to CHP participants (150), WRNMMC Cardiology & Integrated Health Program (50) and Executive Leadership (50)	Annually	100%
Deliver 1 new Healthy Living Cookbook	24	60%
Develop 1 new clinical decision support tool for providers	36	100%
Deliver 1 new portable stress management (Tension Tamer) tool	24-36	80%
Develop ICHP Healthy Lifestyle Index	24-36	100%
Website development/implementation plan finalized	35-36	80%

Study 1B/D: Cardiovascular Health Program (CHP Registry (addresses Specific Aims 3 & 5); includes sub protocol to CHP Registry for data analysis only ("Measuring Effects of Behavioral Changes on Biological Outcomes for Health Readiness"):

Study Milestone	**Timeline (Months)**	**% Completed**
WRNMMC IRB approval of protocol modification.	20	100%
HRPO acknowledgement of protocol modification.	21	100%
CRADA signed for Registry protocol.	20	95%
Other necessary agreements as appropriate completed (i.e. DSA).	24-30	50%
Development of sub protocol for data analysis of registry data (new requirement by WRNMMC DRP).	28-30	100%
Submission/approval of data analysis protocol.	30	90%
Signed agreements for sub protocol as appropriate.	30	0%
Met enrollment predictions of 35 subjects per quarter. *(% = # actual prospectively enrolled/cumulative quarterly projected enrollment during award period of performance)*	4-36	Unable to report a % due to halting enrollment
Comparative analyses of CHP LMI outcomes performed	Annually	100%
Findings disseminated to sponsor, staff, data safety monitor, SAB and scientific communities through required reports, abstract, manuscript submissions	Annually	100%
Development and completion of data dictionary	12-24	100%
All ICHP patient generated data migrated to RIMS	6-12	100%

Completed IMS structured team appointments in domains of nutrition, exercise, stress and sleep	12-36	100%
Clinical decision support tools to capture patient family history and incorporate into CVD risk scoring systems built electronically	19-60	50%
Patient healthy lifestyle optimization impact factor score built	19-60	100%
Migration of IMS to new hosting site complete	22-28	50%
All data reviewed and quality checks completed	Quarterly	100%
Interim data analysis performed	Annually	100%
New phenotype of CVD risk profile identified	24-36	40%
Manuscript published	24-36	80%

Study 1C: ICHP Biorepository (specific aim is addressed under Study #4-Specific Aim 6).

Study Milestone	Timeline (Months)	% Completed
Protocol development/submission to IRB	24-28	80%
All IRB approvals received.	30-31	0%
CRADA and other necessary agreements signed.	24-31	0%
Initial planning for biorepository completed	25-36	50%

Study 2: Assessing Risk Factors for Cardiovascular Disease in Individuals with Major Injury (With or Without Amputation) versus No Injury (continuing effort):

1) To identify the specific risk factors that maycontribute to an increased CVD risk in military personnel with major injury.
2) To develop a comprehensive CVD risk profile in military personnel with major injury.
3) To theorize the pathophysiology behind the changes in CV risk profiles in those individuals with major injury.
4) To develop treatment strategies specifically targeted for a more precise CV risk stratification in populations with major injuries.

Study Milestone	Timeline (Months)	% Completed
All ICHP supported data collection completed as coordinated with PI.	12-36	100%
All appropriate surveys scores and ICHP CV risk score calculations completed, validated and recorded in research record.	1-36	100%
Support and consult for data analysis	1-36	50%

Study 3: CHP Cognitive-Behavior Therapy for Insomnia (CHP CBT-I) Study (continuing effort):

1) To evaluate the feasibility and acceptability of CBT-I within the CHP program (Phase 1; N=12).
2) To determine the variability of the effect of CHP compared to CHP + CBT-I on the primary outcome (sleep efficiency) (Phase 1).
3) To determine the effectiveness of CHP compared to CHP + CBT-I on the improvement of sleep outcomes in a subset of CHP patients diagnosed with insomnia (Phase 2; N-64).
4) To determine the effectiveness of CHP compared to CHP + CBT-I on symptoms of fatigue, insomnia severity, depression, perceived stress, and sleep-related quality of life (Phase 2).

5) To examine data regarding the impact of the CHP program compared to CHP + CBT-I on secondary cardiovascular risk factors in a subset of CHP patients with insomnia (Phase 2).

Study Milestone	Timeline (Months)	% Completed
1st participant consented, screened and enrolled	1	100%
CBT-I intervention begins	2-3	100%
Phase 1 data analyzed for CBT-I feasibility	7-8	15%
Report findings from 6 month follow-up assessments through abstracts/presentations to sponsor, research team, data safety monitor, SAB and scientific community.	8-9	0%
Modifications complete and processes finalized	9	100%
1st participant consented, screened and enrolled in Phase 2, Study 3	9	0%
Phase 2, Study 3 begins	9	0%
Report findings from overall studies to sponsor, research team, data safety monitor, SAB, and scientific community.	Quarterly	100%
Manuscript submitted for publication	35-36	0%

Study 4: UPLIFT (Ultra-Personalized Laboratory-Risk Intervention For Treatment) for Cardiovascular Health: Cardiovascular (CV) Disease (CVD) Risk Study (new effort):

Part 1 is a PROTOCOL MODIFICATION of an existing approved WRNMMC protocol (eIRB #20525 A Pilot Study: Smallpox/Influenza Vaccination and Myopericardial Injury/Inflammation; PI: Dr. Limone Collins) and requiring collaboration with the Immunization Healthcare Branch (IHB), Defense Health Agency
Part 2 is a stand-alone prospective observational cohort study (eIRB #2017UPLIFT)

Study 4: UPLIFT (Ultra-Personalized Laboratory-Risk Intervention for Treatment) for Cardiovascular Health: Cardiovascular (CV) Disease (CVD) Risk Study (new effort):

***Part 1 converted to PROTOCOL MODIFICATION of an existing protocol (eIRB #20525) and requiring collaboration with the Immunization Healthcare Branch (IHB), Defense Health Agency (DHA)**
***Part 2 converted to a stand-alone prospective observational cohort study (eIRB #2017UPLIFT)**

Study 4 UPLIFT Part 1 Specific Aims:
Specific Aim 1 (*Study aim #7 in protocol modification*): To compare the prevalence of predictive biomarkers for future cardiac events and/or myocarditis/heart failure risk in healthy vaccines that are not in the healthy cohort.
Specific Aim 2: To determine the annual incidence rates of CVD related new outpatient diagnoses and/or hospitalizations up to 15 years post original study enrollment and compare incidence between those with evidence of baseline moderate/severe CVD risk to those with low baseline CVD risk (based on hsTnI) and to background population rates.

Study Milestone	Timeline (Months)	Completed
Letters of support received from DHA/IHB, SBE, Abbott, Labcorp (Liposcience), UOHSC, OMRF, Hyperion and Army Analytic Unit	6-24	100%
Signed CRADA with SBE and HJF/ICHP	6-12	100%

Approved DSA with SBE	19-24	0%
Signed agreements with DHA/IHB	19-24	0%
Signed agreements with SBE and DHA/IHB	19-24	0%
Approved DSA with DHA/IHB	19-24	80%
Signed agreements with ABBOTT Labs	19-24	75%
Signed DSA with ABBOTT Labs	19-24	70%
Signed agreements with Labcorp (Liposcience)	19-24	60%
Approved DSA with Labcorp (Liposcience)	19-24	0%
Signed agreements with UOHSC	19-24	40%
Approved DSA with UOHSC	19-24	30%
Signed agreements with OMRF	19-24	0%
Approved DSA with OMRF	19-24	0%
Signed agreements with Army Analytic Unit	19-24	10%
Signed DSA with Army Analytic Unit	19-24	0%
Signed agreements with Hyperion, if required	19-24	0%
Signed DSA with Hyperion, if required	19-24	0%
Scientific review of protocol modification conducted	6-12	100%
Local IRB submission/approval at WRNMMC (Part 1).	6-12	100%
All approvals for protocol implementation (Part 1).	8-12	100%
Local IRB approval at WRNMMC received (Part 2). (see comment below)	8-12	95%
All approvals received for protocol implementation (Part 2).	8-12	20%
All sample shipment for testing completed to ABBOTT.	12-24	0%
All sample shipment for testing completed to Liposcience	12-24	0%
Testing results received from ABBOTT Labs & verified	18-24	0%
Testing results received from Liposcience & verified	18-24	0%
All result data reviewed and cleaned in preparation of analyses	18-24	0%
Data exploration display and final coordination of analysis plan completed	18-24	0%
All sample testing data cleaned and QC for final datasets for analysis	18-28	0%
1st Manuscript completed and submitted	24-30	0%
Manuscript accepted, second manuscript preparation	32-36	0%
New CVD diagnosis (inpatient/outpatient) surveillance plan completed and submitted to MHS database manager collaborators (e.g. Army Analytic Unit or other to be determined)	18-24	0%
Redacted data set including CVD risk assessment parameters, demographics, clinical and laboratory data linked to MHS database surveillance outcomes returned for final analysis	21-30	0%
2nd round of surveillance data for CVD relevant diagnoses & events completed with consideration for a second manuscript	36-60	0%

UPLIFT STUDY 4: Part 2 Specific Aims:

Specific Aim 1: To determine the prevalence of hsTnI (coupled with us-CRP, suPAR, NT-pro-BNP and Gal-3) risk predictive elevations [sex adjusted levels published as surrogate markers of CVD mortality and morbidity] in patients with obstructive versus no visible CVD.

Specific Aim 2: To determine, by sex, validity of using a screening questionnaire built on a single-question for each of the major CVD risk confounders in relation to more comprehensive validated questionnaires.

Specific Aim 3: To characterize novel patterns of systemic inflammation/injury contributing to CVD progression, by sex, that may increase rates of major CVD events in the context of long-term surveillance (MHS databases).

Specific Aim 4: To characterize changes in CVD risk associated measures overtime with usual standard of care, by sex.

Specific Aim 5: To use large data set mapping techniques, single question screening items addressing comprehensive lifestyle as well as occupational/environmental confounders of risk in relation to primary predictive CVD risk measures and more in-depth validated survey screening tools in a clinically symptomatic population.

Study Milestone	Timeline (Months)	% Completed
1st participant consented, screened and enrolled	12-18	0%
First blood draw processed, QC'd for labeling, rapid separation, prepare aliquots, rapid freezing to preserve troponin stability	12-18	0%
Study 2 begins	12-18	0%
30% of enrollment goals achieved	4-18	0%
40-50% enrollment goals achieved	24-36	0%
over 70% enrollment goals achieved	37-60	0%
25% of subjects completed 1 year follow-up (of total with N~150-200)	28-36	0%
40-50% of subjects completed 1 year follow-up (of total with N=~240-300)	37-59	0%
Interim analysis plan finalized with statisticians	24-28	0%
Interim analysis for pilot data presentation completed	32-36	0%
Iterative analyses with final comprehensive data review completed for presentation and manuscript preparation	37-60	0%
Development and completion of data dictionary	12	100%
30% of sample shipment for testing to ABBOTT completed	24-32	0%
50% All samples shipped for testing to Liposcience	33-48	0%
Testing results received from ABBOTT Labs & verified – 30% complete by 36 months	24-60	0%
Testing results received from Liposcience & verified – 30% complete by 36 months	24-60	0%
>70% of subjects enrolled with results	48-60	0%
Data Safety Monitor presentation content completed	24-36	0%
Completed Data Safety Monitor review with implementation of recommendations in progress for completion	28-36	0%
Continued Data Safety Monitor data review for option years and ongoing enrollment	24, 48	0%
Sample testing data cleaned and QC for final spreadsheet	48-56	0%
1st Manuscript completed and submitted	36-42	0%
Second manuscript preparation draft	36-58	0%
Dissemination of initial findings (abstracts, presentation, publication, DOD reports) with summary of implications for MHS health promotion priorities	36-60	0%
Obtain outcomes surveillance data set on 30-40% of total enrollment cohort	37-48	0%
Obtain outcomes surveillance data set on 50-60% of total enrollment cohort	52-60	0%
Summary interim data report, presentation and manuscript preparation	52-60	0%
Dissemination of initial findings (abstracts, presentation, publication, DOD reports) with summary of implications for MHS health promotion priorities	52-60	0%

Specific Aim 6 (Biorepository): Establish a biologic sample repository (plasma, serum, whole blood, saliva, DNA, RNA) for staged testing and cost-effective approaches for evolving hypotheses testing and biomarker modeling/validation. ***(See Study 1C)***

Study Milestone	Timeline (Months)	% Completed
1st 30% of samples collected, processed and recorded in tracking	28-39	0%
All study samples collected, processed and recorded in tracking system	37-60	0%

Specific Aim 7: To determine the annual incidence of new CVD relevant diagnoses (hospitalizations, outpatient visits) in study cohorts (from Part 1a, 1b, 2 and 3) following primary enrollment and compare this incident rate to matched healthy controls from the MHS diagnostic coding data repository.

Study Milestone	Timeline (Months)	% Completed
Implementation of outcomes surveillance plan and data obtained for final analysis and manuscript preparation Part 1a	25-32	0%
Implementation of outcomes surveillance plan and data obtained for final analysis and manuscript preparation (Part 1b)	52-60	0%
Implementation of outcomes surveillance plan and data obtained for final analysis and manuscript preparation (Part 2)	48-60	0%

Specific Aim 8: To facilitate research study enrollment and data-capture on site (WRNMMC Cardiac Cath Lab, Immunization Clinic, Internal Medicine Prevention & Health Clinic, FBCH Cardiology, etc.) as well as institutional biorepository inventory tracking and required monitoring of individual sample locations/movements/disposal.

Study Milestone	Timeline (Months)	% Completed
Database structure verified to accommodate mission requirements and improve workflow efficiency	*18-48*	80%
ICHP study data migrated to RIMS	*18-60*	0%
Process for sample bar coding and database tracking established and verified	*18-24*	25%
Biorepository database tracking system established in support of protocol	*24-36*	25%
Survey modification and adaptation to REDcap system for electronic delivery	*18-24*	95%

The following MAJOR TASK applies to ALL STUDIES (#1-4) within the ICHP Platform.

Oversight of protocol scientific content and data quality, Studies 1-4
Major Task 1: Establish/convene oversight committee (SAB) and Data Safety Monitor

Study Milestone	Timeline (Months)	% Completed
Data Safety Monitor identified	*1-2*	0%
SAB established	*4-6*	100%
Teleconferences with Data Safety Monitor conducted	*Semi-Annually*	0%
SAB convened at least annually	*Annually*	100%

What was accomplished under these goals?

Below find abstracts of our results published:

Kashani M, Eliasson AH, Walizer EM, Fuller CE, Engler RJ, Villines TC, Vernalis MN. Early empowerment strategies boost self-efficacy to improve cardiovascular health behaviors. *Glob J Health Sci* 2016 Feb 2;8(9):55119. doi: 10.5539/ghis.v8n9p322.

Background: Self-efficacy, defined as confidence in the ability to carry out behavior to achieve a desired goal, is considered to be a prerequisite for behavior change. Self-efficacy correlates with cardiovascular health although optimal timing to incorporate self-efficacy strategies is not well established. We sought to study the effect of an empowerment approach implemented in the introductory phase of a multicomponent lifestyle intervention on cardiovascular health outcomes. **Design:** Prospective intervention cohort study. **Methods:** Patients in the Integrative Cardiac Health Project Registry, a prospective lifestyle change program for the prevention of cardiovascular disease were analyzed for behavioral changes by survey, at baseline and one year, in the domains of nutrition, exercise, stress management and sleep. Self-efficacy questionnaires were administered at baseline and after the empowerment intervention, at 8 weeks. **Results:** Of 119 consecutive registry completers, 60 comprised a high self-efficacy group (scoring at or above the median of 36 points) and 59 the low self-efficacy group (scoring below median). Self- efficacy scores increased irrespective of baseline self-efficacy but the largest gains in self- efficacy occurred in patients who ranked in the lower half for self-efficacy at baseline. This lower self-efficacy group demonstrated behavioral gains that erased differences between the high and low self-efficacy groups. **Conclusions:** A boost to self-efficacy early in a lifestyle intervention program produces significant improvements in behavioral outcomes. Employing empowerment in an early phase may be a critical strategy to improve self-efficacy and lower risk in individuals vulnerable to cardiovascular disease.

Eliasson A, Kashani M, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. Targeted behavioral interventions improve disturbed sleep. *Sleep* 2016;39:A397.

Introduction: Sleep is an established risk factor for cardiovascular disease (CVD). CVD prevention programs are an ideal setting to assess patients for disturbed sleep. For our CVD prevention program, we report the frequency of disturbed sleep and improvement of important outcomes. **Methods:** At baseline, patients completed validated questionnaires: Berlin Questionnaire for sleep apnea, Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESS), and Stanford Fatigue Scale. After CVD risk assessment by a nurse practitioner, patients attended a healthy lifestyle workshop with didactics on healthy sleep practices, experiential stress reduction, and food demonstration. All patients received personalized lifestyle prescriptions. Patients with abnormal sleep surveys received customized sleep recommendations. Over 12 months, patients were coached on diet, exercise, and stress management. Validated surveys were repeated at graduation. Means and standard deviations provide descriptive statistics. Two sample t-tests measure statistical significance for changes from baseline to graduation. **Results:** Of 455 consecutive program completers, 59% women, there were 61% white, 31% black, 4% Hispanic, 2% Asian, 2% other. Fiftyone patients (11%) entered the program with previously diagnosed sleep apnea. Screening for sleep apnea was positive in 217 more patients (48%) consequently referred for polysomnography. Of the remaining 187 patients (41%), 68% had poor sleep quality (mean PSQI 7.8±2.8, normal sleeper <5 points), mean sleep duration 6.6±1.2 hours, ESS 7.3±4.4, and fatigue score 3.4±2.2. Of patients with poor sleep quality (68%), PSQI improved 2.2 points, $p<0.001$; 54% improved sleep duration 30 minutes, $p=0.007$; 71% improved ESS 3 points, $p<0.001$, and 58% improved fatigue 1.2 points, $p<0.001$. **Conclusions:** Our CVD prevention program provides an opportune mechanism to identify sleep disturbances. Nearly 2/3 of our population screens positive for sleep apnea and a majority of the remainder experience poor sleep quality and duration. Targeted interventions for improved sleep are effective and support CVD risk modification.

Engler R, Kashani M, Eliasson A, Walizer E, Fuller C, Villines T, Vernalis M. Blood pressure elevations below hypertension threshold linked to insulin resistance and dyslipidemia: An under-recognized cardiovascular disease risk phenotype. Presented at Military Health System Research (MHSRS) Symposium 2016.

Background: Cardiovascular disease (CVD) morbidity/mortality risk has been directly correlated to blood pressure (BP) levels with lower levels, even below "normal ranges", associated with reduced CVD risk. Yet current clinical guidelines only address treatment for frank hypertension (equal/over 140/90 mmHg).There is increasing interest in earlier and more precise identification of CVD risk particularly for enhanced lifestyle management interventions to prevent disease and reduce lifetime risks. Metabolic dysfunction characterized by insulin resistance predicts future risk for type 2 diabetes mellitus (T2DM) and is potentially reversible. The homeostatic model assessment (HOMA) is a calculated value that reflects hepatic insulin resistance (IR). Early preclinical diabetes with increased IR affects a large population (86 million Americans) and has gone largely unrecognized. Improving the precision of CVD risk assessments in order to guide earlier more effective intervention strategies can reduce the burden of future CVD risk complications. **Methods:** Between July 2005 and July 2015, consecutive subjects entering the Integrative Cardiac Health Project (ICHP) Registry (a 12-month prospective CVD Risk Reduction Program) were assessed for BP category and prevalence of metabolic risk factors by measuring anthropometrics and CVD-relevant laboratory parameters including insulin resistance by HOMA. HOMA values greater than 2.0 to 3.0 are associated with increased CVD risk in adult populations. BP was categorized as not elevated (less than 120/80), modestly elevated (between 120/80 and 140/90, also described as prehypertension) and hypertensive (equal/over 140/90). Comparisons were made between subjects with no BP elevation, modest BP elevation and hypertensives for differences in CVD risk factors using t-test analysis. These BP groups were compared for the following CVD risk parameters: fasting glucose (Gluc), hemoglobin A1C (HgbA1C), HOMA-IR, low density lipoprotein (LDL), high density lipoprotein (HDL), triglycerides (TG), body mass index (BMI), and waist circumference (WC). **Results**: Of 352 subjects (56% women, mean age 53 ± 13.5years, 61% white, 22% black, 5% Hispanic), 114 (32%) had no elevation in BP,154 (44%) had modest elevation in BP and 84 (24%) were hypertensive. There were no differences between the hypertensive group and those with modest elevation in BP. There were significant differences in means (+/- SD: standard deviation) between those without elevated BP and the group with modestly elevated BP for the variables detailed: Gluc [93.9(16.7) vs 100.6(14.9), p=0.001]; HgbA1C [5.5(0.06) vs 5.7(0.06), p=0.02]; HOMA [2.89(2.6) vs 3.75(3.8), p=0.01]; HDL[60.4(17.0) vs 55.2(13.6), p=0.009]; TG [97.6(50.7) vs 115.7(66.1), p=0.012]; BMI[28.2(5.8) vs 30.5(5.5), p=0.0006]; WC [94.3(15.1) vs 102.8(14.1), p=0.0001]. There were no significant differences in LDL levels [108.5(28.7) vs 115.0(38.0), p=0.12]. **Conclusion**: We demonstrate that among subjects with pre-hypertension, there is a significant prevalence of insulin resistance, dyslipidemia and obesity. Modest elevations in BP may identify subjects with metabolic syndrome who may benefit from enhanced preventive interventions. Given the many military service associated confounders exacerbate CVD risk, there is a need for improved earlier diagnosis of clinical conditions that can and should be addressed to maintain optimum health of the force.

Kashani M, Eliasson A, Walizer E, Fuller C, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Multidisciplinary cardiovascular team review captures preclinical disease. *J Am Coll Cardiol*. 2017; 69(11S):2103. doi.org/10.1016/S0735-1097(17)35492-X

Background: To ensure uniform application of AHA/ACC assessment guidelines for our 12-month cardiovascular (CV) health program and for early identification of preclinical disease, we conduct a CV team review of each patient with input from each team expert: nurse practitioner (NP), dietitian, exercise physiologist, stress coach, cardiologist and sleep specialist.

Case: Patients complete validated lifestyle questionnaires, anthropometrics and lab tests upon entry. The following 4 asymptomatic women with no heart disease were initially classified low risk by Framingham risk score (FRS).

Age	Sex	Race	FRS	Premature Family History	Body Mass Index (kg/m^2)	Blood Pressure (mmHg)	Glucose (mg/dL)	Exercise (min/wk)	Stress Score	New Sleep Apnea	# New Risks Captured
30	F	White	Low	***Pos***	***33.8***	101/65	95	***100***	***High***	***Pos***	5
49	F	White	Low	***Pos***	***31.7***	113/80	98	**30**	Low	***Pos***	4
65	F	White	Low	***Pos***	***37.0***	***148/80***	***108***	**105**	Low	Neg	5
46	F	Black	Low	***Pos***	***31.2***	***122/85***	96	225	***High***	***Pos***	5

Decision-making: The NP leads a review, a mechanism to assign CV risk thresholds to guide intensity of interventions. The 4 patients were reclassified as high risk per positive family history. Based on reclassification, the team identified new risk factors/preclinical disease: obesity, hypertension/prehypertension, prediabetes, sedentary lifestyle, high stress and sleep apnea prompting intensive recommendations for lifestyle modification. **Conclusion:** These cases highlight the value of a methodical, integrative and systematic CV team review as a venue to enhance identification of risk factors in the preclinical state in order to improve precision of interventions, enhance safety and empower patients.

Kashani M, Eliasson A, Fuller C, Walizer E, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Arresting insulin resistance with an integrative health intervention. *J Am Coll Cardiol*. 2017; 69(11S):1853. doi.org/10.1016/S0735-1097(17)35242-7

Background: Insulin resistance (IR) is the first signal of glucose dysmetabolism. IR precedes the development of prediabetes and eventually frank diabetes. Interventions which reverse this pathophysiology also benefit other risk factors of cardiovascular disease (CVD). We examined the effect of an integrative health intervention (beyond traditional approaches) on the CVD risk profile of subjects with IR characterized by elevated Homeostatic Model Assessment (HOMA). **Methods:** Consecutive subjects of the Integrative Cardiac Health Project Registry, a 12-month CVD health intervention focusing on four pillars: nutrition, exercise, stress and sleep improvement, completed validated questionnaires and laboratory tests. Subjects were categorized for IR (HOMA $\geq$ 2.8).

Differences were analyzed using t-test. **Results:** Of 630 subjects, 70 had diabetes and were excluded from analysis, 207 subjects (33%) had IR by HOMA (63% women, mean age 55 ± 12 years, 56% White, 36% Black, 4% Hispanic). Of 207 IR subjects, 70 (34%) reverted to normal HOMA values upon completion of the intervention.

Risk Factor (n=207)	Baseline	12-month	p
Fasting Glucose (mg/dL)	99.3 ± 11.5	96.4 ± 11.5	0.009
Fasting Insulin (uIU/mL)	19.4 ± 7.9	16.4 ± 9.3	0.0001
HOMA [(Glucose x Insulin)/405]	4.78 ± 2.21	3.96 ± 2.40	0.0001
Total Cholesterol (mg/dL)	181.1 ±	172.6 ±	0.03
Low Density Lipoprotein (mg/dL)	109.9 ±	103.2 ±	0.004
Triglyceride (mg/dL)	139 ± 109	117 ± 63	0.03
Body Mass Index (kg/m^2)	32.4 ± 4.8	31.6 ± 4.9	0.08
Rate Your Plate (78 points)	60.4 ± 7.4	66.1 ± 6.2	0.0001
Aerobic Exercise Time (min/week)	124 ± 127	191 ± 120	0.001
Perceived Stress Scale (56 points)	21.2 ± 8.7	17.6 ± 8.2	0.0001
Pittsburg Sleep Quality Index (21	7.3 ± 4.0	5.7 ± 3.8	0.0001
Fatigue Score (10 points)	4.5 ± 2.3	3.4 ± 2.3	0.0001

Conclusions: As characterized by this population, a comprehensive approach to CVD risk reduction is warranted given the elevated risk facing menopausal women. An integrative health intervention, beyond traditional measures, emphasizing combined improvements in nutrition, exercise, stress and sleep can arrest the pathophysiology of IR, preventing development of diabetes.

