## COMMITTEE FINDINGS:

1. The information given in the Informed Consent, under the Description of Research by investigator is complete, accurate, and understandable to a research subject or surrogate who possesses standard reading and comprehension skills.

   | ✗ | YES |
   | □ | NO  |
   | □ | NA  |

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances.

   | ✗ | YES |
   | □ | NO  |
   | □ | NA  |

3. Every effort has been