Kashani M, Eliasson A, Walizer E, Fuller C, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Reversing prediabetes when diet and exercise are not enough. (Accepted to PCNA 2017 Annual Symposium)

Background: Diet and exercise are primary interventions for the management of cardiovascular disease (CVD). Despite healthy dietary patterns and substantial amounts of exercise in our patient population, prediabetes persists. We sought to determine if factors other than diet and exercise are associated with prediabetes reversal. **Hypothesis:** We hypothesized that non- traditional lifestyle factors play a role in the reversal of prediabetes. **Methods:** Participants in our Integrative Cardiac Health Project Registry underwent comprehensive evaluation for CVD risk by a nurse practitioner including cardiac-relevant laboratory tests and validated questionnaires for diet (Rate-Your-Plate, RYP), exercise (minutes/week), perceived stress (Perceived Stress Scale, PSS), and sleep (Pittsburgh Sleep Quality Index). Patients with prediabetes, defined by fasting glucose 100 to 139 mg/dL, were assessed after a 12-month healthy lifestyle coaching intervention. Differences were assessed using paired t-tests. **Results:** Of 146 participants with prediabetes, 76 (52%) reversed

prediabetes by fasting glucose. These reversers (mean age 64.2±13.0 years, 60% women, 64% White, 24% Black, 12% other) averaged healthy diet scores at baseline and exercised more than 150 minutes per/week as currently recommended in guidelines. Stress and sleep scores improved substantially in response to the intervention. Significant improvements were seen in reversal of insulin resistance as demonstrated by HOMA<2.8.

	Diet (RYP) of 78 points	Exercise min/week	Perceived Stress of 56 points	Sleep Quality of 21 points	Glucose mg/dL	Insulin mU/L	HOMA [Glu*ins]/405
Baseline	62.6±7.7	169±133	21.0±8.4	6.8±3.4	105.0±5.4	13.2±9.1	3.4±2.4
12 Months	67.2±5.2	205±103	17.3±6.8	5.5±3.7	93.1±4.8	9.6±6.6	2.2±1.5
p value	<0.0001	0.07	<0.0001	0.002	<0.0001	<0.0001	<0.0001

Conclusions: Given that lifestyle behavior modification is the cornerstone of prediabetes reversal, the addition of stress and sleep management to a regimen of diet and exercise is both valuable and critical to ensure a comprehensive approach to achieve normal glucose metabolism and prevent the onset of diabetes.

Kashani M, Eliasson A, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. A single measurable outcome tool for tracking behavioral change. *Circulation: Cardiovascular Quality and Outcomes*. 2017;10:A206 (Accepted to AHA QCOR 2017 Scientific Session)

Background: Although healthy lifestyle behaviors have been shown to significantly reduce cardiovascular disease (CVD), offsetting even genetic risk, most CVD programs focus solely on risk scores rather than calculating health improvement. We sought to validate a newly developed quantitative composite healthy lifestyle behavioral score, the Optimal Health Impact Factor (OHIF), which captures behavioral change by attainment of thresholds established by clinical guidelines. **Methods:** Patients in the Integrative Cardiac Health Project's 12-month Registry, a prospective lifestyle change program for the prevention of CVD, underwent traditional risk assessment by a nurse practitioner. Additionally, at baseline and 12-months, OHIF scores were calculated using validated questionnaires in the following four domains: nutrition (Rate-Your- Plate), exercise (minutes of continuous exercise per week), stress (Perceived Stress Scale) and sleep (Pittsburgh Sleep Quality Index). Each domain has a gradient of three behavioral threshold scores (not at goal, red=1; almost to goal, amber=2; at goal, green=3) for a maximum of 12 possible OHIF points representing optimal health behaviors. All patients received motivational health coaching by a multidisciplinary team. Data were analyzed by t-tests,

comparing measures at baseline and at 12-months. **Results:** Of 225 consecutive completers (48% men, age 56.8 ± 12.9 years, 145 White, 54 Black, 26 other, 61% at high risk by family history of CVD in first order relatives), 160 (71%) showed clinically and statistically significant improvements in the four behavioral domains and selected laboratory data.

	Change in OHIF Score by Behavioral Domain					**Lab Data**	
n = 225	**Diet (of 3 pts)**	**Exercise (of 3 pts)**	**Stress (of 3 pts)**	**Sleep (of 3 pts)**	**OHIF Score (of 12 pts)**	**T Chol (mg/dl)**	**LDL Chol (mg/dl)**
Baseline	2.54 ± 0.52	2.12 ± 0.83	2.41 ± 0.83	2.26 ± 0.52	9.32 ± 1.56	187.7 ± 40.9	114.1 ± 35.5
12-Month	2.88 ± 0.33	2.56 ± 0.64	2.61 ± 0.74	2.56 ± 0.51	10.61 ± 1.39	176.4 ± 39.4	105.2 ± 34.2
p value	<0.0001	<0.0001	0.007	<0.0001	<0.0001	0.003	0.007

Conclusions: Improvements in healthy lifestyle behaviors captured by the OHIF score correlate significantly with improvements in critical CVD risk factors, even in a population with high genetic risk. The OHIF score emphasizes gradients of positive lifestyle behavior change for both patient and provider to facilitate development of an actionable behavioral health plan to reduce CVD. Clinicians who calculate a CVD risk score may also find clinical value in calculating a composite OHIF score as a single measurable outcome tool for tracking behavioral changes longitudinally.

Eliasson A, Kashani M, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. A novel lifestyle change program identifies and improves cardiovascular risks in middle-aged women. (Accepted to American Thoracic Society 2017 Meeting)

Rationale: Cardiovascular disease (CVD) is the leading cause of death in women over age 25, killing nearly twice as many women in the United States as all types of cancer combined. Women with CVD often present with atypical symptoms and identification of risk with traditional risk assessment tools remains unrecognized. We sought to identify CVD risk for women attending our cardiovascular health program (CHP) and to utilize a comprehensive intervention to improve relevant behaviors in this vulnerable, potentially overlooked population. **Methods:** Consecutive subjects entering the CHP completed validated behavioral surveys in four domains of cardiovascular health: diet, exercise, perceived stress and sleep. The surveys included Rate-Your-Plate for diet, queries for exercise minutes per week in periods of at least 10 minutes, Perceived Stress Scale, and total sleep time. Surveys were completed before and after a 12-month multifaceted lifestyle change program. Upon entry, subjects were assessed for maladaptive behaviors for CVD and a FRS was calculated by a nurse practitioner. Subjects then received

personalized motivational health coaching from an interdisciplinary team. Behavioral changes were evaluated using paired t-tests. **Results:** Of 248 consecutive program completers, 128 (52%) were women, mean age 56.2 ± 13.0 with racial diversity (76 White, 37 Black, 3 Hispanic, 3 Asian, 9 other). Upon entry to the CHP, numerous risk factors for CVD were confirmed in these women including high proportions of family history of premature CVD (44%), menopause (52%), diagnosis of depression (31%), high likelihood for obstructive sleep apnea (50%), abnormal carotid intimal media thickness (58%), obesity (mean body mass index 30.2 kg/m^2), insulin resistance (mean Homeostatic Model Assessment 2.92), prediabetes (mean HgA1C 5.74%), and CRP (mean 0.355 mg/dL). Only 3 of 128 (2%) were smokers and all 3 quit. Despite extensive indicators of high risk, mean Framingham Risk Score of 4.9 indicated low risk for CVD. After 12 months of motivational health coaching from the interdisciplinary team, clinically relevant improvements were demonstrated in each behavioral category.

n=128	Rate-Your-Plate (26-78 points)	Exercise (min/week)	Perceived Stress Scale (0-56 points)	Total Sleep Time (hrs/ 24 hrs)
Baseline	62 ± 7	143 ± 139	21 ± 9	6.5 ± 1.3
12-months	68 ± 5	219 ± 187	17 ± 8	6.9 ± 1.2
t test	<0.0001	0.0003	0.0004	0.01

Conclusion: Middle-aged, perimenopausal women are at a substantially increased risk for CVD, risk that may go undetected with conventional assessment. Our CHP targets this population by using a comprehensive approach to identify cardiometabolic risks combined with validated questionnaires to quantify maladaptive lifestyle behaviors. Improving maladaptive behaviors with a novel and personalized health program reduces overall CVD risk and ultimately lowers the leading cause of death among women.

Eliasson A, Kashani M, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. Prevalence of sleep disturbances and their consequences in patients at risk for cardiovascular disease. (Accepted APSS 2017 Scientific Session)

Introduction: Disturbed sleep is strongly associated with incident cardiovascular disease (CVD). We report the prevalence of sleep disturbances and their sequellae in patients attending our CVD prevention program, a population at increased risk of CVD. **Methods:** At program entry, patients completed validated questionnaires: Berlin Questionnaire for sleep apnea, Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESS), and Stanford Fatigue Scale. Means and standard deviations provide descriptive statistics and Pearson correlations describe pertinent associations. **Results:** Of 485 consecutive program participants (mean age 60.5±13.6 years, 70% women, 65% White, 27% Black, 4% Hispanic, 5% other) only 11% were diagnosed with coronary disease and 2% with stroke. Screening for sleep apnea was positive in 49% of participants and sleep apnea was previously diagnosed in 26%. Mean PSQI was 7.1±3.9, with 39% normal sleepers (PSQI<5), 43% with mild derangement, 13% moderate, and 5%

severe. Mean total sleep time (TST) was 6.3±1.3 hours with only 41% getting the recommended 7 or more hours per night. Of the other participants, 30% slept 6 to 7 hours, and 28% slept less than 6 hours. Mean sleep latency was prolonged at 19.0±26.7. Mean ESS was 8.7±5.5 but 40% scored in the sleepy range (ESS≥10 of 24). Mean fatigue score was 4.3±2.4 with 47% scoring in the fatigued range (score≥5 of 10). Increased levels of perceived stress were strongly correlated with poor sleep quality (*Pr*=0.452) and increased fatigue scores (*Pr*=0.430), and mildly correlated with daytime sleepiness (*Pr*=0.267). **Conclusions:** Participants in our CVD prevention program, a population at increased risk for CVD, show evidence of substantial sleep disturbances. Nearly 3/4 of our population screens positive for sleep apnea and a majority experiences poor sleep quality and low TST. Poor sleep quality and consequent daytime symptoms correlate with increased levels of perceived stress, magnifying CVD risk.

Tschiltz N, Eliasson A, Halsey J, Walizer E, Kashani M, Villines T, Vernalis M. Dietitians in the kitchen impact cardiovascular disease prevention. (Accepted Society for Nutrition Education and Behavior 2017)

Objective: To describe a successful dietetics intervention in an integrative cardiovascular health program. **Target Audience:** Dietitians caring for patients at risk for cardiovascular disease (CVD). **Theory, Prior Research, Rationale:** Amid the CVD epidemic, opportunities to learn basic cooking skills are decreasing while rates of eating out are continually increasing. Our research kitchen offers a unique opportunity to teach simple, Mediterranean-style, heart-healthy cooking techniques for use at home. **Description:** The Integrative Cardiovascular Health Program (ICHP) follows evidence-based guidelines to measure CVD risk and contributory lifestyle behaviors. Subsequent interventions include a workshop, behavioral prescriptions, and coaching follow-up over 6 months, including appointments with a dietitian for diabetes education. The four-hour interactive workshop presents overviews on diet, exercise, stress management, and sleep. The program's capstone is a food preparation demonstration and Mediterranean-style meal in the research kitchen by a Culinary Institute of America-trained chef/Registered Dietitian. The goal is to teach simple recipes that taste good and empower attendees to plan, shop and prepare healthy meals at home. **Evaluation:** After workshop participation, patients (n=603, mean age 57±12 years, 44% men) expressed strong likelihood to try Mediterranean-style recipes (mean 3.8 of 4 points). Satisfaction was 99% with the Mediterranean-style meal. Confidence was strong in 95% of patients regarding where to shop for food. At program completion, 88 of 161 patients with prediabetes (55%) normalized fasting glucose. Of 221 patients with hypercholesterolemia, 96 (43%) normalized total cholesterol. Overweight patients (n=491, 81%) averaged 2.1 kg weight loss. **Conclusions and Implications:** Interactive experiences in a research kitchen with dietitians teaching recipe planning, shopping, and meal preparation, enhance cardiovascular health outcomes.

Kashani M, Eliasson A, Walizer E, Fuller C, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Reversing prediabetes when diet and exercise are not enough. (Poster presented at the PCNA 23rd Annual Symposium, Denver, CO, 7-9 April 2017)

Background: Diet and exercise are primary interventions for the management of cardiovascular disease (CVD). Despite healthy dietary patterns and substantial amounts of exercise in our patient population, prediabetes persists. We sought to determine if factors other than diet and exercise are associated with prediabetes reversal. **Hypothesis:** We hypothesized that non- traditional lifestyle

factors play a role in the reversal of prediabetes. **Methods:** Participants in our Integrative Cardiac Health Project Registry underwent comprehensive evaluation for CVD risk by a nurse practitioner including cardiac-relevant laboratory tests and validated questionnaires for diet (Rate-Your-Plate, RYP), exercise (minutes/week), perceived stress (Perceived Stress Scale, PSS), and sleep (Pittsburgh Sleep Quality Index). Patients with prediabetes, defined by fasting glucose 100 to 139 mg/dL, were assessed after a 12-month healthy lifestyle coaching intervention. Differences were assessed using paired t-tests. **Results:** Of 146 participants with prediabetes, 76 (52%) reversed prediabetes by fasting glucose. These reversers (mean age 64.2±13.0 years, 60% women, 64% White, 24% Black, 12% other) averaged healthy diet scores at baseline and exercised more than 150 minutes per/week as currently recommended in guidelines. Stress and sleep scores improved substantially in response to the intervention.
Significant improvements were seen in reversal of insulin resistance as demonstrated by HOMA<2.8.

	Diet (RYP) of 78 points	Exercise min/week	Perceived Stress of 56 points	Sleep Quality of 21 points	Glucose mg/dL	Insulin mU/L	HOMA [Glu*ins]/405
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Conclusions: Given that lifestyle behavior modification is the cornerstone of prediabetes reversal, the addition of stress and sleep management to a regimen of diet and exercise is both valuable and critical to ensure a comprehensive approach to achieve normal glucose metabolism and prevent the onset of diabetes.

Eliasson A, Kashani M, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. A novel lifestyle change program identifies and improves cardiovascular risks in middle-aged women. *Am J Respir Crit Care Med* 2017;195:A5376

Rationale: Cardiovascular disease (CVD) is the leading cause of death in women over age 25, killing nearly twice as many women in the United States as all types of cancer combined.
Women with CVD often present with atypical symptoms and identification of risk with traditional risk assessment tools remains unrecognized. We sought to identify CVD risk for women attending our cardiovascular health program (CHP) and to utilize a comprehensive intervention to improve relevant behaviors in this vulnerable, potentially overlooked population. **Methods:** Consecutive subjects entering the CHP completed validated behavioral surveys in four domains of cardiovascular health: diet, exercise, perceived stress

and sleep. The surveys included Rate-Your-Plate for diet, queries for exercise minutes per week in periods of at least 10 minutes, Perceived Stress Scale, and total sleep time. Surveys were completed before and after a 12- month multifaceted lifestyle change program. Upon entry, subjects were assessed for maladaptive behaviors for CVD and a FRS was calculated by a nurse practitioner. Subjects then received personalized motivational health coaching from an interdisciplinary team. Behavioral changes were evaluated using paired t-tests. **Results:** Of 248 consecutive program completers, 128 (52%) were women, mean age 56.2 ± 13.0 with racial diversity (76 White, 37 Black, 3 Hispanic, 3 Asian, 9 other). Upon entry to the CHP, numerous risk factors for CVD were confirmed in these women including high proportions of family history of premature CVD (44%), menopause (52%), diagnosis of depression (31%), high likelihood for obstructive sleep apnea (50%), abnormal carotid intimal media thickness (58%), obesity (mean body mass index 30.2 kg/m^2), insulin resistance (mean Homeostatic Model Assessment 2.92), prediabetes (mean HgA1C 5.74%), and CRP (mean 0.355 mg/dL). Only 3 of 128 (2%) were smokers and all 3 quit. Despite extensive indicators of high risk, mean Framingham Risk Score of 4.9 indicated low risk for CVD. After 12 months of motivational health coaching from the interdisciplinary team, clinically relevant improvements were demonstrated in each behavioral category.

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Conclusion: Middle-aged, perimenopausal women are at a substantially increased risk for CVD, risk that may go undetected with conventional assessment. Our CHP targets this population by using a comprehensive approach to identify cardiometabolic risks combined with validated questionnaires to quantify maladaptive lifestyle behaviors. Improving maladaptive behaviors with a novel and personalized health program reduces overall CVD risk and ultimately lowers the leading cause of death among women.

Eliasson A, Kashani M, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. Prevalence of sleep disturbances and their consequences in patients at risk for cardiovascular disease. *SLEEP* 2017;40:A390.

Introduction: Disturbed sleep is strongly associated with incident cardiovascular disease (CVD). We report the prevalence of sleep disturbances and their sequelae in patients attending our CVD prevention program, a population at increased risk of CVD. **Methods:** At program entry, patients completed validated questionnaires: Berlin Questionnaire for sleep apnea, Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESS), and Stanford Fatigue Scale. Means and standard deviations provide descriptive statistics and Pearson correlations describe pertinent associations.

Results: Of 485 consecutive program participants (mean age 60.5±13.6 years, 70% women, 65% White, 27% Black, 4% Hispanic, 5% other) only 11% were diagnosed with coronary disease and 2% with stroke. Screening for sleep apnea was positive in 49% of participants and sleep apnea was previously diagnosed in 26%. Mean PSQI was 7.1±3.9, with 39% normal sleepers (PSQI<5), 43% with mild derangement, 13% moderate, and 5% severe. Mean total sleep time (TST) was 6.3±1.3 hours with only 41% getting the recommended 7 or more hours per night. Of the other participants, 30% slept 6 to 7 hours, and 28% slept less than 6 hours. Mean sleep latency was prolonged at 19.0±26.7. Mean ESS was 8.7±5.5 but 40% scored in the sleepy range (ESS≥10 of 24). Mean fatigue score was 4.3±2.4 with 47% scoring in the fatigued range (score≥5 of 10). Increased levels of perceived stress were strongly correlated with poor sleep quality (*Pr*=0.452) and increased fatigue scores (*Pr*=0.430), and mildly correlated with daytime sleepiness (*Pr*=0.267). **Conclusions:** Participants in our CVD prevention program, a population at increased risk for CVD, show evidence of substantial sleep disturbances. Nearly 3/4 of our population screens positive for sleep apnea and a majority experiences poor sleep quality and low TST. Poor sleep quality and consequent daytime symptoms correlate with increased levels of perceived stress, magnifying CVD risk.

Tschiltz N, Halsey J, Eliasson A, Kashani M, Walizer E, Villines T, Vernalis M. Dietitians in the kitchen impact cardiovascular disease prevention. *J Nutr Educ Behav*. 2017;49(7S1):S34. Doi.org/10.1016./j.jneb.2017.05.316.

Objective: To describe a successful dietetics intervention in an integrative cardiovascular health program. **Target Audience:** Dietitians caring for patients at risk for cardiovascular disease (CVD). **Theory, Prior Research, Rationale:** Amid the CVD epidemic, opportunities to learn basic cooking skills are decreasing while rates of eating out are continually increasing. Our research kitchen offers a unique opportunity to teach simple, Mediterranean-style, heart-healthy cooking techniques for use at home. **Description:** The Integrative Cardiovascular Health Program (ICHP) follows evidence-based guidelines to measure CVD risk and contributory lifestyle behaviors. Subsequent interventions include a workshop, behavioral prescriptions, and coaching follow-up over 6 months, including appointments with a dietitian for diabetes education. The four-hour interactive workshop presents overviews on diet, exercise, stress management, and sleep. The program's capstone is a food preparation demonstration and Mediterranean-style meal in the research kitchen by a Culinary Institute of America-trained chef/Registered Dietitian. The goal is to teach simple recipes that taste good and empower attendees to plan, shop and prepare healthy meals at home. **Evaluation:** After workshop participation, patients (n=603, mean age 57±12 years, 44% men) expressed strong likelihood to try Mediterranean-style recipes (mean 3.8 of 4 points). Satisfaction was 99% with the Mediterranean-style meal. Confidence was strong in 95% of patients regarding where to shop for food. At program completion, 88 of 161 patients with prediabetes (55%) normalized fasting glucose. Of 221 patients with hypercholesterolemia, 96 (43%) normalized total cholesterol. Overweight patients (n=491, 81%) averaged 2.1 kg weight loss. **Conclusions and Implications:** Interactive experiences in a research kitchen with dietitians teaching recipe planning, shopping, and meal preparation, enhance cardiovascular health outcomes.

Eliasson A, Kashani M, Walizer E, Fuller C, Engler R, Villines T, Vernalis M. Military leaders are vulnerable to cardiovascular disease risk. [Presented as poster at the Military Health System Research Symposium (MHSRS), Kissimmee, FL, 27 August 2017]

Background: Cardiovascular disease (CVD) is the leading cause of death and disability in the United States and the leading cause of death in active duty (AD) service members (SMs) over the age of 39. Of SMs seen for cardiovascular (CV) complaints in Operation Enduring Freedom, 15% needed air-evacuation from theater. In Operation Iraqi Freedom, CV complaints accounted for 8% of air-evacuations causing a substantial loss of personnel from senior leadership. In order to develop an actionable prevention plan, we sought to catalogue reversible risk factors for CVD in senior leaders attending the Integrative Cardiac Health Project (ICHP) Registry at Walter Reed Bethesda. **Methods:** Between October 2011 and April 2016, consecutive senior leaders, defined as E-7 and above, and O-5 and above, entering the Integrative Cardiac Health Project Registry (a 12-month prospective CVD risk reduction program) were assessed with validated behavioral questionnaires, anthropometrics and CVD-relevant laboratory tests. Blood pressure was categorized as normal (≤120/80 mmHg), pre-hypertensive (>120/80 and <140/90) and hypertensive (≥140/90). Fasting blood glucose (FBG) was categorized as normal (<100 mg/dL), pre-diabetes (100 to ≤140), or diabetes (≥140). Two sample t-tests evaluated differences between active duty (AD) members and retirees. **Results:** Among 117 senior leaders (35% AD, mean age±SD 59.6±11.3 years, 73% men, 82 Whites, 27 Blacks, 3 Latinos, 5 others), previously diagnosed CVD risks were common: lipid disorders 71%, hypertension 54%, depression 26%, anxiety 23%, heart disease 13%, prediabetes 35%, diabetes 5%, and obstructive sleep apnea (OSA) 44%. While only 3% were current smokers, 26% were former smokers. Framingham risk score for heart disease showed moderate risk in 10% and high risk in 28%. Mean body mass index (BMI) was 30.2±5.8 kg/m2 (obese category) with only 21% in normal BMI range. Mean percent body fat was 31.1±8.8. Mean blood pressure was 128/80 mmHg but 22% were currently measured to have systolic hypertension, 16% had diastolic hypertension, 53% had systolic prehypertension and 32% diastolic prehypertension. Mean fasting blood glucose was 100.2±15.7 mg/dL (prediabetes), and 5% had values diagnostic of diabetes and 35% prediabetes. Questionnaire screening found 49% at high risk for OSA in those not already diagnosed with OSA. From questionnaires, 19% admitted to being depressed now. Total sleep time averaged 6.3±1.4 hours per night and 62% slept less than the recommended 7 hours, 34% less than 6 hours, and 12% less than 5 hours. For these catalogued conditions, AD were not different from retirees except for age (49.2±6.8 vs 65.1±9.1, p<0.001), dyslipidemia (59% vs 78%, p=0.03), diagnosed diabetes (2% vs 14%, p=0.04) and prediabetes (22% vs 42%, p=0.047). **Conclusion:** Senior leaders in the military, including those on active duty, have numerous reversible risk factors for CVD. These risk factors persist despite ready access to primary care and wellness programs. Systematic approaches for therapeutic lifestyle change and intensified medical interventions are urgently needed to prevent the development of CVD and to reverse this leading cause of death and disability among military leaders.

Eliasson A, Kashani M, Walizer E, Fuller C, Tschiltz N, Halsey J, Turner E, Grunewald M, Engler R, Villines T, Vernalis M. Improving health behaviors in military senior leaders. (Abstract accepted AMSUS 2017)

Background: Senior leaders in the military serve as role models for junior officers and enlisted members. Role models set the example for health behaviors such as staying tobacco free, eating healthfully, exercising regularly, properly managing stress levels, and getting adequate sleep. Each of these health domains is critical for personal health outcomes as well as for the health and readiness of the total force and should be exemplified by our military leaders. We sought to catalogue health behaviors among senior leaders attending the Integrative Cardiac Health Project (ICHP) Registry at Walter Reed Bethesda. **Methods:** Between October 2011 and April 2016,

consecutive senior leaders, defined as E-7 and above, and O-5 and above, entering the ICHP Registry (a 12-month prospective CVD risk reduction program) were assessed with validated behavioral questionnaires in the domains of diet, exercise, stress and sleep. Two sample t-tests evaluated differences between active duty (AD) members and retirees. **Results:** Among 117 senior leaders (35% AD, mean age±SD 60.0±7.3 years, 73% men, 82 Caucasian, 27 African- American, 3 Hispanic, 5 others), only 3% were current smokers, 26% were former smokers.
Mean dietary score (Rate-Your-Plate) was 60.7±7.6 of 78 points but 45% showed unhealthy dietary choices. Mean exercise was 146±116 minutes/week, below the recommended150 minutes/week. Mean perceived stress level was 18.7±8.5 of 65 points but 15% indicated increased stress levels and another 15% showed extreme stress. Total sleep time averaged 6.3±1.4 hours per night and 62% slept less than the recommended 7 hours, 34% less than 6 hours, and 12% less than 5 hours. For each of these health behaviors, there was no statistical difference between active duty members and retirees. **Conclusions:** Senior leaders in the military set a fairly good example for smoking. However, there are substantial opportunities to improve dietary choices, exercise habits and stress management and sleep behaviors. Sleep behaviors especially do not conform to recommendations with two thirds of leaders getting less than the recommended total sleep time. Systematic approaches for health behavior improvement are needed to improve outcomes and readiness, especially in senior leaders who serve as role models for junior officers and enlisted members.

Kashani M, Eliasson A, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Tailored prediabetes program improves cardiovascular risk. [Abstract accepted 67th Annual Scientific Session of the American College of Cardiology (ACC 2018) Scientific Session, Orlando, FL, 10-12 March 2018.]- *Winner of Best CV team Award at ACC*

Background: Although prediabetes is associated with increased cardiovascular disease (CVD) risk, it is not often targeted in CVD prevention programs. We sought to evaluate the impact of a tailored prediabetes program to reverse prediabetes and lower CVD risk. **Methods:** Consecutive subjects of the Integrative Cardiac Health Project Registry, a 12-month CVD Risk Reduction Program completed validated questionnaires focusing on nutrition, exercise, stress and sleep improvement. Subjects were assessed for CVD risk and coached for lifestyle behavior change. Excluding diabetics, subjects were categorized as prediabetic (glucose > 100 mg/dL or HbA1C > 5.7%) or not prediabetic. Differences were analyzed using t-test. **Results:** Of 566 subjects (74% women, mean age 55.6 ± 12.5 years, 64% White, 28% Black, 8% Other), 311 (55%) had prediabetes (mean HbA1C 5.9%; glucose 98 mg/dL at baseline). Subjects with prediabetes had statistically more frequent diagnoses of sleep apnea 29% vs 19%, hypertension 56% vs 34%, dyslipidemia 76% vs 65%, higher BMI 30.5 vs. 28.3 kg/m2 and greater carotid intima medial thickness 0.79 vs 0.71 mm. Of prediabetics, 236 (76%) improved in all behavioral domains and reverted to normal values in either glucose or HbA1C.

Behavioral Domain (n=311)	Baseline	12-month	p value
Rate Your Plate (of 78 points)	62.0 ± 7.3	66.6 ± 2.0	<0.0001
Aerobic Exercise Time (min/week)	147.6 ± 126.2	205.6 ± 117.6	<0.0001
Perceived Stress Scale (of 56 points)	20.6 ± 8.33	18.0 ± 7.81	<0.0001
Pittsburg Sleep Quality Index (of 21 points)	6.9 ± 3.9	5.6 ± 3.7	<0.0001

Conclusion: Prediabetic patients require a comprehensive tailored program to target their pathophysiology. Our integrative program encouraged improvements in nutrition, exercise, stress and sleep behaviors showing promise for prediabetes reversal and overall CVD health.

Kashani M, Eliasson A, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Reaching behavioral goals with an integrative cardiovascular health model. [Abstract accepted to the 2018 International Congress on Integrative Medicine & Health (ICIMH), Baltimore, MD, 8-11 May 2018.]

Purpose: Cardiovascular disease (CVD) is the number one killer in westernized countries. Therapeutic lifestyle change targeting CVD risk is a first-line intervention. The Integrative Cardiac Health Project is a prospective Registry of patients attending a 12-month lifestyle change program encouraging patients to reach behavioral goals in the domains of diet, exercise, stress management and sleep improvement. We report outcomes of this integrative lifestyle change program. **Methods:** At baseline and 12 months, patients completed validated questionnaires assessing their lifestyle behaviors. Goals for the four behavioral domains, established by clinical guidelines, were: nutrition (Rate-Your-Plate >61 of 78 points), exercise (continuous aerobic exercise per week >150 minutes), stress (Perceived Stress Scale >23 of 56 points), and sleep (total sleep time >7 hours per 24 hours and sleep quality by Pittsburgh Sleep Quality Index <6 of 21 points). The intervention consisted of a half day educational workshop describing the interplay of the four domains on health outcomes, a hands-on stress reduction technique, and a healthy cooking demonstration. Over the subsequent 6 to 12 months, patients attended four team coaching sessions meeting with specialty providers during which personal behavioral goals were identified along with strategies to attain the goals. Differences in behaviors from baseline to completion of the program were assessed with chi square analysis. **Results:** Of 241 consecutive program completers (49% men, age 57.9 ± 12.9 years, 161 White, 54 Black, 9 Hispanic, 4 Asian, 13 other), behavioral improvements were seen in all domains. Observed behavioral changes remained statistically significant even after correction for multiple comparisons. **Conclusions:** An integrative approach to: 1) establish personal health goals and 2) identify practical lifestyle change strategies, empowers patients to reach goals in critical behavioral domains even for behaviors that have been proven historically difficult to affect. These behavioral changes set the stage for improved cardiovascular health.

The following major activities have been accomplished in the past period:

Study 1: Cardiovascular Health Program (CHP) Registry

The following activities have been accomplished during the project period:

1. Reviewed by Scientific Advisory Board and approved 9/28/17
2. 18 participants consented for registry; prospective enrollment=206
3. 328 participants on-site visits (18 new participants, 310 follow-on program visits)
4. 444 coaching calls (off-site program) made by clinical team experts
5. Streamlined outcome assessment with 100% quality control (QC) process implemented. Process working well to reduce backlog; See QC data tables below

6. Input of baseline data in RIMS for those participants who did not have metric data entered when starting program; 100% quality control process put in place
7. Enhancement of prediabetes track to improve our conversion from prediabetes to normal glucose levels
8. Development of strategies within our four pillar program to target lowering insulin levels for CVD prevention and also cancer and brain health benefit
9. Work begun to establish a "setting the stage" initiative for pre-emptive behaviors in the military setting
10. Continuing to develop patient tools, such as military-specific cookbooks to accommodate the busy and high stress environment
11. Preparation begun to modify ICHP's Research Information Management System to accept and analyze personalized behavioral approaches for health behavior change
12. Development &/or updating of program marketing materials to reflect current mission/ vision (i.e. ICHP program brochure, onsite ICHP model display boards, patient handout materials)
13. Clinical outcomes on Active Duty and Retired Senior Leaders who have participated in CHP in preparation for MHS Conference abstract submission and manuscript publication
14. ICHP invited Dr. Kashani to review manuscript per editor invitation as subject matter expert in family history as CVD risk factor for *European Journal of Clinical Investigation*

Quality Control Process Results:

Table 1. Demographics and Comorbid Illnesses

	all Subjects n=648	men n=276 (43%)	women n=372 (57%)	p value*
Age±SD, years	55.4±12.5	56.6±12.8	54.5±12.2	0.03
Race				
White	62%	69%	57%	0.43
African-American	29%	23%	34%	
Hispanic	4%	4%	4%	
Asian	2%	1%	2%	
Other	3%	3%	3%	
Family History of CVD	75%	73%	77%	0.38
Active Smoker	4%	6%	3%	0.17
Comorbid Illnesses				
Dyslipidemia	71%	81%	65%	0.054
Hypertension	49%	55%	45%	0.09
Obstructive Sleep Apnea	25%	38%	15%	0.001**
Depression	23%	20%	27%	0.96
Anxiety	21%	17%	25%	0.78
Diabetes Mellitus	11%	10%	12%	0.83
Coronary Artery Disease	11%	20%	5%	0.001**
Stroke	2%	3%	2%	0.46

*p-value for t-test between men and women

**statistically significant after correction for multiple comparisons

Table 2. Anthropometric data

	all BMI n=648	**all WC_{men} n=276**	**all WC_{women} n=372**	**all Sys BP n=648**	**all Dias BP n=648**
Pre	30.5±5.5	102.6±12.6	97.6±14.1	128±14	80±9
Post	29.4±5.4	101.0±11.9	95.0±14.0	125±14	78±9
p value*	<0.001	<0.001	<0.001	<0.001	<0.001
#, % improved	391, 60%	173, 63%	262, 70%	370, 57%	356, 55%
	BMI≥25 n=535, 83%	**WC_{men}>103 n=126, 46%**	**WC_{women}>89 n=231, 62%**	**Sys BP>120 n=440, 68%**	**Dias BP>80 n=290, 45%**
Pre	31.5±4.8	113.6±8.9	105.9±10.6	135±11	88±4
Post	30.8±4.9	110.8±8.9	102.7±11.3	129±13	82±8
p value*	<0.001	<0.001	<0.001	<0.001	<0.001
#, % improved	335, 63%	89, 71%	170, 74%	305, 69%	205, 71%
#, % now normal	34, 6%	19, 15%	31, 13%	130, 30%	129, 44%

BMI = body mass index in kg/m^2, WC = waist circumference in cm, Sys BP = systolic blood pressure in mm Hg, Dias BP = diastolic blood pressure in mm Hg

Table 3. Laboratory Data

	all Tot Chol n=648	**all LDL n=648**	**all Trig n=648**	**all FBG** n=574**	**all HOMA** n=574**
Pre	187.0±42.8	111.2±34.8	116.6±79.7	93.6±10.1	2.7±1.9
Post	180.6±38.9	105.5±32.8	104.59±5	92.4±10.4	2.6±2.0
p value*	<0.001	<0.001	<0.001	=0.002	=0.013
#, % improved	362, 56%	354, 55%	377, 58%	300, 52%	320, 56%
	Tot Chol≥200 n=246, 38%	**LDL≥100 n=389, 60%**	**Trig≥150 n=134, 21%**	**FBG≥100 n=141, 22%**	**HOMA≥2.8 n=211, 33%**
Pre	229.1±29.7	133.0±25.3	225.9±111.8	106.8±7.2	4.7±1.9
Post	206.7±35.7	119.0±29.3	165.2±84.9	100.7±10.1	3.9±2.9
p value*	<0.001	<0.001	<0.001	<0.001	<0.001
#, % improved	181, 74%	251, 65%	115, 86%	102, 72%	149, 71%
#, % now normal	105, 43%	90, 23%	73, 54%	72, 51%	74, 35%

*p value for comparisons between Pre and Post intervention values

**patients with diabetes excluded

Tot Chol = total cholesterol in mg/dL, LDL = low density lipoprotein in mg/dL, Trig = triglycerides in mg/dL, FBG = fasting blood glucose in mg/dL, HOMA = homeostatic model assessment in mass units mg/dL

Table 4. Antihypertensive Medications in All Patients (n = 648)

Any BP Medication (n = 310 of 648, 52%)	BP Medications Taken	n (%)
One Agent (n = 126, 41%)	Diuretic	37 (29%)
	ACEi	32 (25%)
	β Blocker	23 (18%)
	ARB	16 (13%)
	α Blocker	9 (7%)
	Other	9 (7%)
Two Agents (n= 106, 34%)	Diuretic-ACEi	20 (19%)
	Diuretic-ARB	17 (16%)
	Diuretic-β blocker	14 (13%)
	Diuretic-CCB	6 (6%)
	ACEi-β blocker	10 (9%)
	ACEi-CCB	7 (7%)
	ARB-Other	16 (15%)
	Other	14 (13%)
Three Agents (n = 60, 19%)	Diuretic-ACEi-β blocker or Diuretic-ARB-CCB	60 (19%)
Four or More Agents (n = 18, 6%)	Usually α Blocker added	18 (6%)
During the 12 month intervention, 597 of 648 patients (92%) had no changes in BP medication; 19 (3%) decreased or stopped BP medication; 32 (5%) increased or started BP medication.		

BP = blood pressure, ACEi= angiotensin, β blocker = beta blocker, ARB = angiotensin receptor blocker, α Blocker = alpha blocker, CCB = calcium channel blocker

Table 5. Dyslipidemia Medications in All Patients (n = 648)

Any Lipid Medication (n = 248 of 648, 38%)	Lipid Medications Taken	n (%)
One Agent (n = 205, 83%)	Statin	193 (94%)
	Niacin	5 (2%)
	Fibrate	4 (2%)
	Other	3 (1%)
Two Agents (n= 39, 16%)	Statin-ezetimibe	19 (49%)
	Statin-niacin	16 (41%)
	Statin-fibrate	4 (10%)
Three Agents (n = 4, 1%)	Statin- ezetimibe-niacin	4 (1%)
During the 12 month intervention, 584 of 648 patients (90%) had no changes in lipid medication; 18 (3%) decreased or stopped lipid medication; 46 (7%) increased or started lipid medication.		

Statin = HMG-CoA reductase inhibitor

Table 6. Diabetes Medications in All Patients (n = 648)

Any Diabetes Medication (n = 56 of 648, 9%)	Diabetes Medications Taken	n (%)
One Agent (n = 31, 55%)	Metformin	25 (81%)
	Pioglitazone	3 (10%)
	Glipizide	1 (3%)
	Insulin	1 (3%)
	DPP4	1 (3%)
Two Agents (n= 19, 34%)	Metformin-glipizide	9 (47%)
	Other	10 (53%)
Three Agents (n = 6, 11%)	Multiple regimens	na
During the 12 month intervention, 626 of 648 patients (10%) had no changes in diabetes medication; 4 (1%) decreased or stopped diabetes medication; 18 (3%) increased or started diabetes medication.		

DPP4 = dipeptidyl peptidase 4 inhibitor

Table 7. Antidepression Medications in All Patients (n = 648)

Any Antidepression Medication (n = 100 of 648, 15%)	Antidepression Medications Taken	n (%)
One Agent (n = 74, 74%)	SSRI	30 (41%)
	SNRI	12 (16%)
	TCA	12 (16%)
	SARI	6 (8%)
	NDRI	6 (8%)
	Other	3 (4%)
Two Agents (n= 21, 21%)	SSRI-plus other	na
Three Agents (n = 5, 5%)	Various regimens	na
During the 12 month intervention, 618 of 648 patients (95%) had no changes in antidepression medication; 10 (2%) decreased or stopped antidepression medication; 20 (3%) increased or started antidepression medication.		

SSRI = selective serotonin reuptake inhibitor, SNRI = serotonin-norepinephrine reuptake inhibitor, TCA = tricyclic antidepressant, SARI = serotonin antagonist and reuptake inhibitor, NDRI = nicotine and dopamine reuptake inhibitor.

Table 8. Blood Pressure, Lipids, Glucose, HOMA for Patients with <u>No Change in Medication during Intervention</u>

	all Sys BP n=505	**all Dias BP n=505**	**all Tot Chol n=505**	**all LDL n=505**	**all Trig n=505**	**all FBG* n=456**	**all HOMA* n=456**
Pre	127±13	79±9	186.8±41.5	111.2±34.91	114±82.1	96.5±17.8	2.9±2.2
Post	125±13	77±9	181.2±38.9	105.6±32.1	104±60.2	94.9±17.2	2.7±2.3
p value	=0.002	<0.001	0.0001	<0.0001	=0.0001	=0.01	=0.002
#, % improved	296, 59%	284, 56%	282, 56%	271, 54%	285, 56%	269, 53%	286, 57%
	Sys BP>120 n=343, 68%	**Dias BP>80 n=217, 43%**	**Tot Chol≥200 n=188, 37%**	**LDL≥100 n=307, 61%**	**Trig≥150 n=99, 20%**	**FBG≥100* n=109, 24%**	**HOMA≥2.8* n=165, 36%**
Pre	135±10	88±6	229.1±24.7	132.4±26.0	217.1±68.9	107.3±7.0	4.6±1.9
Post	129±13	82±8	209.1±34.2	119.4±28.9	161.7±80.7	100.6±10.5	3.6±1.8
p value	<0.001	<0.001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
#, % improved	242, 71%	159, 73%	137, 73%	195, 64%	84, 85%	79, 72%	118, 72%
#, % now normal	104, 30%	102, 47%	73, 39%	65, 21%	52, 53%	55, 50%	62, 38%

* p value for comparisons between Pre and Post intervention values

**patients with diabetes excluded

Sys BP = systolic blood pressure in mm Hg, Dias BP = diastolic blood pressure in mm Hg, Tot Chol = total cholesterol in mg/dL, LDL = low density lipoprotein in mg/dL, Trig = triglycerides in mg/dL, FBG = fasting blood glucose in mg/dL, HOMA = homeostatic model assessment in mass units mg/dL

Table 9. Lifestyle Behavior Change (Baseline to Outcome)

Lifestyle Behaviors	Baseline (mean score, % at goal)	Outcome (mean score, % at goal)	p value	% of Subjects Improved from Baseline
Rate-Your-Plate Dietary Score (26 to 78 points)	60.9±7.4 (53%)	66.6±6.2 (86%)	<0.0001	85%
Exercise Time (≥150 minutes/week)	150.2±138.4 (44%)	223.7±182.4 (66%)	<0.0001	65%
Perceived Stress Score (0 to 56 points)	20.9± 8.7 (65%)	17.4±8.1 (79%)	<0.0001	64%
Pittsburg Sleep Quality Index (0 to 21 points)	7.1±3.9 (28%)	2.9±3.6 (49%)	<0.0001	61%
Sleep Duration (hours/night)	6.3±1.3 (41%)	6.6±1.2 (50%)	<0.0001	44%
Epworth Sleepiness Score (0 to 24 points)	8.8±4.9 (64%)	7.4±4.6 (77%)	<0.0001	57%
Fatigue Score (0 to 10 points)	4.3±2.4 (53%)	3.4±2.3 (70%)	<0.0001	53%

Study 2: Assessing Risk Factors for Cardiovascular Disease in Individuals with Major Injury (With or Without Amputation) versus No Injury

The following activities have been accomplished during the project period:

1) This protocol was reviewed by the ICHP Scientific Advisory Board and approved 9/28/17
2) New WRNMMC dietetic interns participated in recruitment/enrollment as part of their various clinical rotations.
3) Total enrollment = 100
4) ICHP continued to support CV specific data collection for subjects, specifically the collection and reading of EKGs.
5) Study underwent a post-approval compliance & monitoring audit conducted WRNMMC DRP in December 2017; ICHP assisted in the preparation work.
6) Annual Continuing Review was approved by WRNMMC DRP as of 23 January 2018; acknowledged by MRMC HRPO on 15 February 2018.

Study 3: CHP Cognitive-Behavior Therapy for Insomnia (CHP CBT-I) Study

The following activities have been accomplished during the project period:

1) Reviewed by Scientific Advisory Board and approved 9/28/17
2) No new enrollment this past year due to ICHP-CHP enrollment issues (low census at WRNMMC))
3) The annual Continuing Review was approved by WRNMMC DRP on 25 May 2017 with HRPO acknowledgement as of 28 June 2017. USUHS provided concurrence on 28 September 2017.

4) 2 USUHS students (CPT Elizabeth Belleau and LTJG Julia Garza) identified for delivery of CBT intervention and added as AIs to the study; modification approved by WRNMMC Department of Research Programs on 17 July 2017 with USUHS concurrence on 18 August 2018.
5) MAJ Ware reassigned out of area to complete doctoral program requirements and LTJG Lee (USUHS student) added to protocol as Associate Investigator to replace MAJ Ware in delivering CBT intervention when recruitment resumed; however, no new enrollment since 1st quarter due to ICHP-CHP enrollment issues as discussed above.
6) LTJG Lee completed her USUHS work this summer; 2 new USUHS students identified for delivery of CBT intervention once enrollment resumes. These 2 students will be added to protocol as AIs in the next quarter.
7) ICHP kept communication lines open with MAJ Ware, LTJG Lee and new USUHS students during this transition process.
8) Annual Continuing Review (for expiration on 7 Jun 17) submitted to WRNMMC IRB via eIRB system on 8 Apr 17; pending approval.
9) Amendment approved by WRNMMC IRB on 23 May 16 to add LTJG Lee as an AI, inclusion of new HIPAA preparatory research provision, and edits to correct previous inconsistencies in the protocol.

Study 4: UPLIFT (Ultra-Personalized Laboratory-Risk Intervention For Treatment) for Cardiovascular Health: Cardiovascular (CV) Disease) Risk Study

The following activities have been accomplished during the project period:
1) Reviewed by Scientific Advisory Board and approved 9/28/17
2) Part 1 submission – amendment to approved IHB protocol; approved 15 Nov 2017 by the WRNMMC DRP (100% complete); approval documents forwarded to HRPO for 2nd level review in December, acknowledgement pending. Waiting for WRMNNC start letter.
3) Part 2 submission - protocol development (80% complete).
    a. Finalized eligibility criteria.
    b. Finalized screening protocol.
    c. Finalized consent forms & human subjects protocol content.
    d. Finalized survey/questionnaire packet.
    e. Pathology Impact Statement obtained.
    f. Letters of support from collaborators obtained.
    g. Identified scientific reviewer; awaiting scientific review.
4) Data sharing agreement submitted between IHB and SBE signed by WRNMMC DRP and forward to DHA Privacy Officer.
5) Data sharing agreement between SBE, USAMRMC and HJF near completion; under review
6) Coordinate with Fort Detrick [Systems Biology Enterprise (SBE), Integrative Medicine Division site for data sharing agreements and CRADA between SBE, USAMRMC, HJF and WRNMMC (80% complete)
7) Joint agreements between ABBOTT LABS: ABBOTT specific application revised
8) Joint agreements between LabCorp (Liposciences Division) and HJF: redirected to be a fee for service contract – pending

9) Revised drafts of letters of support have been developed with Oklahoma Medical Research Foundation (OMRF) as well as the University of Oklahoma Science Center (UOHSC) for the purpose of scientific collaboration/consultation in support of ICHP's UPLIFT research initiatives/protocol development/data analysis planning that include autoimmunity and systemic inflammation as a part of the risk factors relevant to CVD risk. ICHP submitted approval request to USAMRAA on 18 April 2018 to add collaboration work to the current approved SOW. A fee for service contracting vehicle will have to be developed.
10) Coordinated with Army Analytic Unit for MHS database surveillance strategies and costs, letter of support: Letter of support completed.
    a. Refinements in the final agreement for UPLIFT Part 2 will be delayed until data collection has been completed for the initial partial analysis (at least 2-3 years into the study launch).
11) Establish revised Data Dictionary and Data Management Plan (80% complete)
12) Complete and review data dictionary elements for data repository and analysis planning (75% complete)
13) Participated in multiple meetings with WRNMMC DRP Business Cell to discuss the initiation and execution of necessary agreements for both Part 1 and Part 2 and what is required to move forward with Part 1 protocol preparatory work.
14) Develop cost-effective database management for new protocol (e.g., modify existing databases for use in current protocol and/or develop new collaborations to support complex data management/analyses-e.g. SysBioCube Program-see also https://sysbiocube-abcc.ncifcrf.gov/) (50% complete)
    a. REDcap solution for granular survey data collection via electronic link is under development given the fact that the primary database may be modified till 1 year after the launch of the study given logistics and contracting issues for those changes.
15) Coordinate with Fort Belvoir site for material transfer agreements (MTAs) and data sharing/clinical trial agreements (CTAs) submission (10% complete)
    a. This action is ON HOLD because of budget and personnel limitations that make supporting more than one site NOT feasible.
16) Dr. Emily Brede, Clinical Research Coordinator, hired and on-boarded primarily in support of UPLIFT Part 1 and Part 2. Training completed.
17) Medical Laboratory Technician position posted. This person will be responsible for obtaining, processing, storing and tracking blood and saliva samples for UPLIFT and a future ICHP biorepository.
18) Coordinated with Fort Detrick [Systems Biology Enterprise (SBE), Integrative Medicine Division site for data sharing agreements and CRADA between SBE, USAMRMC, HJF and WRNMMC (80% complete)
19) Joint agreements between ABBOTT LABS, HJF, MRMC, WRNMMC (70% complete)
20) Joint agreements between LabCorp (Liposciences Division), HJF, MRMC, WRNMMC (70% complete)
21) Coordinated with Army Analytic Unit for MHS database surveillance strategies and costs, letter of support (50% complete)
22) Established Data Dictionary and Data Management Plan (85% complete)
23) Complete and review data dictionary elements for data repository and analysis planning (75% complete)

24) Developed cost-effective database management for new protocol (e.g., modify existing databases for use in current protocol and/or develop new collaborations to support complex data management/analyses-e.g. SysBioCube Program-see also https://sysbiocube-abcc.ncifcrf.gov/) (35% complete)
25) Coordinated with Fort Belvoir site for material transfer agreements (MTAs) and data sharing/clinical trial agreements (CTAs) submission (5% complete) Placed on hold.

Resulting activities that are **not protocol specific**:

1) In a pre-brief to Health Affairs, on May 9th, 2018, Dr. Vernalis presented the goals and projects of ICHP to Dr. Rauch. This was received positively.
2) ICHP presented to the Health Readiness Working Group on May 21st, 2018 at the Pentagon. The ICHP approach and scientific projects were approved by JROC.
3) Transition logistics meetings with Dr. Pangaro, Dr. Haigney, Dr. Vernalis and Dr. Kashani continued. General discussions: ICHP history and logistics regarding financials; how to add new USUHS protocols
4) Per Dr. Pangaro, Chief of Medicine USUHS, provided instruction for development of ICHP *Organograph* to depict new ICHP home at USUHS.
5) Per Dr. Pangaro, ICHP provided a "Do, Plan, Dream" presentation in anticipation of transition to USUHS.
6) ICHP program manager hand carried multiple POS' for resubmission at Credentials office 11/18
7) Phone call with Dr. Rauch 11/8/18, to provide update and relating concerns that USUHS had intentions of repurposing ICHP Congressionally mandated monies to change ICHP's scientific direction to their own interests WITHOUT including any input from ICHP to the USUHS governance board, as promised by them.
8) HJF President assured Dr. Vernalis, after meeting with Dr. Thomas, USUHS president, that ICHP would receive "an impartial review of the program".
9) As a result of a meeting with Dr. Haigney, incoming USU Oversight Director, in August 2018, COL Weina placed an administrative hold on all ICHP protocols without justifiable reasons.
10) COL Chung met with entire ICHP staff and reassured team that transition was moving forward and all positions would transfer to "ICHP 2.0" and ICHP scientists would brief USUHS Governance Board regarding ICHP science details
11) USUHS Governance Board convened privately; there was no representation from ICHP scientists
12) Subsequently, meetings with USUHS halted. COL Chung disengaged from discussions Aug 2018.
13) Officially notified by HJF on 12/4/18 that USUHS never intended to provide ICHP governance and that historical ICHP projects will close as ICHP funds were repurposed for USUHS use.
14) Sent Dr. Rauch an email on 12/6/18 to update him regarding the plan to close ICHP
15) Dr. Vernalis met with ICHP staff regarding intent to close 12/12/18
16) Meeting with WRNMMC DRP (COL Weina) and ICHP 12/13/18 to discuss way forward; ability to analyze registry data and what can be accomplished before 31 March – decision not to pursue analysis due to lack of time to identify a replacement PI for COL Todd Villines, who is retiring from military service.
17) Closure meeting at HJF 12/19/18 – plan for personnel and discussion of what activities needed to be outlined for closure
18) Multiple teleconferences with HJF regarding ICHP close-out plans and procedures.

19) Planned and prepared for transfer of data for DRP review.
20) Continued patient phone calls to notify of ICHP's impending closure.
21) Preliminary discussions regarding bio-sampling handling with Windber.
22) Migration, security practices for vulnerability testing with RIMS.
23) Initial ICHP budget for close-out devised.
24) Letter drafted to communicate ICHP closure to Scientific Advisory Board.
25) NEC meeting regarding termination of security plan for migration of the research information management system
26) Lipoprotein (a) and Obesity manuscripts under review.

Regulatory Protocol and Activity Status (if applicable).

(a) ***Human Use Regulatory Protocols***

TOTAL PROTOCOLS: 7 human subject research protocols have supported the accomplishment of the SOW.

Protocol (1 of 7 total):

Protocol [HRPO Assigned Number]: unassigned as yet.

Title: Cardiovascular Health Program (CHP) Study ***Companion Protocol to CHP Registry (new protocol – Study 1A)***

Submitted to and Approved by: Submitted to WRNMMC DRP on 29 June 2018.

Status: Placed on administrative hold by WRNMMC DRP as of 10 Aug 18.

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review: Nothing to report.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation: Nothing to report.

Protocol (2 of 7 total):

Protocol [HRPO Assigned Number]: A-19322.2

Title: Cardiovascular Health Program (CHP) Registry (**Study 1B**)

Target required for clinical significance: NA (registry protocol)

Target approved for clinical significance: up to 5000

Status: WR IRB approved protocol closure on 4 March 2019; awaiting HRPO acknowledgement.

(i) Number of subjects recruited/original planned target: 1383/5000
Number of subjects screened/original planned target: 1383/5000

Number of patients enrolled/original planned target: 1164/5000 *[231 have prospectively consented]; enrollment placed on hold in August 2017 per WRNMMC DRP compliance audit.*
Number of patients completed/original planned target: 648*/5000

NOTE:
*6-month onsite program finishers at WRAMC/WRNMMC

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review: Nothing to report.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation: Nothing to report.

Protocol (3 of 7total):

Protocol [HRPO Assigned Number]: unassigned as yet

Title: The Integrative Cardiac Health Project (ICHP) Registry and Biospecimen Repository (ICHP BioBank) - **(new protocol - Study 1C)**

Target required for clinical significance:

Target approved for clinical significance:

Submitted to and Approved by: Not yet submitted.

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review: Nothing to report.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation: Nothing to report.

Protocol (4 of 7total):

Protocol [HRPO Assigned Number]: A-19322.1

Title: Assessing Risk Factors for Cardiovascular Disease in Individuals with Traumatic Amputations

Target required for clinical significance: 369

Target approved for clinical significance: 405

Submitted to and Approved by:

- Modification to revise data collection forms – approved by WRNMMC IRB on 29 Nov 18.
- Modification to remove ICHP investigators – approved by WRNMMC IRB on 6 Dec 18.

Status:

(i) Number of subjects recruited/original planned target: 97/405
Number of subjects screened/original planned target: 97/405
Number of patients enrolled/original planned target: 97/405

Number of patients completed/original planned target: 6/405

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review: Nothing to report.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation: None.

Protocol (5 of 7 total):

Protocol [HRPO Assigned Number]: A-19322.3

Title: Integrative Cardiac Health Project Cognitive-Behavior Therapy for Insomnia (ICHP CBT-I)

Target required for clinical significance: 44

Target approved for clinical significance: 76

Submitted to and Approved by: NA

Status:

(i) Number of subjects recruited/original planned target: 23/76
Number of subjects screened/original planned target: 23/76
Number of patients enrolled/original planned target: 6/76
Number of patients completed/original planned target: 4/76

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:

- HRPO acknowledgement of closure received 25 Oct 18.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation: None.

Protocol (6 of 7 total): **UPLIFT Part 1 (Modification to an existing WRNMMC approved protocol – PI: Dr. Limone Collins, Immunization Healthcare Branch)**

Protocol [HRPO Assigned Number]: A-19322.4

Title: A Pilot Study: Smallpox/Influenza Vaccination and Myopericardial Injury/Inflammation

Target required for clinical significance:

Target approved for clinical significance:

Submitted to and Approved by: HRPO acknowledgement received 16 April 2018.

Status: Awaiting WRNMMC DRP Start Letter for modification work.

(i) Number of subjects recruited/original planned target: No new recruitment planned for this study, analysis of existing samples only.
Number of subjects screened/original planned target: No new recruitment planned for this study, analysis of existing samples only.
Number of patients enrolled/original planned target: No new recruitment planned for this study, analysis of existing samples only.
Number of patients completed/original planned target: No new recruitment planned for this study, analysis of existing samples only.

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review: Modification to remove ICHP investigators submitted and pending WRNMMC IRB approval.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation: Nothing to report.

Protocol (7 of 7 total): **UPLIFT Part 2 (new protocol).**

Protocol [HRPO Assigned Number]: unassigned as yet.

Title: UPLIFT (***U***ltra-***P***ersonalized ***L***aboratory-Risk ***I***ntervention ***F***or ***T***reatment) for Cardiovascular Health: Cardiovascular (CV) Disease (CVD) Risk Study

Target required for clinical significance:

Target approved for clinical significance:

Submitted to and Approved by: Submitted to WRNMMC IRB on 14 June 2018; initial administrative revisions submitted to WRNMMC DRP on 7 August 2018.

Status (this quarter): Administratively withdrawn by WRNMMC DRP as of 23 Aug 18.

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review: Nothing to report.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation: Nothing to report.

27) **Use of Human Cadavers for Research Development Test & Evaluation (RDT&E), Education or Training**

No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW).

(c) Animal Use Regulatory Protocols

No animal use research will be performed to complete the Statement of Work.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of

expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

During the period of performance, the project provided clinical staff with numerous opportunities for professional development in their respective fields of expertise. Opportunities existed not only to disseminate the project's research findings, but also to expand individual knowledge relating to current trends and findings in the scientific community. A listing of the conferences and training opportunities attended by ICHP clinical staff is outlined below.

- The Medical Director, Associate Medical Director and Senior Physicians Consultants attended specialty conferences not only to present ICHP scientific findings, but also to attend scientific sessions in their respective areas of expertise:
    - American Heart Association's 2017 Scientific Sessions Quality of Care and Outcomes Research (QCOR)
    - Preventive Cardiovascular Nurses Association (PCNA) 23rd Annual Symposium
    - WRNMMC Department of Research Programs, 2017 Research and Innovation Month
    - WRNMMC Department of Research Programs, 2017 Spring Research Summit (2 presentations)
    - American Thoracic Society (ATS) 2017 Meeting
    - Associated Professional Sleep Societies (APSS) 2017 Scientific Session
    - Society for Nutrition Education and Behavior
    - Military Health System Research (MHSRS) Symposium 2017
    - 66th Annual Scientific Session of the American College of Cardiology (ACC 2018) Scientific Session
    - AMSUS (Association of Military Surgeons of the United States), The Society of Federal Health Professionals) Annual Meeting (November)
- The ICHP Dietitians (2), the Exercise Health Coach and the Stress Reduction Specialist successfully completed the training necessary to sit the first National Health Coach certification. All 4 staff members passed this national certification exam and received their credentials as "National Board Certified Health & Wellness Coach (NBC-HWC)".

How were the results disseminated to communities of interest?

ICHP has disseminated findings to communities of interest in the following manner:

1) Publications/presentations to the American Heart Association, the Preventive Cardiovascular Nurses Association, the American Thoracic Society, the Associated Professional Sleep Societies, the Military Health System Research Symposium, the Society of Nutrition Education and Behavior and the WRNMMC Department of Research 2017 Research and Innovation Month as referenced throughout this report.
2) Presentation to the American Heart Association
3) Presentation to the American College of Cardiology and the Preventive Cardiovascular Nurses Association
4) Briefing to the Joint Staff as part of the Competency Based Assessment document
5) Presentation to the WRNMMC Advanced Nursing Practice Group on the Integrative Cardiac Health Project's Cardiovascular Health Program.

6) Coordination Meeting with Systems Biology Enterprise staff in support of ICHP protocols, enhanced data analysis, storage, collaboration opportunities
7) Presentation to IHB Chief of Vaccine Research regarding science relevant to collaboration with ICHP.
8) Presentation to Amputee Center, WRNMMC, on cardiovascular disease risk in injured wounded warriors
6) USUHS Cardiology Meeting: explore collaboration regarding atrial fibrillation risk and lifestyle changes
7) Presentation to COL Brian Hemann, Chief, Department of Medicine, WRNMMC
8) Presentation to COL Matthew Jezior, Chief of Cardiology, WRNMMC
9) Presentation to the Dr. Mark Haigney, Chief of Cardiology, Uniformed Services University
10) Presentation to Dr. Louis Pangaro, Chief of Medicine, Uniformed Services University
11) Presentation to Dr. Yvonne Maddox, Vice President for Research, Uniformed Services University
12) Presentation to Department of Nursing, Uniformed Services University
13) Cardiovascular Disease Risk and ICHP Research for Internal Medicine Staff at WRNMMC

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Nothing to Report. Program closure.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?

Because of the translational nature of this research, we received guidance from Dr. Rauch, Health Affairs, and MRMC, that our metric of success should be focused on impacting clinical practice guidelines (see Appendix 1). An ICHP manuscript was included as evidence to support the new Clinical Guideline change to include family history as a significant CVD risk factor by the American Heart Association and American College of Cardiology Expert Panel 2013 for New Guidelines in CVD Risk assessment. This evidence also impacted the 2014 Mayo Clinic CVD Risk Reduction Guidelines. ICHP's life management model has been translated into practice complementing the US Army Surgeon General's Executive Health and Wellness Program. Upon request of the OTSG of the Army, ICHP developed a customized model for Executive Health to address issues relevant to our nation's leaders (stress, travel and jet lag). Two interactive and educational workshops along with personalized lifestyle prescriptions for each leader and/or spouse were provided with a high level of satisfaction from the Surgeon General. Lieutenant General Patricia Horoho recognized ICHP's full support of the MHS strategic focus on Health and Wellness, when she stated that "ICHP provides a phenomenal model for initiating integrative wellness programs throughout the military. The evidence-based approach of the ICHP team compliments military medicine." In her testimony to Congress' House Appropriations Committee on April 2, 2014, LTG Horoho stated "ICHP is the only COE that specifically addresses obstacles

related to healthy living in the military. ICHP is synchronized with Army Medicine's movement to improve health."

In addition to above, 2 ICHP manuscripts below were cited as evidence for the following national clinical guidelines in this period alone:

1) Impact: The new national prevention guidelines, American College of Cardiology/American Heart Association, state collecting family history of sudden cardiac death in general practice provides opportunities to personalize risk factor counseling and modification.

Manuscript citation: Kashani M, Eliasson A, Vernalis M, Costa L, Terhaar M. Improving assessment of cardiovascular disease risk by using family history: An integrative literature review. *J Cardiovasc Nurs* 2013 Nov-Dec;28(6):E18-E27.

Guideline Citation: Al-Khatib SM, Yancy CW, Solis P, et al. 2016 AHA/ACC Clinical Performance and Quality Measures for Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. *J Am Coll Cardiol* 2016;Dec 19:[Epub ahead of print].

2) Impact: The new guideline quotes directly from the ICHP manuscript that 'empowering patients early in the timeline of a lifestyle behavior modification program can confer major health benefits.'

Manuscript citation: Kashani M, Eliasson AH, Walizer EM, Fuller CE, Engler RJ, Villines TC, Vernalis MN. Early Empowerment Strategies Boost Self-Efficacy to Improve Cardiovascular Health
Behaviors. *Glob J Health Sci* 2016 Feb 2;8(9):55119. doi: 10.5539/ghis.v8n9p322.

Guideline citation: Barbara Riegel, PhD, Debra K. Moser, PhD, Vice Chair; Harleah Buck, et al., on behalf of the American Heart Association Council on Cardiovascular and Stroke Nursing; Council on Peripheral Vascular Disease; and Council on Quality of Care and Outcomes Research. Self-Care for the Prevention and Management of Cardiovascular Disease and Stroke: A Scientific Statement for Healthcare Professionals From the American Heart Association. *J Am Heart Assoc* 2017 Aug 31;6(9). pii: e006997. doi: 10.1161/JAHA.117.006997.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

a. ICHP's findings have significantly impacted the Wounded Warrior Program at WRNMMC by advancing CV risk assessment and future overall risk estimation in traumatic injury.
b. ICHP's advanced CV risk assessment has been utilized at WRNMMC's Executive Medicine.
c. In collaboration with the DHA Immunization Health Branch, ICHP is now poised to identify the prevalence of preclinical CV risk in an Active Duty pre-deployment population, meeting the CBA intent.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

ICHP has created a lifestyle management program specific to the military which has demonstrated successful results in reducing CV risk and improving overall health of the servicemember.

ICHP has created numerous decision support tools that have impacted national guidelines/knowledge tools/products that will enhance science and medicine.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Below is an outline of events which have culminated in the closing of ICHP:

1. The Walter Reed Bethesda, Department of Research Programs, under the direction of COL Peter Weina, initiated an audit of ICHP in August 2017. This audit found no research regulatory violations. However, COL Weina deemed that ICHP was not officially affiliated with a governmental agency even though ICHP was affiliated with MRMC under the Cooperative Agreement W81XWH-16-2-0007 in response to a BAA; Project Title: Integrative Cardiac Health Project (ICHP). Subsequently, the WRNMMC Command, changed the Rules of Engagement that were in place since ICHP's inception in 2000 for clinical privileging which created a) critical obstructions to hospital privileges/ credentialing and b) prevented ICHP from seeing new research participants in the ICHP assigned site, Building 17, as part of the BRAC. ICHP received no Command guidance for Plans of Supervision despite multiple requests until this fall. In the months prior to the audit, the previous Commander, COL Heimall, facilitated a successful Environment of Care risk assessment to integrate ICHP as a component of WRNMMC. No risk was identified.

2. In May 2018, ICHP pre-briefed Dr. Rauch, Health Affairs and members of his team on the ICHP projects prior to the Health Readiness Working Group (HRWG) meeting on May 21, 2018 at which time the HRWG approved the planned projects. During the pre-brief, Dr. Rauch stated that it would be best if the Uniformed Services University of the Health Sciences (USUHS) had

administrative oversight of ICHP in lieu of USAMRAA for the purpose of scaling ICHP for a precision medicine initiative involving expanded collaborations (e.g., Systems Biology Collaboration Center, Integrative Systems Biology; Immunization Healthcare Branch, Defense Health Agency; Enterprise; etc.) as well as an outreach effort within the MHS.

3. During early transition planning meetings between ICHP Medical Director and Associate Director with the USUHS Chief of Medicine (Dr. Pangaro) and Chief of Cardiology (Dr. Haigney), the discussions evolved into the unilateral decision that USUHS would, once the existing contract expired, launch a new contract with a redesign of the program and change in research direction. There was no opportunity to review the science content of the existing protocols or new next generation protocols in a collaborative manner that was inclusive of the existing ICHP platform and significant infrastructure development. Repeated requests for an impartial, multidisciplinary scientific review process and consideration of inclusiveness of existing ICHP content in the new platform to be evolved were ignored.

4. Second hand information was transmitted to the ICHP leadership that a USUHS Governance Meeting was convened without any input from or discussion with the ICHP senior investigator team. This meeting was chaired by Dr. Haigney who had previously stated that he was not interested in nor did he "believe in" prevention but was only interested in starting a new program called MICOR with a different direction. This meeting confirmed the decision to eliminate the ICHP program in its entirety once the existing contract expired. The plan for USUHS to take over the oversight of ICHP as of 1 October 2018 was ultimately cancelled and delayed until the existing contract of work was ended 31 March 2018.

5. In August 2018, COL Weina and the incoming USUHS Oversight Director decided to place an administrative hold on all ICHP protocols until a plan for moving ICHP forward to USUHS was established. Though ICHP protocols were placed on hold, ICHP has not completely ceased implementing project related tasks as per the approved SOW. The detail information as to which project related tasks that ICHP has been implementing was previously communicated to you (letter dated 9/21/2018). Please be aware that all the 14-project staff have been conducting the tasks at the ICHP office located at WRNMMC.

6. ICHP Medical Director and Associate Director were informed by the Henry M. Jackson Foundation leadership (President Caravalho and Ms. Crosby) that the USUHS President, Dr. Thomas and Dean Kellerman had informed them that USUHS had not intended to continue ICHP and instead were looking for a new, fresh start program This information was new and clarified USUHS intent to not incorporate ICHP into the new expanded program This is contrary to several previous meetings with USUHS in which ICHP staff and protocols were to be absorbed. The meeting was held on December 4, 2018, however other communication between President Caravalho and President Thomas were held months prior concerning a fair and smooth transition of the ICHP program.

7. COL Weina and members of the WRNMMC DRP met with the ICHP executive team and HJF representatives on December 13, 2018 and presented a path to formally analyze and publish ICHP's results. The latter would be impossible to accomplish before the final closure date of March 31, 2019.

Sequence of events that led to decision to closeout historical ICHP:
Letter from Dr. Vernalis to Mr. Meinberg, Grants Officer, USAMRAA

Dear Mr. Meinberg,

I am writing to notify you that we are closing out ICHP by the end of March 31, 2019. We have developed a phase out plan and will begin implementing the tasks in the phase out plan effective January 7, 2019. Please see the attached SOW, budget and budget justification for the detailed plan.

I have summarized below the sequence of events that led to the decision to closeout ICHP.

2. The Walter Reed Bethesda, Director of Research Management Programs, under the direction of COL Peter Weina initiated an audit of ICHP in August 2017. This audit found no research regulatory violations. However, COL Weina deemed that ICHP was not officially affiliated with a governmental agency even though ICHP was affiliated with MRMC under the Cooperative Agreement W81XWH-16-2-0007 in response to a BAA; Project Title: Integrative Cardiac Health Project (ICHP). Subsequently, the WRNMMC Command, changed the Rules of Engagement that were in place since ICHP's inception in 2000 for clinical privileging which created a) critical obstructions to hospital privileges/ credentialing and b) prevented ICHP from seeing new research participants in the ICHP assigned site, Building 17, as part of the BRAC. ICHP received no Command guidance for Plans of Supervision despite multiple requests until this fall. In the months prior to the audit, the previous Commander, COL Heimall, facilitated a successful Environment of Care evaluation to integrate ICHP as a component of WRNMMC.

3. In May 2018, ICHP pre-briefed Dr. Rauch, Health Affairs and members of his team on the ICHP projects prior to the Health Readiness Working Group (HRWG) meeting on May 21, 2018 at which time the HRWG approved the planned projects. During the pre-brief, Dr. Rauch stated that it would be best if the Uniformed Services University of the Health Sciences (USUHS) had administrative oversight of ICHP in lieu of USAMRAA for the purpose of scaling ICHP for a precision medicine initiative involving expanded collaborations (e.g., Systems Biology Collaboration Center, Integrative Systems Biology; Immunization Healthcare Branch, Defense Health Agency; Enterprise; etc.) as well as an outreach effort within the MHS.

4. During early transition planning meetings between ICHP Medical Director and Deputy Director with the USUHS Chief of Medicine (Dr. Pangaro) and Chief of Cardiology (Dr. Haigney), the discussions evolved into the unilateral decision that USUHS would, once the existing contract expired, launch a new contract with a redesign of the program and change in research direction. There was no opportunity to review the science content of the existing protocols or new next generation protocols in a collaborative manner that was inclusive of the existing ICHP platform and significant infrastructure development. Repeated requests for an impartial, multidisciplinary scientific review process and consideration of inclusiveness of existing ICHP content in the new platform to be evolved were ignored.

5. Second hand information was transmitted to the ICHP leadership that a USUHS Governance Meeting was convened without any input from or discussion with the ICHP senior investigator team. This meeting was chaired by Dr. Haigney who had previously stated that he was not interested in nor did he "believe in" prevention but was only interested in starting a new program called MICOR with a different direction. This meeting confirmed the decision to eliminate the ICHP program in its entirety once the existing contract expired. The plan for USUHS to take over the oversight of ICHP as of 1 October 2018 was ultimately cancelled and delayed until the existing contract of work was ended 31 March 2018.

6. In August 2018, COL Weina and the incoming USU Oversight Director decided to place an administrative hold on all ICHP protocols until a plan for moving ICHP forward to USU was established. Though ICHP protocols were placed on hold, ICHP has not completely ceased implementing project related tasks as per the approved SOW. The detail information as to which project related tasks that ICHP has been implementing was previously communicated to you (letter dated 9/21/2018). Please be aware that all the 14-project staff have been conducting the tasks at the ICHP office located at WRNMMC (8901 Wisconsin Ave, Bldg. 17, Suite 2A & Cardiology Clinic- Bldg. 9 Bethesda, MD 20889).

7. ICHP Medical Director and Deputy Director were informed by the Henry M. Jackson Foundation leadership (President Caravalho and Ms. Crosby) that the USUHS President, Dr. Thomas and Dean Kellerman had informed them that USUHS had not intended to continue ICHP and instead were looking for a new, fresh start program This information was new and clarified USUHS intent to not incorporate ICHP into the new expanded program This is contrary to several previous meetings with USUHS in which ICHP staff and protocols were to be absorbed. The meeting was held on December 4, 2018, however other communication between President Caravalho and President Thomas were held months prior concerning a fair and smooth transition of the ICHP program.

8. Dr. Weina and members of the WRNMMC DRP met with the ICHP executive team and HJF representatives on December 13, 2018 and presented a path to formally analyze and publish ICHP's results. The latter would be impossible to accomplish before the final closure date of March 31, 2019.

Sincerely,

Marina Vernalis DO FACC M
Marina Vernalis
Medical Director and PI, ICHP

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Manuscripts:

Sandrick J, Tracy D, Eliasson A, Roth A, Bartel J, Simko M, Bowman T, Harouse-Bell K, Kashani M, Vernalis M. Effect of a counseling session bolstered by text messaging on self-selected health behaviors in college students: A preliminary randomized controlled trial. *JMIR Mhealth Uhealth* 2017;5(5):e67

Ellsworth DL, Costantino NS, Blackburn HL, Engler, RJM, Kashani M, Vernalis MN. Lifestyle modification interventions differing in intensity and dietary stringency improve insulin resistance through changes in lipoprotein profiles. *Obes Sci Pra* 2016 Sep;2(3):282-292. DOI:10.1002/osp4.54. Epub 25 JUL 2016.

Kashani M, Eliasson AH, Walizer EM, Fuller CE, Engler RJ, Villines TC, Vernalis MN. Early empowerment strategies boost self-efficacy to improve cardiovascular health behaviors. *Glob J Health Sci* 2016 Feb 2;8(9):55119. doi:10.5539/ghis.v8n9p322.

Abstracts:

Tschiltz N, Halsey J, Eliasson A, Kashani M, Walizer E, Villines T, Vernalis M. Dietitians in the kitchen impact cardiovascular disease prevention. *J Nutr Educ Behav*. 2017;49(7S1):S34. doi.org/10.1016./j.jneb.2017.05.316.

Eliasson A, Kashani M, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. Prevalence of sleep disturbances and their consequences in patients at risk for cardiovascular disease. *SLEEP* 2017;40:A390.

Eliasson A, Kashani M, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. A novel lifestyle change program identifies and improves cardiovascular risks in middle-aged women. *Am J Respir Crit Care Med* 2017;195:A5376

Kashani M, Eliasson A, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. A single measurable outcome tool for tracking behavioral change. *Circ Cardiovasc Qual Outcomes*. 2017;10:A206

Kashani M, Eliasson A, Fuller C, Walizer E, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Arresting insulin resistance with an integrative health intervention. *J Am Coll Cardiol*. 2017; 69(11S):1853. doi.org/10.1016/S0735-1097(17)35242-7

Kashani M, Eliasson A, Walizer E, Fuller C, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Multidisciplinary cardiovascular team review captures preclinical disease. *J Am Coll Cardiol*. 2017; 69(11S):2103. doi.org/10.1016/S0735-1097(17)35492-X

Eliasson A, Kashani M, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. Targeted behavioral interventions improve disturbed sleep. *SLEEP* 2016;39:A397.

Ellsworth DL, Costantino NS, Blackburn HL, Engler RJM, Vernalis MN. Cardiac interventions differing in lifestyle modification improve insulin resistance through changes in lipoprotein profiles. *Circulation* 2016;133:AP108.

Kashani M, Eliasson A, Engler R, Villines T, Vernalis M. Women present with non-traditional precursors of CVD. *J Cardiovasc Nurs* 2016;31(1):10A.

Presentations:

Eliasson A, Kashani M, Walizer E, Fuller C, Engler R, Villines T, Vernalis M. Military leaders are vulnerable to cardiovascular disease risk. Military Health System Research Symposium (MHSRS), Kissimmee, FL, 27 August 2017 (poster)

Tschiltz N, Halsey J, Eliasson A, Kashani M, Walizer E, Villines T, Vernalis M. Dietitians in the kitchen impact cardiovascular disease prevention. Society for Nutrition Education and Behavior, Washington DC, 21 July 2017 (poster)
Eliasson A, Kashani M, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. Prevalence of sleep disturbances and their consequences in patients at risk for cardiovascular disease. **Associated Professional Sleep Societies (**APSS) 2017 Scientific Session, Boston, MA, 3-7 June 2017 (poster)

Eliasson A, Kashani M, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. A novel lifestyle change program identifies and improves cardiovascular risks in middle-aged women. American Thoracic Society (ATS) 2017 Meeting, Washington DC, 19-24 May 2017 (poster)

Kashani M, Eliasson A, Walizer E, Fuller C, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Reversing prediabetes when diet and exercise are not enough. Walter Reed National Military Medical Center, Department of Research Program, 2017 Research and Innovation Month, Bethesda, MD, 1-5 May 2017 (Robert A. Phillips Research Award competition poster and podium)

Tschiltz N, Eliasson A, Halsey J, Walizer E, Kashani M, Villines T, Vernalis M. Dietitians in the kitchen impact cardiovascular disease prevention. Walter Reed National Military Medical Center, Department of Research Program, 2017 Research and Innovation Month, Bethesda, MD, 1-5 May 2017 (Paul Florentine Patient and Family-Centered Care competition poster)

Kashani M, Eliasson A, Walizer E, Fuller C, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Reversing prediabetes when diet and exercise are not enough. Preventive Cardiovascular Nurses Association (PCNA) 23rd Annual Symposium, Denver, CO, 7-9 April 2017 (poster)

Kashani M, Eliasson A, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. A single measurable outcome tool for tracking behavioral change. American Heart Association's 2017 Scientific Sessions Quality of Care and Outcomes Research (QCOR), Arlington, VA, 2-3 April 2017 (poster)

Kashani M, Eliasson A, Fuller C, Walizer E, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Arresting insulin resistance with an integrative health intervention. 66th Annual Scientific Session of the American College of Cardiology (ACC 2017) Scientific Session, Washington, DC, 17-19 March 2017 (poster)

Kashani M, Eliasson A, Walizer E, Fuller C, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Multidisciplinary cardiovascular team review captures preclinical disease. 66th Annual Scientific Session of the American College of Cardiology (ACC 2017) Scientific Session, Washington, DC, 17-19 March 2017 (poster)

Engler R, Kashani M, Eliasson A, Walizer E, Fuller C, Villines T, Vernalis M. Blood pressure elevations below hypertension threshold linked to insulin resistance and dyslipidemia: an under-recognized cardiovascular disease risk phenotype. Military Health System Research (MHSRS) Symposium 2016, Kissimmee, FL, 15-18 August 2016 (poster)

Eliasson A, Kashani M, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. Targeted behavioral interventions improve disturbed sleep. APSS, Denver, CO, 11-15 June 2016 (poster)

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Book Chapters:

White K, Dudley-Brown S, and Terhaar, M. (2016). Translation of Evidence into Nursing and Health Care, Second Edition. Chapter 19: Population Health (Exemplar: Mariam Kashani Doctoral Dissertation, Johns Hopkins University, 2013).

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

1) ICHP Information Management System

ICHP contracted with MDM Technologies, through the Henry M. Jackson Foundation, to implement a web-based Clinical Information Management System to support program operations and to obtain, update, store and report on participant data collected by all members of the ICHP clinical team and to support its patient management, diagnostic testing, clinical monitoring and clinical research for all protocols.
The scope of this project was defined in 9 high-level functional areas as follows:
1. Survey packet creation with scoring (web-based capability & calculation of derived)
2. Data input module creation (with field parameters for QA&QC) (audit trail & queries)
3. Data output module creation -- clinical review summary view
4. Data output module creation -- individual patient and provider reports (email also)
5. Data output module creation-- automated and customized aggregate reports over time
6. Mechanism to ID participants (also blind, restrict access and re-id)
7. CRF creation and management (coding and tracking)
8. Data migration
9. Customized scheduling and visit module for program and protocols (trigger events, input modules per appointment type, track workload productivity)

2) Optimal Health Impact Factor (OHIF), a Mechanism to Capture Readiness

Calculation of pre/post values for our Optimal Health Impact Factor (OHIF) score in our existing patients on existing data that we currently display in the output assessment report.

> OHIF scores are calculated using validated questionnaires in the following four domains: nutrition (Rate-Your-Plate), exercise (minutes of continuous exercise per week), stress (Perceived Stress Scale) and sleep (Pittsburgh Sleep Quality Index). Each domain has a gradient of three behavioral threshold scores (not at goal, red=1; almost to goal, amber=2; at goal, green=3) for a maximum of 12 possible OHIF points representing optimal health behaviors.
> These pre/post scores in the actual behavioral fields as shown are to be displayed in a small box on the snapshot.

Kashani M, Eliasson A, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. A single measurable outcome tool for tracking behavioral change. *Circulation: Cardiovascular Quality and Outcomes*. 2017;10: A206 (Presented AHA QCOR 2017 Scientific Session)

3) Deliverable Knowledge Techniques/Products

Cardiovascular Health Model
- Patient Registry for Longitudinal Tracking of Outcome Measures
- Copyrighted SOP Provider Algorithm Manual
- Copyrighted SOP Patient Manual
- Curriculum for Lifestyle Medicine (Applicable for Medical Students)

Multidisciplinary Team Process
Clinical Snapshot (Clinical and Behavioral Data)
Interactive Educational Patient Workshop (Ready for Virtual Distribution)
Interactive Healthy Cooking Demonstration Process (Ready for Virtual Distribution)
ICHP Personalized Lifestyle Prescriptions
Health Coaching Platform
Tension Tamer--Portable Stress Management Tool
ICHP Information Management System (Secure HIPAA-Compliant Web-based Application)
Web-based Surveys for Lifestyle Assessment
Automated Risk Factor-Matched Patient Recommendations
Patient-Provider Web Communication Portal
New Comprehensive Cardiovascular Disease Risk Score (validated)
ICHP Clinical Decision Support Tool for Family History (validated)
Needs Assessment Process to Identify CVD Risk in the Army National Guard
Clinical Patient Tracks
- Weight Management
- Pre-Diabetes
- Insulin Resistance
- Stress Management
- Self-Efficacy

AHA National Clinical Guideline Impact
ACC National Clinical Guideline Impact
Mayo Clinic Guideline Impact
Single Composite Health Readiness Tracker
Advanced Sleep Health Assessment Process
- Process for Sleep Apnea Screening
- Gender-based Characterization of Sleepiness and Fatigue
- Insomnia Assessment and Management Process

Scalable Lifestyle Intervention Population Models
- CHP Windber Highmark Insurance and Meadville Medical Center
- Executive Health OTSG
- Text Health Platform Model, Seton Hill University
- Senior Leader Health (Army War College, WRAMC Nursing)

- **Inventions, patent applications, and/or licenses**

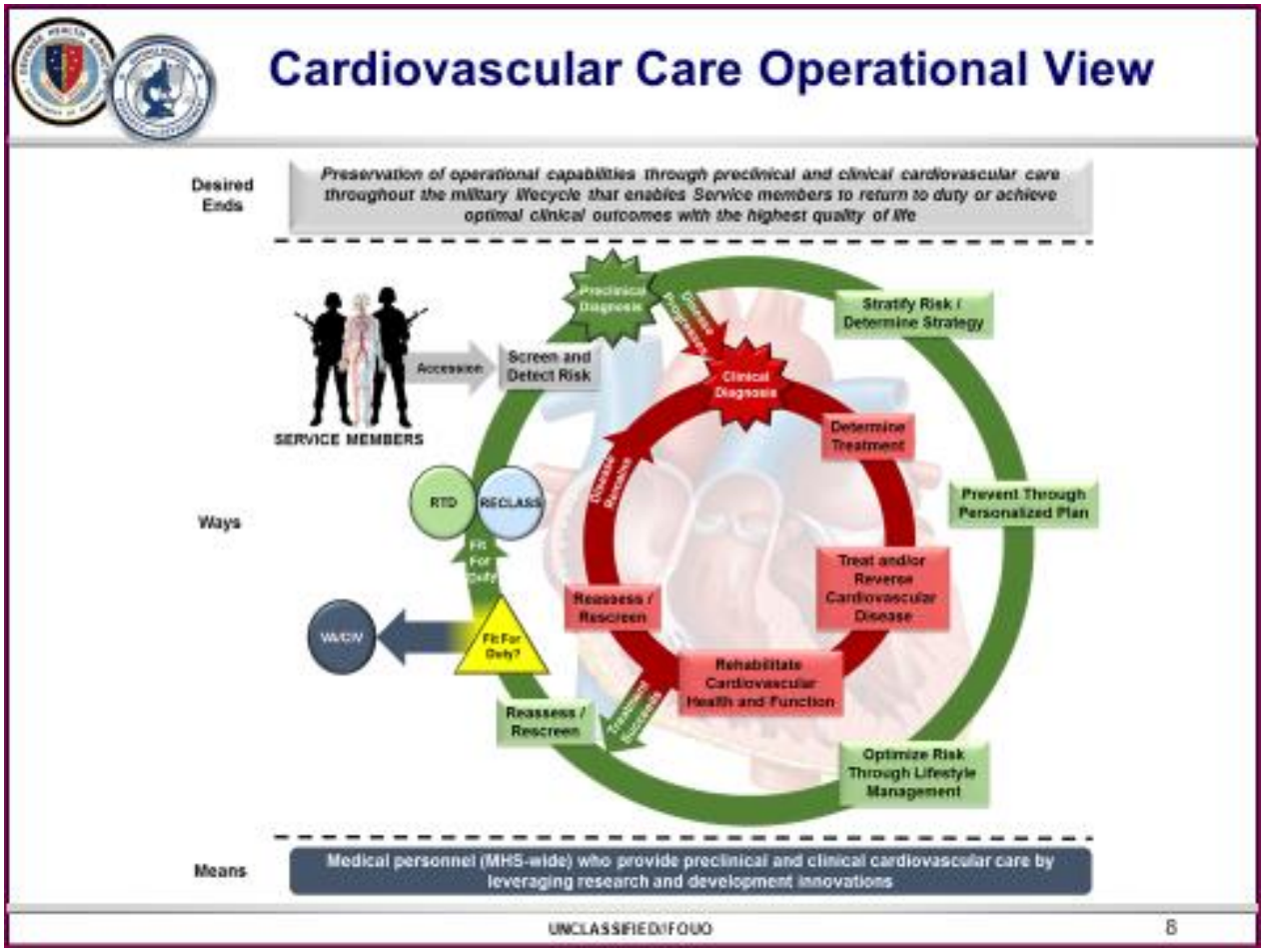
Nothing to Report.

- **Other Products**

ICHP has developed a lifestyle management model for optimal cardiovascular and overall health that is specific for the military as well as applicable to the general population. Through the continued work at ICHP, precision strategies have been identified for the early detection, monitoring and reduction of preclinical disease in military service members in an effort to improve health readiness and Force Health.

Information that improves individual patient risk assessments and risk reduction will enhance the quality of care for service members and beneficiaries as well as advance the knowledge about the challenges facing efforts to reduce disease burden in the future through improved prevention.

The schematic below was developed by ICHP. Cardiovascular Care ICD Approved Capabilities Based Assessment CBA (Booze Allen 2017) – received final approval with input from ICHP Executive team (Dr. Vernalis, Dr. Kashani and Dr. Engler). ICHP protocols are aligned with the Cardio Care capability gaps approved by JROC.
The diagram below is the ICHP developed concept for CV preventive health starting at accession into the military. This concept was approved by JROC.



7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Marina Vernalis, DO, FACC
Project Role: Medical Director, ICHP
Contribution to Project: Dr. Vernalis has performed oversight for all aspects of the project, scientific direction, data analysis/clinical interpretation and manuscript development.

Name: Mariam Kashani, DNP, CRNP
Project Role: Associate Medical Director
Contribution to Project: Dr. Kashani has performed work in the area of scientific direction, participant risk assessment, and interpretation of clinical findings, dissemination of findings to providers, study design, implementation, data collection, data analysis /clinical interpretation and manuscript preparation.

Name: Arn Eliasson, MD
Project Role: Clinical/Research Physician Consultant
Contribution to Project: Dr. Eliasson has performed work in the area of sleep medicine and study design, data analysis/clinical interpretation and manuscript preparation.

Name: Renata Engler, MD
Project Role: Research Physician Consultant
Contribution to Project: Dr. Engler has performed work in the area of scientific direction, study design, data analysis/clinical interpretation and manuscript preparation.

Name: Darrell Ellsworth, PhD
Project Role: Senior Biomolecular Scientist
Contribution to Project: Dr. Ellsworth is new to the project and has begun protocol development for a biomolecular repository for ICHP.

Name: Elaine Walizer, MSN, RN
Project Role: Director, Clinical Operations
Contribution to Project: Ms. Walizer has performed work in the area of daily on-site execution of research and clinical operations, informed consent, coordination of studies processes, personnel supervision, regulatory document maintenance, protocol management, technical reporting and manuscript preparation.

Name: Emily C. Brede, PhD, RN
Project Role: Clinical Research Coordinator
Contribution to Project: Dr. Brede is new to the project and has performed work in the area of protocol development including methodology/statistics as well as protocol.

Name: Carmen Ching, CRNP, RN
Project Role: Nurse Practitioner
Contribution to Project: Ms. Ching has performed clinical assessment and care management for ICHP participants under the direct supervision of Dr. Kashani.

Name: Melanie Sparks, CRNP, RN
Project Role: Nurse Practitioner
Contribution to Project: Ms. Sparks has performed clinical assessment and care management for ICHP participants under the direct supervision of Dr. Kashani.

Name: Marilyn Grunewald, MSW
Project Role: Stress Reduction Specialist
Contribution to Project: Ms. Grunewald has performed work in the area of the ICHP stress management intervention, data collection and participant engagement/personalized prescriptions.

Name: Joy Halsey, MS, RD, LD
Project Role: Dietitian
Contribution to Project: Ms. Halsey has performed work in the area of the ICHP nutrition intervention and pre-diabetes empowerment package, data collection and participant engagement/personalized prescriptions.

Name: Nancy Tschiltz, MS, RD, LD
Project Role: Lead Clinical Dietitian/Chef
Contribution to Project: Ms. Tschiltz has performed work in the area of the ICHP nutrition intervention, data collection and participant engagement/personalized prescriptions.

Name: Ellen Turner, MS
Project Role: Health Coach, Coordinator
Contribution to Project: Ms. Turner has performed work in the area of the ICHP exercise intervention, data collection and participant engagement/personalized prescriptions.

Name: Kenneth Williams, MS
Project Role: Program & Financial Manager
Contribution to Project: Mr. Williams has performed work in the area of budget management and other daily operational activities.

Name: Claire Fuller, BS
Project Role: Program Manager I
Contribution to Project: Ms. Fuller has performed work in the area of daily on-site management of office functions, facilities management, security, personnel supervision, data management, data analysis.

Name: Christa Caporiccio
Project Role: Administrative Assistant
Contribution to Project: Ms. Caporiccio has performed work in the area of daily office clerical functions, patient scheduling and record management.

Name: Sharon Gibbons
Project Role: Administrative Assistant Contribution to Project: Ms. Gibbons has performed work in the area of daily office
clerical functions, patient scheduling and record management.

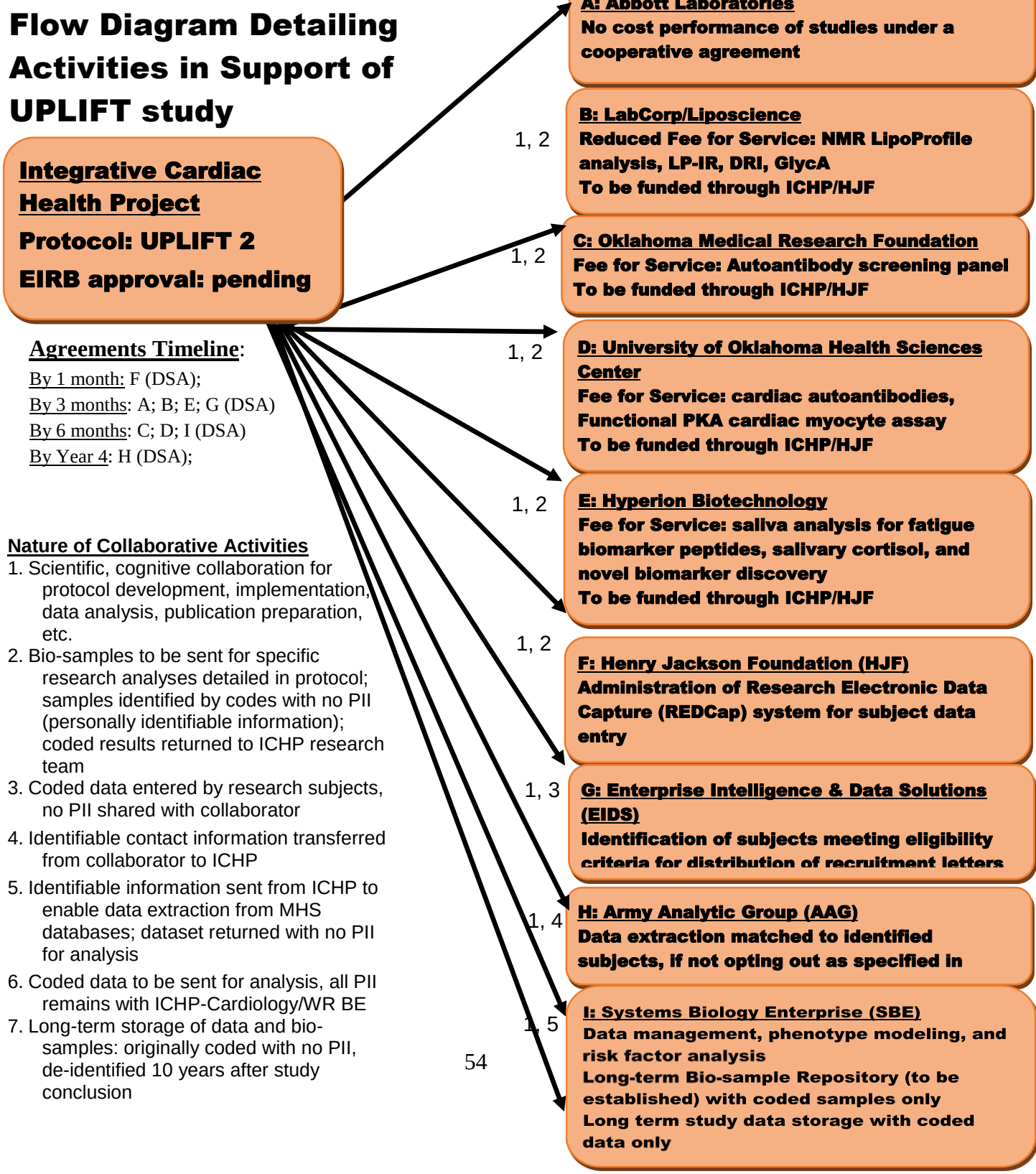
Name: Peta-Gay Llewellyn
Project Role: MRI Technician
Contribution to Project: Ms. Llewellyn has performed work in the area of performing, analyzing and preliminarily interpreting cardiovascular ultrasound studies.

Name: Audra Nixon
Project Role: Administration Director
Contribution to Project: Ms. Nixon has performed work in the area of financial management, space management, personnel management and development, contracts and purchasing and bioinformatics administrative support.

Was there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Nothing to Report

What other organizations were involved as partners?



Relationships/Collaborations

ICHP with Abbott Laboratories

- Performance of special testing as outlined in protocol as part of scientific collaboration
    - hsTnI, BNP/NT-pro-BNP, suPAR, Gal-3, usCRP
    - Samples will be shipped to Abbott Laboratories under an agreement
    - Samples will be coded with no PII or HPI information available to Abbott Laboratories
- Scientific collaboration in review of statistical analysis plan and publication preparation.
- No PII will be shared.

ICHP-LabCorp – Fee for Service Contract performance of NMR lipoprotein Labs

- Collaboration for scientific purposes for interpretation of tests (to be included in contracting document)

ICHP-Dr. Cunningham (UOHSC)

- Sole source contracting for performance of cardiac specific autoantibodies (fee for service)
- Scientific collaboration for interpretation of results (to be included in contracting service)
- Participation in preparation of scientific publications

ICHP- Dr. James, Judith (OMRF)

- Sole source contracting for performance of autoimmunity autoantibodies screening (fee for service);
- Scientific collaboration for interpretation of results (to be included in contracting service)
- Participation in preparation of scientific publications

ICHP- Dr. John Kalns (Hyperion Biotechnology)

- Sole source contracting for performance of saliva sample testing: fatigue panel, cortisol, biomarker discovery (fee for service);
- Scientific collaboration for interpretation of results (to be included in contracting service)
- Participation in preparation of scientific publications

ICHP-HJF

- HJF will administer Research Electronic Data Capture (REDCap) System that allows subject to enter responses to survey data directly
- HJF will be responsible for all network and data security
- Only coded data will be entered into REDCap, PII will remain with ICHP at WRNMMC

ICHP-AAG

- AFTER all testing and data validation is completed, detailed plan for extracting outcomes data from MHS databases and link to testing results for modeling of predictive risk validation of biomarkers and overall clinical risk profile
- This is a MOD that will be developed at the end of 2018 (earliest)

ICHP with Systems Biology Enterprise (Ft. Detrick)

- Working together to form a long-term collaboration with SBE in support of secure data and biosamples repository for this and other protocols under the IHB.
- Data storage would be coded with no PII
- Biological sample storage would be coded with no PII

Conclusion

The Integrative Cardiac Health Project located on the Walter Reed National Military Medical Center campus, a Center of Excellence accomplished a great deal during this award:

1. Developed an integrative, comprehensive lifestyle management model for optimal cardiovascular (CV) and overall health, specific for the Department of Defense and applicable to the general population. This model was sustainable and was embraced by the military population, receiving a consistent 3.9 out of 4.0 rating regarding patient satisfaction, resulting higher self-efficacy and quality of life among participants.
2. Identified precise strategies for early detection, monitoring and reduction of preclinical/clinical CV and related chronic disease risks for improved clinical outcomes
3. Provided a systems approach for dynamic development of scientific cardiovascular wellness. Numerous ICHP publications demonstrate the success of using this multicomponent, total body CV risk approach which has shown significant improvements in, body composition, CV clinical risk factors and behaviors consistent with healthy lifestyles: nutrition, exercise, stress and sleep.

ICHP built an infrastructure platform which served as a "virtual laboratory" for forward thinking science that translated research findings into usable, personalized medicine tools and solutions. The Military Health System (MHS) required a new approach to bridge gaps to translate research to practice. ICHP has proven its value not only to the DoD but to the public by impacting four national Clinical Practice Prevention Guidelines, American Heart Association National Guidelines on CV Risk Assessment and Sudden Cardiac Death, American College of Cardiology and the Mayo Clinic. The premature closure of ICHP precludes the continuation of this productive line of scientific research and its ability to affect the CV health of active duty service members and beneficiaries.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*
N/A

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

Appendix 1

STATEMENT OF WORK – Revised 18 April 2018
Revised January 2, 2019
PROPOSED START DATE December 24, 2018

Site 1: Integrative Cardiac Health Project (ICHP)
& Cardiology Service
Walter Reed National Military
Medical Center (WRNMMC)
8901 Wisconsin Ave
ICHP - Bldg. 17, Suite 2A &
Cardiology Clinic - Bldg 9
Bethesda, MD 20889
PI: Marina Vernalis, DO (MV)
IRB PI: COL Todd Villines, MC, USA (TV)

Site 2: Systems Biology Enterprise (SBE)
Collaborators: Dr. Marti Jett and Dr. Rasha Hammamieh

Site 3: Abbott Laboratories
Collaborators: Dr. Agim Beshiri and Dr. Gillian Murtagh

Site 4: LabCorp/Liposcience
Collaborators: Dr. Margery A. Connelly and Dr. James Otvos

Site 5: University of Oklahoma Health Sciences Center (UOHSC)
Collaborators: Dr. Madeleine W. Cunningham

Site 6: Oklahoma Medical Research Foundation (OMRF)
Collaborators: Dr. Judith A. James

Abbreviations: CBT-I = Cognitive-Behavioral Therapy for Insomnia; CHP = Cardiovascular Health Program; CRADA = Cooperative Research and Development Agreement; DHA = Department of Health Affairs; DOD = Department of Defense; DRP = Department of Research Programs; HIPAA = Health Insurance Portability and Accountability Act; HJF = Henry M. Jackson Foundation; HRPO = Human Research Protection Office; ICHP = Integrative Cardiac Health Project; IHB = Immunization Healthcare Branch; IMS = Information Management System; IRB: Investigational Review Board; LMI(s) = Lifestyle Management Intervention(s); NEC = Network Enterprise Center; ORP = Office of Research Protections; SAB = Scientific Advisory Board; SOW = Statement of Work; WRNMMC = Walter Reed National Military Medical Center.

ICHP Personnel:

Name	Title	Initials	End date (Anticipated)
Marina Vernalis	Executive Medical Director/PI	MV	3/31/19
Mariam Kashani	Associate Medical Director	MK	3/31/19
Arn Eliasson	Clinical/Research Physician Consultant	AE	3/31/19
Renata Engler	Research Physician Consultant	RE	1/7/19
Darrell Ellsworth	Senior Biomolecular Scientist	DE	1/7/19
Elaine Walizer	Director, Clinical Operations	EW	3/31/19
Claire Fuller	Program Manager/Data Outcomes Specialist	CF	3/31/19
Carmen Ching	Research Nurse Practitioner	CC	3/31/19
Ellen Turner	Exercise Physiologist	ET	3/31/19
Joy Halsey	Clinical Dietitian	JH	3/31/19
Marilyn Grunewald	Stress Management Specialist	MG	3/31/19
Emily Brede	Clinical Research Coordinator	EB	1/7/19
Sharon Gibbons	Administrative Assistant	SG	1/7/19

<u>Study 1A & 1B:</u> ICHP Cardiovascular Health Program (CHP), a lifestyle management intervention (LMI) specifically designed for the military population

	Timeline (Months)	Responsible Parties
<u>SOW Study 1A: Cardiovascular Health Program (CHP) Study.</u>		
Major Task 1: Archive ICHP CHP LMI and other related intellectual property for long-term storage.		
Review all existing electronic and hardcopy CHP files for archiving or destruction.	34-35	Completed
Coordinate with HJF and WRNMMC on secure transfer of all electronic program files.	33-35	Completed
Package and inventory all hardcopy files (as appropriate) for transfer to HJF.	35	Completed
Ship all hardcopy files to HJF for long-term storage.	36	Completed
Milestone Achieved: All intellectual property files transferred to HJF for long-term storage.	36	Completed
Major Task 2: Archive ICHP CHP/CPP research patient records for long-term storage.		
Develop and test redaction QA checklist.	34	Completed
Train personnel on record redaction,	34	Completed
Redact all patient identifiers from ~1200 patient research records. (n=1383)	34-36	Completed
Purge any clinical information from ~1200 patient records.	34-36	Completed
Provide 100% quality assurance review on redacted records.	34-36	Completed
Package and inventory ~1200 records for long-term storage at HJF.	36	Completed
Ship all hardcopy research records to HJF.	36	Completed
Milestone Achieved: All CPP/CHP patient records redacted of patient identifiers.	36	Completed
Milestone Achieved: All patient research records transferred to HJF for long-term storage.	36	Completed

SOW Study 1B: CHP Registry

Major Task 1: Close out protocol at WRNMMC DRP and ORP/HRPO.		
Prepare closure report documents for WRNMMC IRB submission.	33	Completed
Submit closure report to WRNMMC IRB for approval.	34	Completed
Final submission of protocol closure to HRPO.	35	Completed
Milestone Achieved: WRNMMC IRB approval of protocol closure.	35	Completed
Milestone Achieved: HRPO acknowledgement of protocol closure.	36	Completed
Major Task 2: Archive all regulatory files for protocol.		
Review regulatory binder for completeness of files (protocol, consents, continuing reviews, modifications, 2nd level reviews and all approvals.	33-34	Completed

	Timeline (Months)	Responsible Parties
Digitize all required files for long-term storage including consents. (Will have in hardcopy.)	34-35	Completed
Prepare data file(s) for long-term storage (de-identify, transfer to secure digital archive).	34-35	Completed
Destroy any files upon study closure as outlined in protocol/consent (i.e. master list, working copies of documents).	35	Completed
Prepare final list of all publications/presentations associated with this protocol and archive in digital format (includes publication clearances).	34-35	Completed
Milestone Achieved: All regulatory records, source documents, consents, HIPAA Authorization and data files archived for long-term storage at HJF.	36	Completed
Major Task 3: Archive patient generated data in IMS.		
Notify MDM of program closure.	33	Completed
Notify NEC on program closure.	33	Completed
Collaborate with MDM and HJF to secure and transfer data and IMS architecture to HJF for long-term storage. – In progress – need to verify that files can be opened at HJF (Marianne/Dai)	34-35	Completed
Milestone Achieved: MDM notified of program closure.	33	Completed
Milestones Achieved: All ICHP patient generated data in IMS archived for long term storage at HJF.	35	Completed
Milestone Achieved: NEC notified of program closure.	33	Completed

SOW Study 2: Assessing Risk Factors for Cardiovascular Disease in Individuals with Major Injury (With or Without Amputation) versus No Injury

Major Task 1: Provide ORP/HRPO with any final regulatory documents.		
Obtain WRNMMC IRB approval modifying protocol to remove ICHP investigators from study.	34	Completed
Approval letter, modification form and any other required documents sent to HJF and HPRO/ORP.	34	Completed
Milestone Achieved: Modification approval sent to HRPO/ORP.	34	Completed

SOW Study 3: CHP Cognitive-Behavior Therapy for Insomnia (CHP CBT-I) Study *(*closed 31 Aug 2018*)*

Major Task 1: Archive CBT-I Study research patient records for long-term storage.		
Provide 100% quality assurance review on patient research records (6 records) (100% redacted and completeness).	33	Completed
Digitize records/consents for long-term storage at HJF. (Provide in hard copy)	33	Completed
Milestone Achieved: All CBT-I Study patient records redacted of patient identifiers.	33	Completed
Major Task 2: Archive all regulatory files for protocol.		
Review regulatory binder for completeness of files (protocol, consents, continuing reviews,	34	Completed

	Timeline (Months)	Responsible Parties
modifications, 2nd level reviews and all approvals.		
Digitize all required files for long-term storage including consents. Will provide in hard copy.	34	Completed
Destroy any files upon study closure as outlined in protocol/consent (i.e. master list, working copies of documents). – Master list and working copies of documents destroyed.	34	Completed
Securely transfer records to HJF.	36	Completed
Milestone Achieved: All regulatory records, source documents, consents, HIPAA Authorization and data files archived for long-term storage at HJF.	36	Completed

Study 4 Part 1 & 2: UPLIFT (**U***ltra-***P***ersonalized* **L***aboratory-Risk* **I***ntervention* **F***or* **T***reatment*) **for Cardiovascular Health: Cardiovascular (CV) Disease (CVD) Risk Study**

SOW Part 1 UPLIFT: Modification of an existing protocol (eIRB #20525) as a collaboration with the Immunization Healthcare Branch (IHB), Defense Health Agency (DHA).		
Major Task 1: Provide ORP/HRPO with any final regulatory documents.		
Obtain WRNMMC IRB approval modifying protocol to remove ICHP investigators from study.	34	Completed
Approval letter, modification form and any other required documents sent to HJF and HRPO/ORP.	34	Completed
Milestone Achieved: Modification approval sent to HRPO/ORP.	34	Completed

SOW UPLIFT STUDY 4 Part 2: **UPLIFT** (**U***ltra-***P***ersonalized* **L***aboratory-Risk* **I***ntervention* **F***or* **T***reatment*) **for Cardiovascular Health: Cardiovascular (CV) Disease (CVD) Risk Study (prospective study)**

Major Task 1: Archive any intellectual property related to this project.		
Review all existing electronic and hardcopy UPLIFT files for archiving or destruction.	33-34	Completed
Coordinate with HJF and WRNMMC on secure transfer of all electronic program files.	35	Completed
Milestone Achieved: All study intellectual property securely transferred to HFJ.	36	Completed
Major Task 2: Notify all study collaborators and other study related departments/activities of ICHP program closing.		
Notify the following study collaborators: SBE, Abbott Labs, LabCorp/Liposcience, UOHSC, OMRF, Hyperion, and Army Analytic Unit.	34	Completed
Notify CarePoint on protocol dissolution.	33-34	Completed
Close accounts with RedCap, if appropriate.	33-34	Completed
Milestone Achieved: SBE notified of program closure.	34	Completed

	Timeline (Months)	Responsible Parties
Milestone Achieved: Abbott Labs notified of program closure.	34	Completed
Milestone Achieved: LabCorp/Liposcience notified of program closure.	34	Completed
Milestone Achieved: UOHSC notified of program closure.	34	Completed
Milestone Achieved: OMRF notified of program closure.	34	Completed
Milestone Achieved: Hyperion notified of program closure.	34	Completed
Milestone Achieved: Army Analytics Unit notified of program closure.	34	Completed
Milestone Achieved: CarePoint notified of program closure.	34	Completed
Milestone Achieved: RedCap accounts closed and HJF notified.	34	Completed

The following MAJOR TASKS apply to the ICHP Closure and are not related to any of the specific protocols listed above.

Major Task 1: Archive all other ICHP regulatory files and intellectual property for long-term storage.		
Review regulatory binder for completeness of files (protocol, consents, continuing reviews, modifications / amendments, 2nd level reviews and all approvals. These files include the following ICHP closed protocols: 1. ZENITH (randomized Evaluation of a Novel prevention program on vascular function and aTHerosclerosis) Trial 2. Non-Invasive Coronary Artery Disease Reversal (CADRe) Follow-up Study (CADRe 5 Year) 3. Better Adherence to Therapeutic Lifestyle Efforts (BATTLE) 4. Outcomes of the Cardiovascular Prevention Program (CPP) 5. Army Reserve Component Personalized Empowerment Program (ARCPEP) 6. Seton Hill University-Personal Empowerment Program (SHU-PEP), formerly called Army Reserve Component Personal Empowerment Program 2 (ARCPEP2) 7. Validation of the ICHP Cardiovascular Risk Score 8. Exploring the Predictive Patterns of the Natural History of Pre-Diabetes: Proof of Principle Study 9. Isolation, Amplification, and Genotyping of DNA from Serum Samples in the Department of Defense Serum Repository (DoDSR): A Proof of Principle Study 10. Non-Invasive Coronary Artery Disease Reversal Program (CADRe Study)	34-35	Completed
Review ~ ~~1000~~ patient study records to ensure de-identification prior to ~~digitization/~~hardcopy storage. (As of 3/14/19 – 2255 records have been redacted/QA'd.)	34-35	Completed
~~Digitize~~ Package all required files and patient records for long-term storage including consents, as appropriate.	34-35	Completed

	Timeline (Months)	Responsible Parties
Prepare data file(s) for long-term storage (de-identify, transfer to secure digital archive).	34-35	Completed
Destroy any files upon study closure as outlined in protocol/consent (i.e. master list, working copies of documents).	34-35	Completed
Coordinate with HFJ Regulatory Affairs on destruction ~~or long-term storage~~ of 19 blood samples (ZENITH protocol).	34-35	Completed
Coordinate with HJF regarding blood samples currently stored at WRI.	34-35	In progress
Prepare final list of all publications/presentations associated with this protocol and archive in digital format (includes publication clearances).	34-35	Completed
Coordinate with HJF and WRNMMC on secure transfer of all electronic program files.	34-35	Completed
Package and inventory all hardcopy files (as appropriate) for transfer to HJF.	36	Completed
Ship all hardcopy files to HJF for long-term storage.	36	Complete
Milestone Achieved: All required program and regulatory records, source documents, consents, HIPAA Authorization and data files archived for long-term storage at HJF.	36	Completed
Milestone Achieved: Blood samples either destroyed or long-term storage established.	36	Completed
Major Task 3: Prepare and execute ICHP physical space closure.		
Develop plan on compilation, transfer and storage of electronic and hardcopy intellectual property and other program information.	33-34	Completed
HJF asset review and collection.	34-35	Completed
Cleaning, inventory and preparation for Research Kitchen closure (includes notification of Preventive Medicine).	34-35	Completed
Quotes for moving vendor solicited and obtained.	33-34	Completed
Quotes for shredding vendor identified.	33-34	Completed
Packing of personal items and other office items; turn-in assets (all assets from staff turned in).	34-36	Completed
Milestone Achieved: Moving vendor and moving date identified.	35	Completed
Milestone Achieved: Shredding vendor bins in place at ICHP space.	35	Completed
Milestone Achieved: All HJF assets turned-in. (IT equipment turned in to HJF)	35-36	Completed
Milestone Achieved: Research Kitchen closed.	36	Completed
Major Task 3: Closeout of budget, legal documents (CRADAs, contracts) and other final administrative tasks.		
Review and dissolve CRADA with SBE. – SBE notified CRADA dissolution as of 3/8/19.	33	Completed
Close all outstanding purchase orders and other financial obligations.	33-35	Completed
Notify SAB of program closure.	34	Completed

	Timeline (Months)	Responsible Parties
Preparation of final scientific report for sponsor.	35-36	Completed
Submission of all final report documents (budget, technical report, Quad charts) to HJF for review.	36	Completed
Submission of all final report (budget, technical report, Quad charts) to sponsor.	36	Completed
Necessary personnel actions submitted to HJF as required.	35	Completed
Milestone Achieved: All members of ICHP SAB notified of program closure.	34	Completed
Milestone Achieved: CRADA with SBE dissolved.	34	Completed
Milestone Achieved: All financial obligations mitigated.	36	Completed
Milestone Achieved: All appropriate personnel actions submitted to HJF.	35	Completed
Milestone Achieved: Final technical report submitted to sponsor.	36	Completed

Appendix 2

-----Original Message-----
From: Davey, Regina L MAJ USARMY MEDCOM USAMRMC (US)
Sent: Wednesday, November 13, 2013 4:29 PM
To: 'Shriver, Craig D COL MIL US WRNMMC'; Hamilton, Chad A Lt Col MIL US WRNMMC; 'Maxwell, George L.'; Vernalis, Marina N CTR (US); Buckenmaier, Chester C III COL USARMY USUHS (US); Chester Buckenmaier; Modlin, Randolph E COL USARMY (US); 'Grimes, Jamie B MIL US WRNMMC'; McLeod (RET), David G C MIL US USA WRNMMC
Cc: 'Bronfman, Lee T CTR NNMC'; 'Nixon, Audra H CTR US WRNMMC'; 'Kevin Toruno'; 'Thomas Conrads'; 'Kelly Kiser'; McGhee, Laura L MAJ USARMY (US); Scherer, John M COL USARMY (US); 'mcontreras@cpdr.org'; 'Shryer, Amber Ms. CIVILIAN'; 'Read, Robert Mr - CIVILIAN'; 'Whitmeyer, Antoinette'; Stephen Rice; Tinling, Walter W CIV (US)
Subject: JPC-8 Health Affairs Review Meeting - Centers of Excellence (UNCLASSIFIED)

Classification: UNCLASSIFIED
Caveats: NONE

CoE Directors,

Many of you are aware that Health Affairs (HA) wanted to conduct a review of your programs, but there was insufficient time at the JPC-8 review meeting held last week. HA typically reviews all programs annually, and the last review of your programs was conducted at the JPC-8 meeting held in 2012.

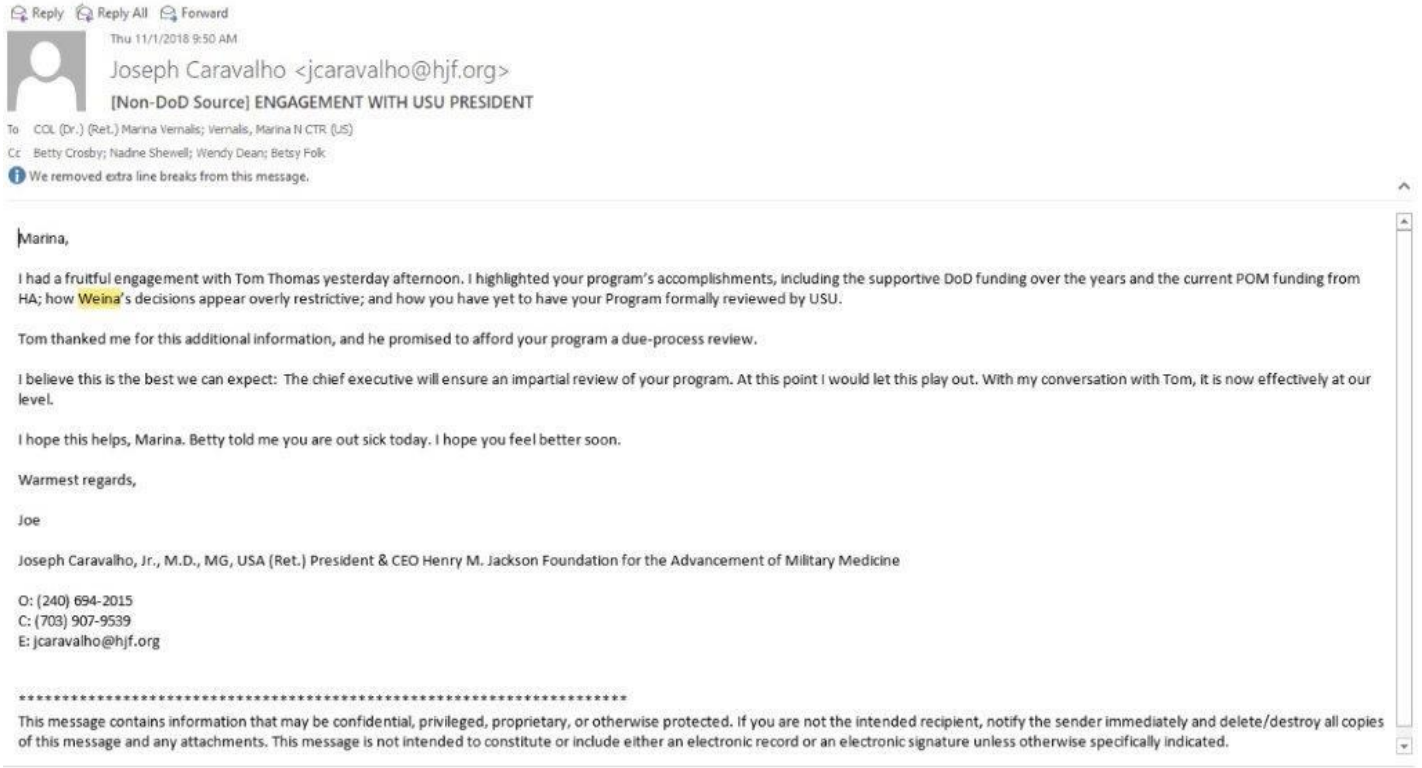
A comment from Dr. Terry Rauch (HA) at the JPC-8 meeting last week was to schedule the CoE reviews at Health Affairs by the end of the year, date TBD. While this will be difficult to schedule on such short notice, we wanted to make you aware so you can begin working on your slides. Guidance received so far is that your slides should focus on what you have done and where you plan on taking your programs. Improvements in clinical practice that you have developed and implemented should be highlighted as well as any CPGs you have created.

We're awaiting additional information from Dr. Rauch and will send you more guidance shortly.

Respectfully,

Regina L. Davey
MAJ, MS
JPC-8/CRMRP
(301) 619-7255 (office)
(240) 586-0590 (mobile)

Appendix 3



Reply Reply All Forward

Thu 11/1/2018 9:50 AM

Joseph Caravalho <jcaravalho@hjf.org>

[Non-DoD Source] ENGAGEMENT WITH USU PRESIDENT

To COL (Dr.) (Ret.) Marina Vernalis; Vernalis, Marina N CTR (US)

Cc Betty Crosby; Nadine Shewell; Wendy Dean; Betsy Folk

We removed extra line breaks from this message.

Marina,

I had a fruitful engagement with Tom Thomas yesterday afternoon. I highlighted your program's accomplishments, including the supportive DoD funding over the years and the current POM funding from HA; how Weina's decisions appear overly restrictive; and how you have yet to have your Program formally reviewed by USU.

Tom thanked me for this additional information, and he promised to afford your program a due-process review.

I believe this is the best we can expect: The chief executive will ensure an impartial review of your program. At this point I would let this play out. With my conversation with Tom, it is now effectively at our level.

I hope this helps, Marina. Betty told me you are out sick today. I hope you feel better soon.

Warmest regards,

Joe

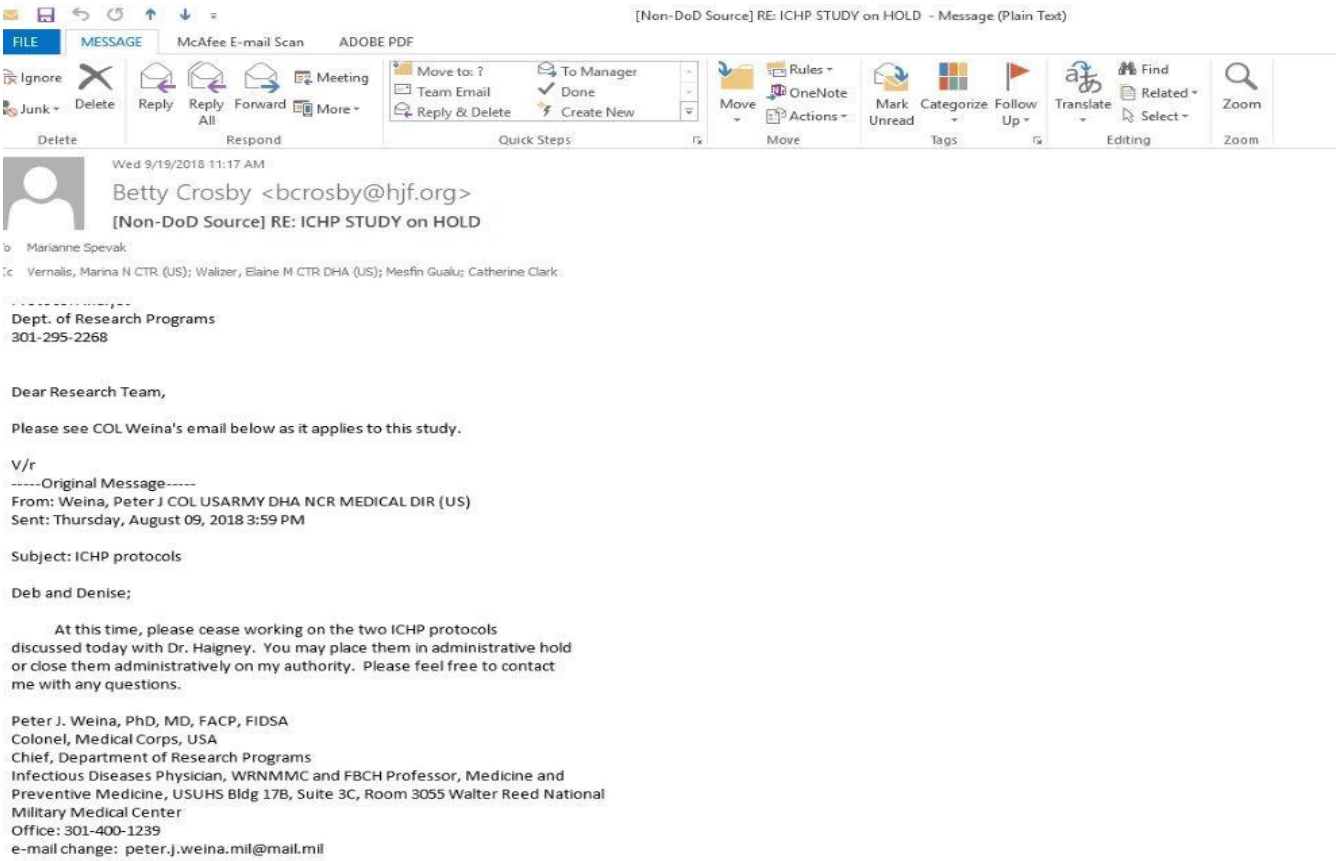
Joseph Caravalho, Jr., M.D., MG, USA (Ret.) President & CEO Henry M. Jackson Foundation for the Advancement of Military Medicine

O: (240) 694-2015
C: (703) 907-9539
E: jcaravalho@hjf.org

****

This message contains information that may be confidential, privileged, proprietary, or otherwise protected. If you are not the intended recipient, notify the sender immediately and delete/destroy all copies of this message and any attachments. This message is not intended to constitute or include either an electronic record or an electronic signature unless otherwise specifically indicated.

Appendix 4


[Non-DoD Source] RE: ICHP STUDY on HOLD - Message (Plain Text)
FILE
MESSAGE
McAfee E-mail Scan
ADOBE PDF
Ignore
Junk
Delete
Reply
Reply All
Forward
Meeting
More
Move to: ?
Team Email
Reply & Delete
To Manager
Done
Create New
Move
Rules
OneNote
Actions
Mark Unread
Categorize
Follow Up
Translate
Find
Related
Select
Zoom
Delete
Respond
Quick Steps
Move
Tags
Editing
Zoom
Wed 9/19/2018 11:17 AM
Betty Crosby <bcrosby@hjf.org>
[Non-DoD Source] RE: ICHP STUDY on HOLD
Marianne Spevak
Vernalis, Marina N CTR (US); Walizer, Elaine M CTR DHA (US); Mesfin Gualu; Catherine Clark
Dept. of Research Programs
301-295-2268
Dear Research Team,
Please see COL Weina's email below as it applies to this study.
V/r
-----Original Message-----
From: Weina, Peter J COL USARMY DHA NCR MEDICAL DIR (US)
Sent: Thursday, August 09, 2018 3:59 PM
Subject: ICHP protocols
Deb and Denise;
At this time, please cease working on the two ICHP protocols discussed today with Dr. Haigney. You may place them in administrative hold or close them administratively on my authority. Please feel free to contact me with any questions.
Peter J. Weina, PhD, MD, FACP, FIDSA
Colonel, Medical Corps, USA
Chief, Department of Research Programs
Infectious Diseases Physician, WRNMMC and FBCH Professor, Medicine and Preventive Medicine, USUHS Bldg 17B, Suite 3C, Room 3055 Walter Reed National Military Medical Center
Office: 301-400-1239
e-mail change: peter.j.weina.mil@mail.mil

Appendix 5

Integrative Cardiac Health Project
Complete List of Peer-reviewed Publications & Presentations

Manuscripts in Scientific Journals:

Sandrick J, Tracy D, Eliasson A, Roth A, Bartel J, Simko M, Bowman T, Harouse-Bell K, Kashani M, Vernalis M. Effect of a counseling session bolstered by text messaging on self-selected health behaviors in college students: A preliminary randomized controlled trial. *JMIR Mhealth Uhealth* 2017;5(5):e67

Ellsworth DL, Costantino NS, Blackburn HL, Engler, RJM, Kashani M, Vernalis MN. Lifestyle modification interventions differing in intensity and dietary stringency improve insulin resistance through changes in lipoprotein profiles. *Obes Sci Pra* 2016 Sep;2(3):282-292. DOI:10.1002/osp4.54. Epub 25 JUL 2016.

Kashani M, Eliasson AH, Walizer EM, Fuller CE, Engler RJ, Villines TC, Vernalis MN. Early empowerment strategies boost self-efficacy to improve cardiovascular health behaviors. *Glob J Health Sci* 2016 Feb 2;8(9):55119. doi:10.5539/ghis.v8n9p322.

Kashani M, Eliasson A, Vernalis M, Bailey K, Tehaar M. A systematic approach incorporating family history improves identification of cardiovascular disease risk. *J of Cardiovasc Nurs* 2015 Jul-Aug;30(4):292-297. doi:10.1097/JCN.0000000000000163. Epub 2014 May 20.

Ellsworth DL, Mamula KA, Blackburn HL, McDyer FA, Jellema GL, van Laar R, Costantino NS, Engler RJ, Vernalis MN. Importance of substantial weight loss for altering gene expression during intensive cardiovascular lifestyle modification. *Obesity (Silver Spring)* 2015 Jun;23(6):1312-9. doi:10.1002/oby.21079. Epub 2015 May 9.
http://onlinelibrary.wiley.com/doi/10.1002/oby.21079/epdf

Blackburn HL, McErlean S, Jellema GL, van Laar R, Vernalis MN, Ellsworth DL. Gene expression profiling during intensive cardiovascular lifestyle modification: Relationships with vascular function and weight loss. *Genomics Data* 2015;4:50-53. http://dx.doi.org/10.1016/j.gdata.2015.03.001

Eliasson AH, Kashani MD, Howard RS, Vernalis MN, Modlin RE. Fatigued on Venus, sleepy on Mars-gender and racial differences in symptoms of sleep apnea. *Sleep Breath.* 2015 Mar;19(1):99-107. doi: 10.1007/s11325-014-0968-y. Epub 2014 Mar 15.

Eliasson AH, Rogers GG, Kashani MD, Vernalis MN. Do dental self-care habits correlate with oral health? *Journal of Health Science* 2014;2:428-435.

Ellsworth DL, Croft DT Jr, Weyandt J, Sturtz LA, Blackburn HL, Burke A, Haberkorn MJ, McDyer FA, Jellema GL, van Laar R, Mamula KA, Vernalis MN. Intensive cardiovascular risk reduction induces sustainable changes in expression of genes and pathways important to vascular function. *Circ Cardiovasc Genet* 2014 Apr;7:151-160. doi:10.1161/CIRCGENETICS.113.000121. Epub 2014 Feb 21. http://circgenetics.ahajournals.org/content/7/2/151.long

Crum-Cianflone NF, Bagnell ME, Schaller E, Boyko EJ, Smith B, Maynard C, Ulmer CS, Vernalis M, Smith TC. Impact of combat deployment and posttraumatic stress disorder on newly reported coronary heart disease among US active duty and reserve forces. *Circulation* 2014 May 6;129(18):1813-20. Epub 2014 Mar 11.

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Marshall DA, Walizer EM, Vernalis MN. Achievement of heart health characteristics through participation in an intensive lifestyle change program (Coronary Artery Disease Reversal Study). *J Cardiopulm Rehabil Prev* 2009;29:84-94. doi:10.1097/HCR.0b013e31819a00b2.

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Marshall DA, Walizer EM, Vernalis MN. Optimal healing environments for chronic cardiovascular disease. *J Altern Complement Med* 2004;10 Suppl 1:S147-55. Review.

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Bailey K, Kashani M, Eliasson A, Vernalis M. Low self-efficacy correlates with increased cardiovascular disease risk. *Circ Cardiovasc Qual Outcomes*. 2013;6:A262 .

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Walizer EM, Marshall DA, Taylor AJ, Vernalis MN. The effect of an intensive 1-year lifestyle intervention program on carotid intima-medial thickness. *Circulation* 2007; 115: e274-275.

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Vernalis MN, Ocuin E, Remaley AT, Scally JP**,** Walizer E, Sampson M, Arthur C, Runner J, Northrup G, Taylor AJ. Lifestyle changes negate the adverse effect of ultra-low fat diets on HDL cholesterol and apoprotein A-I? The Ornish diet and lifestyle modification program. *Circulation* 2001 (Suppl II) 104:e468.

Book Chapters:
White K, Dudley-Brown S, and Terhaar, M. (2016). Translation of Evidence into Nursing and Health Care, Second Edition. Chapter 19: Population Health (Exemplar: Kashani, M).

Maskery S, Ellsworth DL. Research and Application: Examples. In: Biomedical Informatics in Translational Research, Hu H, Mural RJ, Liebman MN, eds. Artech House, Inc (2008) pp. 207-226

Presentations:
2017
Eliasson A, Kashani M, Walizer E, Fuller C, Engler R, Villines T, Vernalis M. Military leaders are vulnerable to cardiovascular disease risk. Military Health System Research Symposium (MHSRS), Kissimmee, FL, 27 August 2017 (poster)

Tschiltz N, Halsey J, Eliasson A, Kashani M, Walizer E, Villines T, Vernalis M. Dietitians in the kitchen impact cardiovascular disease prevention. Society for Nutrition Education and Behavior, Washington DC, 21 July 2017 (poster)

Eliasson A, Kashani M, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. Prevalence of sleep disturbances and their consequences in patients at risk for cardiovascular disease. Associated Professional Sleep Societies (APSS) 2017 Scientific Session, Boston, MA, 3-7 June 2017 (poster)

Eliasson A, Kashani M, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. A novel lifestyle change program identifies and improves cardiovascular risks in middle-aged women. American Thoracic Society (ATS) 2017 Meeting, Washington DC, 19-24 May 2017 (poster)

Kashani M, Eliasson A, Walizer E, Fuller C, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Reversing prediabetes when diet and exercise are not enough. Walter Reed National Military Medical Center, Department of Research Program, 2017 Research and Innovation Month, Bethesda, MD, 1-5 May 2017 (Robert A. Phillips Research Award competition poster and podium)

Tschiltz N, Eliasson A, Halsey J, Walizer E, Kashani M, Villines T, Vernalis M. Dietitians in the kitchen impact cardiovascular disease prevention. Walter Reed National Military Medical Center, Department of Research Program, 2017 Research and Innovation Month, Bethesda, MD, 1-5 May 2017 (Paul Florentine Patient and Family-Centered Care competition poster)

Kashani M, Eliasson A, Walizer E, Fuller C, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Reversing prediabetes when diet and exercise are not enough. Preventive Cardiovascular Nurses Association (PCNA) 23rd Annual Symposium, Denver, CO, 7-9 April 2017 (poster)

Kashani M, Eliasson A, Fuller C, Walizer E, Turner E, Tschiltz N, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. A single measurable outcome tool for tracking behavioral change. American Heart Association's 2017 Scientific Sessions Quality of Care and Outcomes Research (QCOR), Arlington, VA, 2-3 April 2017 (poster)

Kashani M, Eliasson A, Fuller C, Walizer E, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Arresting insulin resistance with an integrative health intervention. 66th Annual Scientific Session of the American College of Cardiology (ACC 2017) Scientific Session, Washington, DC, 17-19 March 2017 (poster)

Kashani M, Eliasson A, Walizer E, Fuller C, Tschiltz N, Turner E, Grunewald M, Halsey J, Engler R, Villines T, Vernalis M. Multidisciplinary cardiovascular team review captures preclinical disease. 66th Annual Scientific Session of the American College of Cardiology (ACC 2017) Scientific Session, Washington, DC, 17-19 March 2017 (poster)

2016

Engler R, Kashani M, Eliasson A, Walizer E, Fuller C, Villines T, Vernalis M. Blood pressure elevations below hypertension threshold linked to insulin resistance and dyslipidemia: an under-recognized cardiovascular disease risk phenotype. Military Health System Research (MHSRS) Symposium 2016, Kissimmee, FL, 15-18 August 2016 (poster)

Eliasson A, Kashani M, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. Targeted behavioral interventions improve disturbed sleep. APSS, Denver, CO, 11-15 June 2016 (poster)

Kashani M, Eliasson A, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. Strategies to boost self-efficacy promote multicomponent behavior changes. Society of Behavior Medicine (SBM) 37th Annual Meeting & Scientific Session, Washington DC, 30 March 2016 (poster)

Ellsworth DL, Costantino NS, Blackburn HL, Engler RJM, Vernalis MN. Cardiac interventions differing in lifestyle modification improve insulin resistance through changes in lipoprotein profiles. American Heart Association (AHA) EPI/Lifestyle 2016 Scientific Sessions, Phoenix, AZ, March 2016 (poster)

2015

Kashani M, Eliasson A, Walizer E, Fuller C, Engler R, Villines T, Vernalis M. Early empowerment strategies boost self-efficacy to improve health outcomes. *(Accepted for presentation - AHA Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke 2015 Scientific Session – sessions canceled.)* Presented at AHA 2015 Scientific Session, Orlando, FL. November 2015 (poster)

Vernalis MN, Engler RJM, Mamula KA, Blackburn HL, Kashani M, Ellsworth DL. Weight loss impact on insulin resistance: A novel lipoprotein insulin resistance index (LP-IR) identifies differing phenotypes of response to lifestyle intervention. Military Health System Research Symposium (MHSRS), Fort Lauderdale, FL, August, 2015 (podium)

Eliasson A, Kashani M, Fuller C, Walizer E, Engler R, Villines T, Vernalis M. High self-efficacy may benefit sleep quality and fatigue. Associated Professional Sleep Societies (APSS), Seattle, WA, June 2015 (poster)

Kashani M, Eliasson A, Engler R, Villines T, Vernalis M. Women present with non-traditional precursors of CVD. Preventive Cardiovascular Nurses' Association 21st Annual Symposium (PCNA), Anaheim, CA, 8-11 April 2015 (poster/moderated session - received 2nd place ribbon in research competition)

Ellsworth DL, Mamula KA, Blackburn HL, Engler RJM, and Vernalis MN. Cardiac lifestyle interventions differing in dietary stringency improve insulin resistance through changes in lipoprotein profiles. The American College of Cardiology (ACC) 64th Annual Scientific Session, San Diego, CA, 14-16 March 2015 (poster)

Kashani M, Eliasson A, Engler R, Turner E, Tschiltz N, Grunewald M, Halsey J, Fuller C, Villines T, Vernalis M. Prediabetes reversal using a novel comprehensive health model. The American College of Cardiology 64th Annual Scientific Session, San Diego, CA, 14-16 March 2015 (poster – received recognition as "Best CV Team" award)

2014

Eliasson AH, Kashani MD, Doody MM, Jones MK, Vernalis MN. Fatigue in women is a key symptom in evaluation of sleep apnea. CHEST 2014, Austin, TX, October 2014 (poster)

Walizer EM, Vernalis MN, Modlin RE. Influence of CIMT as a motivator for health behavior change in a heart health program. AHA EPI/NPAM 2014 Scientific Session, San Francisco, CA, March 19, 2014 (poster)

2013

Vernalis, MV. The results of studies of cardiovascular disease risk and prevention in the military population. Osteopathic Medical Conference & Exposition: 57th Annual Research Conference, September 30, 2013, Las Vegas, NV (podium)

Blackburn HL, Mamula KA, Haberkorn MJ, Burke A, Slavik JE, Sann NJ, Marley KR, Vernalis MN, Ellsworth DL. Differential effectiveness of laparoscopically-adjustable gastric banding versus lifestyle modification for modifying plasma lipoprotein profiles. Obesity 2013: 31st Annual Scientific Meeting, November 11-16, 2013, Atlanta, GA (poster)

Eliasson AH, Kashani M, Bailey K, Vernalis M. Sleep quality improves in adherents to heart health program without change in sleep duration. Affiliated Professional Sleep Society Meeting, June 2013 (poster)

Bailey K, Kashani M, Eliasson A, Vernalis M. Low self-efficacy correlates with increased cardiovascular disease risk. AHA Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke 2013 Scientific Session, Baltimore, MD, 15-17 May 2013 (poster)

Kashani M, Eliasson A, Bailey K, Vernalis M. Systematic inquiry of family history improves CV risk assessment. AHA Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke 2013 Scientific Session, Baltimore, MD, 15-17 May 2013 (poster)

Walizer EM, Vernalis MN, Modlin RE. Adherence to a lifestyle intervention program not improved by visual knowledge of carotid intima atherosclerosis. AHA Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke 2013 Scientific Session, Baltimore, MD, 15-17 May 2013 (poster)

Burke A, Ellsworth DL, Haberkorn MJ, Lechak F, Sullivan J, Adams B, Patney HL, Mamula KA, Vernalis MN, Kashani M. Coaching patients to control hypertension through a team-based, patient-centered program: the cardiovascular risk clinic. Preventive Cardiovascular Nurses Association: PCNA 19th Annual Symposium, May 2-4, 2013, Las Vegas, NV (poster-1st place winner: Innovation in Patient Care category)

Bittman B, Ellsworth DL, Vernalis MN. Stress reduction through creative musical expression impacts biological pathways on the DNA level in individuals with coronary heart disease. National Summit: Arts, Health & Well-being Across the Military Continuum, National Initiative for Arts & Health in the Military, National Endowment for the Arts, April 10, 2013, Walter Reed National Military Medical Center, Bethesda, MD (podium)

2012

Decewicz A, Hicks M, Mamula KA, Burke A, Haberkorn MJ, Patney HL, Vernalis MN, Ellsworth DL. SNPs associated with plasma triglyceride levels influence response during intensive cardiovascular risk reduction. American Society of Human Genetics, 6-10 Nov 12, San Francisco, CA (poster)

Miller EJ, Mamula KA, Leng L, Piecychna M, Vernalis MN, Bucala R, Ellsworth DL. Cardiovascular disease risk factor modification decreases HS-CRP and Macrophage Migration Inhibitory Factor (MIF): Influence of gender. American Heart Association Scientific Sessions 2012, 3-7 Nov 12, Los Angeles, CA (poster)

Eliasson A, Kashani M, Vernalis M. Sleepy on Venus, Fatigued on Mars? TriService American College of Physicians, 1-3 Nov 12, Bethesda, MD (podium)

Modlin RE, Walizer EM, Vernalis MN. CIMT imaging knowledge effect on lifestyle program adherence. TriService American College of Physicians, 1-3 Nov 12, Bethesda, MD (podium)

Eliasson AH. Sleep—the Year in Review. TriService American College of Physicians, 1-3 Nov 12, Bethesda, MD (podium)

Kashani M, Eliasson A, Bailey K, Vernalis M. Novel stress reduction technique improves sleep and fatigue. American College of Chest Physicians, 22 Oct 12, Atlanta, GA (podium)

Sandrick J, Tracy D, Eliasson A, Kashani M, Vernalis M. Do dietary goals correlate with eating behaviors? Food and Nutrition Conference and Expo, 6 Oct 2012, Philadelphia PA (poster)

Ellsworth DL, Croft DT Jr, Burke A, Haberkorn MJ, Patney HL, Mamula KA, Vernalis MN. The importance of weight loss for effecting molecular change during intensive cardiovascular risk reduction. Obesity 2012: 30th Annual Scientific Meeting, 20-24 Sep 12, San Antonio, TX (poster)

Eliasson A, Kashani M, Vernalis M. Sleepy on Venus, Fatigued on Mars? American Thoracic Society, 22 May 2012, San Francisco CA (poster)

Dela Cruz G, Eliasson A, Kashani M, Vernalis M. Oral health and dental self-care habits in recently deployed Army National Guard soldiers. National Oral Health Conference, 30 Apr 2012, Milwaukee MN (poster)

2011

Croft DT Jr, Voeghtly L, Patney HL, Shriver CD, Vernalis MN, Ellsworth DL. Performance of whole-genome amplified DNA isolated from serum and plasma for estimating copy number variation with high density single nucleotide polymorphism arrays. Association for Molecular Pathology (AMP) 2011 Annual Meeting, 17-19 Nov 11, Grapevine, TX (poster)

Voeghtly L, Croft DT Jr, Deyarmin B, Vernalis MN, Shriver CD, Ellsworth DL. Utility of whole genome amplification for assessing copy number variation with high density SNP arrays from formalin-fixed paraffin embedded tissue. Association for Molecular Pathology (AMP) 2011 Annual Meeting, 17-19 Nov 11, Grapevine, TX (poster)

Eliasson A, Kashani M, Hoffman J, Vernalis M. Racial differences in perceived stress, sleep habits, and daytime symptoms. Associated Professional Sleep Societies, Jun 2011, Minneapolis, MN (poster)

Eliasson A, Kashani M, Bailey K, Vernalis M. The Berlin questionnaire identifies a population with traits inhibiting adherence. American Thoracic Society, May 2011, Denver, CO (poster)

Kashani M, Eliasson A, Bailey K, Vernalis M. Novel tool improves CV risk stratification and guides therapy. Quality of Care and Outcomes Research in CV Disease and Stroke, May 2011, Washington DC (poster)

Burke A, Haberkorn J, Lechak F, Sullivan J, Vizza J, Vernalis MN, Ellsworth DL. Stress Therapy Empowers Prevention (STEP): A healthy-lifestyle program for breast cancer patients. National Consortium of Breast Centers Conference, Mar 2011, Las Vegas, NV (poster)

Ellsworth D, Patney HL, Burke A, Haberkorn J, Lechak F, Sullivan J, Vizza J, Neatrour DM, Vernalis MN. Improvement in cardiovascular risk factors in breast cancer patients participating in the Stress Therapy Empowers Prevention (STEP) Program. National Consortium of Breast Centers Conference, Mar 2011, Las Vegas, NV (poster)

Ellsworth DL, Soltow QA, Kolli K, Patney HL, Jones DP, and Vernalis MN. Cardiac rehabilitation involving lifestyle modification alters comprehensive plasma metabolomic profiles defined by LC-FTMS. AHA Nutrition, Physical Activity & Metabolism/CV Disease Epidemiology and Prevention Scientific Session, Mar 2011, Atlanta, GA (poster)

Dela Cruz G, Eliasson A, Kashani M, Bishop A, Russo J, Vernalis M. Health indicators in the Army Reserve Component affect military readiness. Armed Forces Public Health Conference, Mar 2011, Hampton Roads, VA (poster)

Kashani M, Eliasson A, Vernalis M. Sleep parameters associated with hyperinsulinemia increase cardiovascular disease risk. National Sleep Foundation, Mar 2011, Washington, DC (poster)

Saum N, Walizer E, Vernalis M. Feasibility of including limited mindfulness training in an existing therapeutic lifestyle change (TLC) program. Prevention Cardiovascular Nurses Association (PCNA), Mar 2011, Orlando, FL (poster)

Walizer E, Kashani M, Eliasson A, Vernalis M. Integrative Cardiac Health Project risk score improves cardiovascular risk assessment in women with subclinical atherosclerosis**.** Prevention Cardiovascular Nurses Association (PCNA), Mar 2011, Orlando, FL (Poster - 1st place winner: Data-Based Research Category)

2010

Walizer E, Kashani M, Eliasson A, Vernalis M. Integrative Cardiac Health Project Score improves CV risk assessment in women with subclinical atherosclerosis. American College of Physicians, Army Region, 19 Nov 2010, Bethesda, MD (poster)

Kashani M, Eliasson A, Vernalis M. Comprehensive early assessment is critical for CV prevention. American College of Physicians, Army Region, 18 Nov 2010, Bethesda, MD (poster)

Kashani M, Eliasson A, Bailey K, Vernalis M. The need for cardiovascular prevention in young military service members. American College of Physicians, Army Region, 18 Nov 2010, Bethesda, MD (poster)

Eliasson A, Kashani M, Mayhew M, Ude A, Hoffman J, Vernalis M. Reducing perceived stress improves sleep quality—a longitudinal outcomes study. American College of Chest Physicians, 30 Oct 2010, Vancouver, BC (podium)

Mayhew M, Eliasson A, Kashani M, Vernalis M. Should subclinical hypothyroidism be treated to lower cardiovascular risk? American College of Nurse Practitioners, 20 Oct 2010, Tampa, FL (poster)

Vernalis M, Kashani M, Eliasson A. The need for cardiovascular prevention in young military service members. Force Health Protection Conference, Aug 2010, Phoenix, AZ (poster)

Eliasson AH, Kashani M, Mayhew M, Vernalis M. Improving sleep quality correlates with lower weight—A longitudinal outcomes study. Associated Professional Sleep Societies, 5 Jun 2010, San Antonio, TX (poster)

Kashani M, Eliasson A, Vernalis M. Prediabetics improve CV risk profile by reducing stress. American Heart Association Quality of Care and Outcomes Research in CV Disease and Stroke, 19 May 2010, Washington DC (poster)

Eliasson AH, Kashani M, Vernalis M. *Longer sleep time confers cardiovascular health benefit.* American Thoracic Society, 14 May 2010, New Orleans, LA (poster)

Ellsworth DL, Decewicz DJ, Neatrour DM, Burke A, Haberkorn MJ, Patney HL, Vernalis MN. Intensive lifestyle modification for CAD reversal successfully reduces circulating levels of metabolic hormones insulin and leptin. American Heart Association's Arteriosclerosis, Thrombosis and Vascular Biology Scientific Session, 8 April 2010, San Francisco, CA (poster)

Kashani M, Eliasson A, Hoffman J, Vernalis M. Assessing perceived stress provides targets for stroke prevention. American Heart Association International Stroke Conference, 24 Feb 2010, San Antonio, TX (poster)

2009

Turner E, Kashani M, Eliasson A, Vernalis M. Small amounts of regular exercise: a lifetime investment. The Obesity Society, 24 Oct 2009, Washington DC (poster)
Turner E, Kashani M, Eliasson A, Vernalis M. The tortoise and the hare: Differences in slow and fast completers of an integrative lifestyle change program. The Obesity Society, 24 Oct 2009, Washington DC (poster)

Tschiltz N, Eliasson A, Kashani M, Howard R, Vernalis M. Assessing compliance with the mediterranean diet. Food and Nutrition Conference and Exposition, 17 Oct 2009, Denver, CO (poster)

Ellsworth DL, Weyandt J, Love B, Burke A, Haberkorn MJ, Patney HL, Jordan RM, Vernalis MN. A cardiovascular lifestyle change program for heart disease reversal changes patterns of gene expression in peripheral blood. 59th American Society of Human Genetics Annual Meeting, 20 Oct 2009, Honolulu, HI (poster)

Hoffman J, Kashani M, Eliasson A, Vernalis M. High stress may adversely affect military readiness. Force Health Protection Conference, 14 Aug 2009, Albuquerque, NM (poster)

Eliasson AH, Kashani M, Lettieri C, Vernalis M. Correlations between activity and sleep. Associated Professional Sleep Societies, 6 Jun 2009, Seattle, WA (poster)

Eliasson A, Kashani M, Turner E, Vernalis M. Sleep is a critical factor in the maintenance of a healthy weight. American Thoracic Society, 15 May 2009, San Diego, CA (poster)

Mayhew M, Kashani M, Eliasson A, Vernalis M. Added value of an Integrative Cardiovascular Prevention Program. Preventive Cardiovascular Nurses Association Annual Symposium, 16 Apr 2009, Dallas, TX (poster)

Walizer E, Halsey J, Buenaflor G, Saum N, Vernalis M. Successful weight loss intervention utilizing an interdisciplinary team model. Preventive Cardiovascular Nurses Association Annual Symposium, 16 Apr 2009, Dallas, TX (poster)

Kashani M, Eliasson A, Vernalis M, Wu H, Taylor A. Value of a novel cardiovascular risk score. Quality of Care and Outcomes Research in CV Disease and Stroke. 9 May 2009, Washington DC (poster)

2008

Tschiltz N, Kashani M, Eliasson A, Vernalis M. Individuals with diabetes benefit from an integrative program using the Mediterranean diet. Food and Nutrition Conference and Exposition, 25 Oct 2008, Chicago, IL (poster)

Kashani M, Eliasson A, Mayhew, M, Tschiltz N, Turner E, Hoffman J, Vernalis M. Optimal diabetes management using an integrative prevention model. Force Health Protection Conference, 12 Aug 2008, Albuquerque, NM (poster)

Kashani M, Eliasson A, Chrosniak L, Mosier, R, Horoho P, Vernalis M. Reducing nurse stress with an integrative lifestyle change program, a non-stigmatized portal. Force Health Protection Conference, 12 Aug 2008, Albuquerque, NM (poster)

Tschiltz N, Eliasson A, Kashani M, Vernalis M. Do dietary guidelines influence population eating habits? Society for Nutrition Education, Jul 2008, Atlanta, GA (poster)

Kashani M, Eliasson A, Mayhew M, Phillips J, Chrosniak L, Mosier R, Horoho P, Vernalis M. Reducing nurse burnout with an integrative lifestyle change program. Preventive Cardiovascular Nurse Association, 24 Apr 2008, Orlando, FL (poster)

Tschiltz N, Kashani M, Eliasson A, Vernalis M. Individuals with diabetes benefit from an integrative program using the Mediterranean diet. Maryland Dietetic Association, Mar 2008, Rockville, MD (poster)

Ellsworth DL, Weyandt J, Patney HL, Love B, Burke A, Haberkorn MJ, Neatrour DM, Vernalis MN. Changes in global gene expression profiles during a lifestyle change program for heart disease reversal correlate with CAD risk factor improvement. 48th Annual Conference on Cardiovascular Disease Epidemiology and Prevention, 13 Mar 2008, Colorado Springs, CO (poster)

2007

Carlson M, Kashani M, Eliasson A, Vernalis M. The Integrative Cardiac Health Project: A novel approach to cardiovascular disease prevention. Army American College of Physicians Meeting, Oct 2007, San Antonio, TX (podium)

Kashani M, Eliasson A, Chrosniak L, Walizer E, Horoho P, Vernalis M. Military nurses require tailored lifestyle strategies. Force Health Protection Conference, Aug 2007, Louisville, KY (poster)

Kolli K, Katenhusen R, Kirchner D, Patney HL, Weyandt J, Burke A, Haberkorn MJ, Mural RJ, Gitlin E, Ellsworth DL. Label free quantitation of plasma proteins by LTQ-FT. American Society for Mass Spectrometry Annual Meeting, 3 Jun 2007, Indianapolis, IN (poster)

Vernalis MN. New paradigm in cardiovascular prevention. Armed Forces Symposium, American College of Cardiology, May 2007 (podium)

Kashani M, Eliasson A, Chrosniak L, Walizer E, Horoho P, Vernalis M. Military nurses require tailored lifestyle strategies. 13th Annual Symposium of Preventive Cardiovascular Nurses Association, 26 Apr 2007, Minneapolis, MN (poster)

Walizer EM, Marshall DA, Taylor AJ, Vernalis MN. The effect of an intensive 1-year lifestyle intervention program on carotid intima-medial thickness. AHA 47th Annual Conference on Cardiovascular Disease Epidemiology, 28 Feb 2007, Orlando, FL (poster)

2006 and prior years

Marshall D, Walizer E, Vernalis M. Enhancing achievement of healthy lifestyle habits in military healthcare beneficiaries through a lifestyle intervention program. AHA 46th Annual Conference on Cardiovascular Disease Epidemiology and Prevention, 2 Mar 2006, Phoenix, AZ (poster)

Katenhusen RA, Kirchner DR, Preuss AM, Sutton J, Zhu L, Ru C, Wingerd M, Kolli K, Ellsworth DL. Influence of a cardiovascular disease lifestyle intervention on the plasma proteome. Human Proteome Organization Fourth Annual World Congress, 29 Aug 2005, Munich, Germany (poster)

Marshall D, Walizer E, Northrup G, Vernalis M. On-site case management is better than telephonic monitoring for weight loss. International Academy of Cardiology: 12th World Congress on Heart Disease, Jul 2005, Vancouver, BC (poster)

Katenhusen RA, Zhu L, Ru Q, Kirchner D, Orchard TJ, Ellsworth DL. Proteomic profiling of human urine using multi-dimensional protein identification technology. American Society of Mass Spectrometry, 5 Jun 2005, San Antonio, TX (poster)

Marshall D, Walizer E, Vernalis M. Therapeutic lifestyle change: An alternative to high-dose statins for achieving new low density lipoprotein cholesterol goals. American Heart Association 45th Annual Conference on Cardiovascular Disease Epidemiology and Prevention, 29 Apr 2005, Washington, DC (poster)

Marshall D, Walizer E, Vernalis M. Therapeutic lifestyle change (TLC): An alternative to high-dose statins for achieving new LDL goals. American College of Physician Annual Meeting, Army Chapter, 12 Nov 2004, Arlington, VA (podium)

Marshall D, Walizer E, Northrup G, Vernalis M. On-site case management is better than telephonic monitoring for weight loss. American College of Physician Annual Meeting, Army Chapter, 12 Nov 2004, Arlington, VA (podium)

Kashani M, Walizer E, Vernalis M, Marshall DA. Metabolic syndrome patients in an Ornish intensive lifestyle change program exhibit higher perceived stress. 10th Annual Preventive Cardiovascular Nurses Association Symposium, 22 Apr 2004, Orlando, FL (poster)

Walizer E, Kashani M, Vernalis MN, Marshall DA. Favorable impact of the Ornish lifestyle change program on metabolic syndrome. American Heart Association 44th Annual Conference on Cardiovascular Disease Epidemiology and Prevention, 3 Mar 2004, San Francisco, CA (poster)

Marshall D, Walizer E, Vernalis M. Gender differences in C-reactive protein with intensive lifestyle interventions in patients with or at-risk for coronary artery disease. American Heart Association's 2nd Asia Pacific Scientific Forum, 8 Jun 2003, Honolulu, HI (poster)

Vernalis, M. Therapeutic lifestyle change to reduce CHD & CHD risk. Uniformed Services University of Health Sciences, April 2003, Bethesda, MD (podium)

Marshall D, Vernalis M, Walizer E, Arthur C, Northrup G, Kashani M, Darst T, Turner E, Walker M, Greene R, Gadhia-Smith A, Sundstrom S. Early efficacy of intensive lifestyle change in patients with or at risk for coronary artery disease. AHA 43rd Annual Conference on Cardiovascular Disease Epidemiology and Prevention, 5 Mar 2003, Miami, FL (poster)

Walizer E, Vernalis M, Marshall D, Greene R, Sundstrom S, Gadhia-Smith A. Does gender affect the benefit of stress management in an Ornish lifestyle modification program? 9th Annual Preventive Cardiovascular Nurses Association Symposium, 27 Feb 2003, San Francisco, CA (poster)

Vernalis M, Marshall D. Participants in Think Tank on Enhancing Obesity Research at the National Heart, Lung, and Blood Institute, March 2003. Obesity in the Military.

Vernalis, M. Participant in Senate Testimony, Report: Stress and Heart Disease—Hearing Before the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, 16 May 2002. http://olpa.od.nih.gov/hearings/107/session2/reports/heartdiseasehr.asp

Vernalis M, Marshall D, Walizer E, Northrup G, Kashani M, Darst T, Greene R, Turner E, Walker M, Sundstrom S, Gadhia-Smith A. Early efficacy of intensive lifestyle change in patients with or at risk for coronary artery disease. American College of Physician Annual Meeting, Army Chapter, Nov 2002 (poster)

ernalis M, Marshall D, Walizer E, Greene R, Sundstrom S, Gadhia-Smith A. Does gender affect the benefit of stress management in an Ornish lifestyle modification program? American College of Physician Annual Meeting, Army Chapter, Nov 2002 (poster)

Strimel WJ, Vernalis M, Ocuin E, Walizer E, Taylor A. Effect of a low fat diet on markers of inflammation: A potential mechanism of reducing cardiovascular risk. American College of Physician Annual Meeting, Army Chapter, Nov 2001 (poster)

Vernalis M, Ocuin E, Remaley, AT, Scally JP, Walizer E, Sampson M, Arthur C, Runner J, Northrup G, Taylor AJ. Do lifestyle changes negate the adverse effect of ultra-low fat diets on HDL cholesterol and apoprotein A-I?: The Ornish diet and lifestyle modification program. American Heart Association 2001 Scientific Sessions, 11Nov 2001, Anaheim, CA (podium)

Northrup G, Walizer E, Arthur C, Runner J, Vernalis M, Ocuin E. Coronary artery disease reversal program. 7th Annual Preventive Cardiovascular Nurses Association Symposium, April 2001 (poster)

Appendix 6

Timeline: Pre/Post Audit for ICHP Registry

Date	Event or Correspondence
7/17/2017	Email notification to COL Todd Villines and ICHP Team by Diane Beaner (WRMNNC DRP Research Compliance Officer) of the Post-Approval Compliance Monitoring (PACM) "for cause audit"
7/17/2017	Elaine Walizer (ICHP) coordinated audit date with Diane Beaner (8-9 August 2017)
7/17/2017	Diane Beaner sent to Elaine Walizer the PI Self-Assessment tool to be completed for the CHP Registry and CBT-I protocols
7/17/2017	Dr. Vernalis (ICHP) emails COL Peter Weina, WRNMMC DRP Chief, requesting a meeting to address the target concerns of the audit notification (there was no additional follow-up to this request by COL Weina)
7/17/2017	HJF Regulatory Affairs (Marianne Spevak/Julie Lee) notified about audit & HJF pre-audit arranged for 2 August 2017.
7/18/2017	Diane Beaner emails Elaine Walizer for PI Project List for LTC Todd Villines, Dr. Vernalis and Dr. Eliasson (List of ICHP protocols with LTC Villines as PI sent)
8/2/2017	HJF pre-audit conducted; no findings noted
8/8-9/2017	WRNMMC PACM conducted at ICHP. Focused was on CHP Registry study. All regulatory files, consents + 50 patient records reviewed. Minimal time spent on the CBT-I study (only consents reviewed). (NOTE: CHP Registry Continuing Review was approved by WRNMMC IRB on 28 March 2017.)
8/23/2017 5PM	ICHP Research team receives the PACM Audit Summation Report (dated 21 August 2018)
8/24/2017	Enrollment to CHP Registry stopped.
8/28/2017	ICHP (Dr. Renata Engler) provided "Initial Response" email to Diane Beaner.
9/1/2017	COL Weina initiates PACM Action Memo (draft)
9/21/2017	ICHP Response to PACM audit findings sent to Diane Beaner, CAPT Rotruck, CAPT Aslam, COL Weina, COL Naybeck-Beebe, COL Hemann, LTC Jezior, Mr. Hapner (HJF) – this document included the ICHP Action Plan
9/27/2017	COL Weina – read receipt to ICHP Audit Response
10/18/2017	CAPT Saira Aslam email to DRP, WRNMMC Command and ICHP announcing 30 October 2017 meeting with CAPT Rotruck to discuss results of audit, plan for clinical monitoring of subjects enrolled in ICHP protocols & requirements for clinical privileging
10/18/2017 10:47AM	COL Villines email to Drs. Vernalis/Kashani – regarding his conversation with CAPT Saira Aslam: inaccuracies in audit and ICHP response should be acknowledged (she agreed that response should be part of the record), concerns that LCDR Strutts memo only references initial audit findings, CAPT Aslam's hope that DRP would response to ICHP response by submitting an addendum to their original letter based

	on ICHP response, and status of MOU draft and that they were reluctant to finalize it until the role of ICHP and USU is finalized. She stated that USU DOM (Dr. Pangaro) was not supportive of ICHP falling under DOM at USU. COL Villines recommended a meeting with Ms. Beaner and COL Weina to discuss ICHP response and that ICHP response be sent to all those invited to 30 October meeting to ask that it be included in the action memo (recommended to CAPT Aslam).
10/24/2017	Dr. Vernalis email to CAPT Rotruck ("For consideration prior to OCT 30, 2017 WRNMMC-ICHP meeting") asking confirmation that Action Memo refers to a version of the 21 August 2017 letter (Audit Summation Report) that includes the ICHP response to the audit and to include the ICHP response as a reference. She also requested clarification 1) basic clinical services continue while action items are completed & 2) de-identified data analysis can continue. An update on the status of the MOU was requested.
10/24/2017 12:10PM	COL Weina responds to prior email to Dr. Vernalis providing the following clarification: 1) CHP Registry is "on-hold" and any work on protocol would be considered as "continuing non-compliance" and 2) MOU – inappropriate agreement vehicle and "disconnect between the self-identification as a clinical program and/or as a research program is somewhat at the center of the entire discussion".
10/24/2017 12:26	COL Villines email to Dr. Vernalis, Betty Crosby (HJF), Cathy Clark (HJF) in response to COL Weina's email– "we should ensure all data analysis of any type is not going on and that any abstract in preparation should cease and any submitted materials need to be withdrawn if accepted if this is not cleared up prior to abstract publication/presentation. He also asks question: Is ICHP not a federal entity in that it is funded by MRMC (the US Army)? HJF, per his knowledge, is the administrator of this research program, not the overarching "entity".
10/24/2017 12:28	Dr. Vernalis email to COL Villines (Cathy Clark, Betty Crosby cc'd) letting him know she had just finished a call to Betty Crosby and that HJF Legal clarify. She states that COL Weina is incorrect.
10/24/2017 12:29	COL Villines email to Dr. Vernalis, Cathy Clark, Betty Crosby stating "a response to this is needed. Furthermore, ICHP has been operating with the blessing of the WRNMMC Command for years, having briefed the BoD, OTSG and repeated Directors/Commanders.
10/26/2017	ICHP meeting with COL Weina – discussed "his perspective" (red flags – WRNMMC/ICHP Integration MOU push through – Staff Judge Advocate office asked for ICHP to be looked at); funding as P6 monies for research [awarded to non-federal entity (HJF) completely run by contractors] not clinical care research; privileging necessary and documentation of clinical care in AHLTA; charter necessary; co-mingling of research and clinical care; Way Forward.
10/28/2017	CAPT Rotruck email to COL Weina/Dr. Vernalis – acknowledging confidence to resolve remaining questions and increasing meeting time on 30 Oct to 1 hour. Stated he had not seen the MOU until this message and could not comment, but that COL Weina's comments on the issue can provide a way forward.

10/30/2017	WRNMMC-ICHP Meeting with CAPT John Rotruck, WRNMMC Chief of Staff
10/30/2017 5:47PM	Dr. Vernalis email to ICHP Executive Staff re: Meeting with CAPT Rotruck provided a summary of this meeting: -"Overall the meeting went well. It was not confrontational or punitive but served to facilitate our moving forward. We concurred with all the action items. We discussed the CRADA…there will be a bridge CRADA which will be overarching and not per protocol. This may change to a cooperative agreement when we get to USU in April 2019. We discussed a Charter. Cathy Clark will help me with this. We discussed privileges and credentialing. We will all need to be red cross volunteers and provide clinical service as a volunteer in the hospital. More detail to come. Since Building 17 is not a clinical space it cannot occur in our building. They want protocol fixes and agreements completed before JACHO in February. -At the end, I told them that I was concerned about the perception of ICHP since the audit. They said we do good work and once the agreements and protocol fixes they will provide patient parking in our garage, make us a part of their map and give us a dot.mil and will work with us. We will see about the promises. -Meanwhile Todd will be the clinical monitor for the patients currently in the program. I want to hold any new patients for now and no ordering on our end. Todd will cosign labs. -We need to devote all our energy to the mod and the companion protocol. We need the impact statement and agreements but need to have the protocols done."
11/7/2017	Meeting with CAPT Aslam to discuss credentialing (Drs. Vernalis/Kashani/Jezior, E. Walizer) – have to see patients in one of the hospital clinics (Cardiology Mega-clinic is possibility), minimum of 8 patients/quarter, must have peer-reviewed encounters; modify SOW to cover what is needed to maintain clinical privileging, documentation in AHLTHA, need DEA licenses, renew PAR, timeline February 2018. CAPT Aslam would need SOW and contract and then send to lawyer for review. Document plan (does not need to be "official" & attach to Action Item sign off by CAPT Rotruck.
12/15/2018	Dr. Haigney provided the Scientific Review document for the UPLIFT 2 protocol.
12/22/2017	Modification to CHP Registry submitted to WRNMMC IRB.
12/20/2017 11AM	Meeting with Dr. Engler, Freda Krosnick (DRP, Business Cell) to "Finalize Plan For Agreements Related To Eirb # 20525 Mod" (in attendance Dr. Engler, Freda Krosnick, Martin Hindel, Elaine Walizer, Christine Spooner)
12/20/2017 3:44PM	Dr. Engler follow-up email summarizing above meeting: Thank you so much for your time and consideration today. We deeply appreciate your understanding of our efforts and concerns about facilitating a way forward and getting started on the work to implement the work in support of the protocol MOD work. One clarification from Ms Spooner after the meeting: the BIOSAMPLES ARE CONSIDERED PROPERTY OF IHB-DHA (NOT WRNMMC) rather than Walter Reed as

	they were collected at multiple sites between 2004-2010 but are stored locally in the local area. Key Items discussed: Collaborative Research Agreement supporting cooperative research work between 1: Immunization Healthcare Branch-Defense Health Agency (IHB-DHA): Dr. Collins and Ms. Spooner with POC for agreements Ms. Mary Hussain. (protocol PI currently is Dr. Collins, POC for MOD is Dr. Engler) 2: Integrative Cardiac Health Project (ICHP)/HJF/Cardiology: Dr. Vernalis, Ms. Elaine Walizer, Dr. Mariam Kashani 3: Systems Biology Enterprise (SBE) Fort Detrick (see detailed contact info in attached word document regarding collaborations - Dr. Marti Jett, Dr. Rasha Hammamieh (See agreement request form for POC) 4: Abbott Laboratory Scientific Director/Asst Director: Dr. Beshiri and Dr. Murtagh (separate connecting email to follow) #5: Walter Reed NMMC as part of the agreement process [QUESTIONs raised requiring your internal review/considerations] CAVEAT NOTE: ABBOTT requires a single agreement with all components under one document (data sharing, material transfer, privacy, etc.) ISSUE PENDING: I will construct an email outlining our request to obtain a START letter from COL Weina for the protocol work that needs to be done on site and that does not involve those in the collaboration (where shipment of samples or data occurs). I plan to have that ready to send on Tuesday or Wednesday of next week. ATTACHMENTS: 1: eIRB 20525 Protocol MOD with YELLOW HIGHLIGHTS of the parts that are relevant to the agreements and actual PROTOCOL MOD WORK. 2&3: Copies of agreement request forms provided at meeting and via email Earlier 4: Overview of detailed POC information relevant to ALL collaborations involved in the project 5: Protocol Approval letter (NOT start letter)
12/28/2017 1:59PM	Ms. Krosnick's response email to Dr. Engler's summary email: Thank you for your e-mail summarizing our discussions, and for providing the "highlighted" protocol MOD to assist in identifying the parts that are relevant to the potential agreements. This will be helpful. I also appreciate you providing a copy of the 2017 protocol approval letter. I took a closer look at the Agreement Request Forms (ARFs) that you provided and see that the bullet items do not provide any detail as to what each "party" plans to contribute to the collaborative effort. The bullet items should provide the type of detail so that an agreement can be drafted that specifically reflects the roles of the parties. In addition, it is my understanding that you are with HJF, and that HJF will be involved in the study. Recommend that you also reach out to Ms. Elizabeth Johnson (cc'd), who is the POC for agreements with HJF. When HJF is a party, it often takes

	the lead in drafting agreements. Keeping the HJF agreement POC in the loop will assist in the agreement effort. In the meantime, as I mentioned to you in my earlier e-mail of today, our office plans to meet internally to discuss the best way to move forward; and I will be sure to keep you informed.
1/11/2018	Dr. Vernalis reached out to Beth Johnson (HJF CRADA Specialist) to see if Dr. Engler had reached out to her and stating that agreements need to move forward.
1/18/2018	CHP Registry modification retracted due to new information obtained and revisions required (cannot be exempt).
1/18/2018 2:17PM	Beth Johnson email to Dr. Vernalis attaching draft ICHP Umbrella CRADA for review and input. Appendix A (20525 Protocol MOD-UPLIFT Part 1). HJF legal advised only sending umbrella CRADA for consideration at this time. Once this model is negotiated, UPLIFT Part 1 can be sent. Requested markup ASAP, then draft will be sent to WRNMMC.
1/18/2018 3:41PM	Beth Johnson email response to Dr. Vernalis' email above – "not seen this type of language in a CRADA before, but it seems this is the place to describe exactly what is expected (hoped for?) for negotiation." Redline requested for any edits.
1/18/2018 2:28	Dr. Vernalis response to Beth Johnson email (Betty Crosby cc'd) – requested 5 parking spaces for patients in Bldg. 17 parking garage and parking spaces for ICHP providers on campus; designate Bldg. 17 Suite 2A as part of the WRNMMC clinical area.
1/19/2018 10:09AM	Beth Johnson email to Dr. Vernalis and adding Norm Gardner (HJF, Director Clinical Trials Dept.) to email trail – regarding the LOW for ICHP Registry (Umbrella) CRADA - asking if he had seen language regarding WRNMMC providing parking and clinical space for ICHP?
1/19/2018 10:19AM	Norm Gardner response email to Beth Johnson/Dr. Vernalis – stating that language was in our original WRNMMC Master so I don't see why we can't at least ask for it in the SOW.
1/18/2018 2:42PM	Email initiated by Dr. Vernalis to CAPT Saira Aslam regarding "ICHP Progress" – outlined planned submission of registry and companion protocols by end of January; HJF-WRNMMC CRADA status – DRP given ICHP specific task responsibilities as requested, HJF repeatedly contacted DRP 3 times Nov/Dec 2017 with no response and HJF planning to schedule in person meeting; credentialing/privileging issue – Dr. Vernalis applied for DEA number, Dr. Kashani received her DEA number, NPs in process of getting DEA numbers. Obstacle of ICHP personnel working at WRNMMC would require modification to ICHP SOW & most likely will not be approved to spend grant money to cover ICHP staff working at hospital and "volunteer" time beyond their contracted work hours. ICHP personnel should be granted privileges for the scope of clinical work done as part of the research.
1/18/2018 11:42PM	CAPT Aslam responded to Dr. Vernalis' email – for clinical privileging, ICHP staff required to perform clinical work within appropriate Joint Commission (JC) accredited space. Building 17 is not a JC accredited space. Clinical work must be documented in AHLTA & peer-reviewed. Staff not able to meet this requirement at

	time of re-privileging will be placed on a FPPE (Focused Performance Plan Evaluation) within their specialty area. CAPT Rotruck cc'd on this message.
1/29/2018 6:25AM	CAPT Rotruck response to Dr. Vernalis email of 18 Jan 2018 (cc'd-COL Villines, COL Jezior, COL Hemann, COL Weina, CDR Liotta, CAPT Aslam): "I believed we all had a common operating picture on both the research and clinical sides for ICHP after our last group meeting, but based on the e-mail traffic below, I feel that may not be the case. In advance of a meeting with you and CAPT Aslam and other leaders within DMS, I wanted to highlight a few items so that all on this string have absolute clarity: -Bldg 17 is not a Joint Commission accredited clinical space, and there is no intent to ever add it to WRNMMC's Joint Commission application. Anything that would be considered clinical work (vice research) by the Joint Commission should absolutely not be happening in Bldg 17. -Clinical work to maintain currency and competency for clinical privileges at WRNMMC must take place in a Joint Commission accredited space and be documented in an approved electronic health record subject to external peer review (i.e. AHLTA, Essentris, etc). -Peer review of clinical work that can be validated by the Credentials Committee is a requirement to maintain clinical privileges at WRNMMC. -COL Villines is not an authorized Level 1 reviewer for clinical Performance Appraisal Reports or privileging applications. I will address that directly with him, and the UCMJ implications of violating that, in separate correspondence to him and his leadership chain."
1/30/2018	Dr. Vernalis met with COL Weina re: direction of UPLIFT & relationships with Abbott, etc.
1/30/2018 1:28 PM	Dr. Vernalis email to COL Weina (COL Villines, Dr. Kashani, HJF personnel cc'd)– thank you for informing ICHP that an overarching CRADA between WRNMMC & HJF is no longer needed now that USUHS has formally accepted ICHP in the Department of Medicine (FY19). Also Dr. Vernalis' understanding that once ICHP protocols are approved that operations can commence without an overarching CRADA.
1/30/2018 2:50PM	COL Weina email response to Dr. Vernalis to provide the following clarification: 1) An overarching CRADA between WRNMMC and HJF regarding ICHP would likely be overcome by the fact that USUHS has formally accepted ICHP in the USU Department of Medicine for FY19 (assuming Oct 2018). We fully anticipate that an enduring overarching CRADA would take at least that long to negotiate and execute, and therefore starting on one now would likely be fruitless. Should the situation of ICHP being integrated under USUHS change, this line of reasoning would likewise change. 2) Regarding your statement that "It is also my understanding that once our protocols are approved that we could proceed operations without an overarching CRADA" is technically correct with regards to an overarching CRADA specifically. It is important to understand though that those who are WRNMMC Principal Investigators (at this time COL Villines and Dr. Collins) on these protocols cannot start work without an official start letter that verifies any data sharing agreements and/or other types of agreements (CRADAs, MTAs, etc.) have been completed.

	There is of course also the issue of privileging that needs to be addressed and finalized with CAPT Rotruck and CAPT Aslam (outside our lane) before proceeding operations. COL Weina also acknowledged a meeting that took place earlier in the day and provided a more precise understanding of "the direction and scope of the ICHP relationship with Abbott and others. We look forward to completing the CRADA for Dr. Collins as quickly as possible."
1/31/2018 8:34AM	Beth Johnson response to Dr. Vernalis (COL Villines, Betty Crosby, Norm Gardner, Cathy Clark cc'd) – she will modify draft CRADA for UPLIFT Part 1. Asked whether Appendix A will stay the same in regards to clinical space and parking or will that be covered elsewhere?
2/7/2018	CHP Registry modification submitted to WRNMMC IRB
2/21/2018	CHP Registry modification approved by WRNMMC IRB
2/27/2018	WRNMMC DRP released policy on "Databases, Registries & Repositories"
3/9/2018	CHP Registry Continuing Review approved by WRNMMC IRB
4/11/2018	COL Jezior signed Scientific Review Memorandum received from Dr. Haigney (UPLIFT 2 protocol)
8/3/2017	Elaine Walizer (ICHP) received a called from Debbie Kessler (WRNMMC DRP) to ask if Dr. Vernalis had another CV where she is no longer listed as the ICHP Medical Director. She stated she had been directed by her command to inquire.
8/7/2018	Elaine Walizer (ICHP) again received a call from Debbie Kessler (WRNMMC DRP) to relay that she had been instructed to put off any further review of the CHP Companion protocol. Stated that there was a planned meeting for 9 August between COL Weina and Dr. Haigney (USU/Cardiology) to discuss the ICHP protocols.
8/9/2018	COL Weina met with Dr. Haigney and discussed current ICHP protocols since the ICHP program will fall under USUHS Cardiology later in the year. After this meeting, COL Weina sent an email to WRNMMC DRP staff (Debbie Kessler, Denise Neath, Verna Parchment, Robin Howard, Robert Roogow) directing the CHP Companion and UPLIFT 2 protocols to be placed in administrative hold or close them administratively on his authority.
8/10/2018	EIRB message (UPLIFT 2 protocol) received from Denise Neath – official notification referencing above message.
8/13/2018	ICHP Executive Team meeting with COL Chung – wants comprehensive view of ICHP and to address challenges; "clinical" vs "research" program; hostility issues with USU/WRNMMC; privileging issues; appropriate use and stewardship of $$
8/13/2018	eIRB message (CHP Study – Companion Protocol) received from Deborah Kessler – official notification of study being placed on administrative hold.
8/15/2018	Betty Crosby forwarded ERIB UPLIFT email to Marianne Spevak (HJF Regulatory Affairs) – notification of protocols on administrative hold.
9/5/2018	Marianne Spevak email to Denise Neath asking for further documentation for regulatory file on protocols on hold and information on why they are on hold.
9/6/2018	Denise Neath email to Marianne Spevak stating no additional documentation except for COL Weina's email direction and that she has cc'd him on this response.
9/6/2018	COL Weina email to Marianne Spevak regarding protocols on hold:

	ICHP protocols are on administrative hold for the following reasons: #1) ICHP has not been and is currently not officially affiliated with a governmental agency. #2) The current PI for the ICHP protocols is not willing to pursue the protocols with the transition to USU coming up on 01Oct2018. #3) The current Director of ICHP (who is also listed as an associated Investigator) is not privileged at WRNMMC and has no plan to get privileged. #4) There has not been a satisfactory resolution of the for cause audit of ICHP from one year ago. #5) ICHP is folding under USU on 01Oct2018 and the incoming USU Oversight Director and Chief of Medicine at USU concur with an administrative hold until such time as a rational plan for moving forward is established. (not necessarily in that order of priority)
9/24/2018	ICHP Executive Meeting with COL Chung & COL O'Malley (HJF – Betty Crosby and Marianne Spevak in attendance). Dr. Vernalis described ICHP mission and issues to date with USU transition process (ICHP changing mission, issues with DRP); separate out all the various issues (DRP, credentialing, USU transition); current contract with MRMC still binding until 3/31/19. COL O'Malley to take COL Villines place as uniformed PI. Change PI to O'Malley on retrospective data protocol; transition to be under USU Department of Medicine with COL O'Malley as interim director; plans for Governance Board which will include Fran O'Connor, COL O'Malley, Harry Burke, Dr. Mark Haigney, Dr. Turnofsky-Craft and COL Chung (non-voting); Governance Board will direct mission, objectives and science. Develop charter and 1st objective is to appoint spokesperson to brief Dr. Rausch on vision. UPLIFT may be folded into new product. Want to develop scalable program and decide what the modifiable variables are. Current program not scalable and seen as "concierge" medicine. Plan "summit" to have dialogue and planning for future science. New line of funding from congress (Health Affairs to USU). Will need SOW and proposal; may not include HJF and may not be called ICHP. Would like to see as many positions as possible stabilized, but positions may have to be reposted and applied for (timeline unclear). COL Chung has meeting 1 October with USU Finance to discuss funding. Goal is "academic" program. Civilian director may be considered. Process for possible transition of protocols needs to be established; deferment of 2nd level review from MRMC to USU? Plan another meeting with COL Chung after 1 October. Plan meeting with COL O'Malley to discuss current program/science.
10/1/2018	Emily Brede email to Denise Neath - "I was logged in to EIRB today to check some dates and discovered that the protocol had been marked as withdrawn. I checked with the rest of the team, and none of us were notified of this change in status. What does this mean for us moving forward? Do we need to start over with a new protocol submission? I can't figure out how to edit/revise and resubmit."
10/2/2018	Denise Neath response email to Emily Brede – (cc to COL Villines, COL Weina, Robert Roogow, Robin Howard, Dr. Haigney) - "Please see the email below which was sent August 10, 2018. This email was based on a meeting with Dr Haigney. See also the

	third email dated September 6th. If you have any further questions, I have cc'd the key personnel who would best be able to answer." ********** Sent From: Denise N Neath Send To: Todd Christopher Villines, M.D. COL, Emily C BREDE, PhD, Renata JOHANNA Engler, MD, Todd Christopher Villines, M.D. COL, Brian Andrew HEMANN, Robin S Howard, MA [Supervisory Biostatistician], Deborah D Kessler, RN, MSN, Denise N Neath, Verna A Parchment, Robert JASON Roogow, MS, Yaling Zhou, Peter Joseph Weina, PhD, MD COL Project Number: 16-00386 Study Number: 201705UPLIFT Posted: 08/10/2018 07:06:40 AM Title: UPLIFT (Ultra-Personalized Laboratory-Risk Intervention For Treatment) for Health: Cardiovascular (CV) Disease (CVD) Risk Study Project Status: Pending - Submitted for Initial Review Principal Investigator: Villines, Todd Christopher, M.D. COL Message Content: From Denise Neath,RN,CIP Dear Research Team, Please see COL Weina's email below as it applies to this study. V/r Denise -----Original Message----- From: Weina, Peter J COL USARMY DHA NCR MEDICAL DIR (US) Sent: Thursday, August 09, 2018 3:59 PM Subject: ICHP protocols Deb and Denise; At this time, please cease working on the two ICHP protocols discussed today with Dr. Haigney. You may place them in administrative hold or close them administratively on my authority. Please feel free to contact me with any questions. ********** -----Original Message----- From: Weina, Peter J COL USARMY DHA NCR MEDICAL DIR (US) Sent: Thursday, September 06, 2018 8:32 AM To: Neath, Denise N CIV DHA NCR MEDICAL DIR (US) <denise.n.neath.civ@mail.mil>; Marianne Spevak <mspevak@hjf.org> Cc: Grace Dillon <GDillon@hjf.org> Subject: RE: ICHP STUDY on HOLD Subject: RE: ICHP STUDY on HOLD ICHP protocols are on administrative hold for the following reasons: #1) ICHP has not been and is currently not officially affiliated with a governmental agency. #2) The current PI for the ICHP protocols is not willing to pursue the protocols with the transition to USU coming up on 01Oct2018.

	#3) The current Director of ICHP (who is also listed as an associated Investigator) is not privileged at WRNMMC and has no plan to get privileged. #4) There has not been a satisfactory resolution of the for cause audit of ICHP from one year ago. #5) ICHP is folding under USU on 01Oct2018 and the incoming USU Oversight Director and Chief of Medicine at USU concur with an administrative hold until such time as a rational plan for moving forward is established. (not necessarily in that order of priority) Peter J. Weina, PhD, MD, FACP, FIDSA
10/8/2018	Marianne Spevak email response to COL Weina regarding reasons for protocol holds: "COL Weina I have met with the ICHP program and please see the response below in regards to the protocols being placed on hold. # 1: "ICHP has not been and is currently not officially affiliated with a governmental agency." ICHP is affiliated with a governmental agency. Currently ICHP is affiliated with USAMRMC under Cooperative Agreement W81XWH-16-2-0007 in response to a BAA: Project Title: Integrative Cardiac Health Project (ICHP). As of October 1, 2018 the oversight for ICHP will be under USU Department of Medicine. # 2: "The current PI for the ICHP protocols is not willing to pursue the protocols with the transition to USU coming up on 01Oct2018." COL Todd Villines is retiring, but was the official PI of all the protocols until 1OCT2018. The proper procedure will be followed to notify all parties of the PI change to include a protocol modification detailing the personnel changes. # 3: "The current Director of ICHP (who is also listed as an associated Investigator) is not privileged at WRNMMC and has no plan to get privileged." Dr. Marina Vernalis, the Medical Director of ICHP, obtained her Maryland license, Maryland PDMP registration, and Maryland CDS needed for submission for privileging. Her application for the Federal DEA is in progress. In addition she has completed AHLTA training. The Plans of Supervision have been submitted for the Medical Director and her staff and are awaiting approval action by WRNMMC. # 4: "There has not been a satisfactory resolution of the for cause audit of ICHP from one year ago." All action items over which ICHP has authority have been resolved from the for-cause-audit. There has been no follow up response from the Institutional Official or DRP. The ICHP team has been cooperating with DRP in order to move forward. # 5: "ICHP is folding under USU on 01Oct 2018 and the incoming USU Oversight Director and Chief of Medicine at USU concur with an administrative hold until such time as a rational plan for moving forward is established (not necessarily in that order of priority)." ICHP is working with COL Chung, Chief of Medicine at USU, to facilitate a smooth transition. This decision was made prior to official USU authority, which starts 1OCT2018. The protocols are funded through USAMRMC and remain under USAMRMC oversight until the transition is complete. I would be happy to discuss if there are any questions in order to move forward with the ICHP studies."
10/9/2018	COL Weina email response to Marianne Spevak – Ms. Spevak

	I believe there needs to be an open discussion with COL Chung regarding the ICHP program and your responses. There appear to have been some relatively recent developments that call into question some of your responses. Until the 'dust settles' and all issues are satisfactorily addressed, ICHP protocols will remain 'on hold'. Please note, ICHP as an entity of HJF receiving funding from MRMC does not qualify as 'affiliation with a government agency'.
12/13/2018	Meeting of ICHP executive staff, HJF Program Manager, COL Weina and Reviewed action items from audit again. COL Weina mistakenly related action items to a different ICHP protocol, UPLIFT, not the Registry. Once clarified, ICHP met all action items. ICHP wished to write a manuscript and publish results from the ICHP Registry trial but would need to reopen the Registry protocol (COL Weina placed the registry abrupt administrative hold after meeting with Dr. Haigney, USU Chief of Cardiology), and identify a new PI as COL Villines was retiring and obtain administrative approval from DRP. Since the historical ICHP would not transfer to USU thereby closing the historical ICHP program March 29, 2019 , it would be prohibitive to accomplish these tasks in this timeframe.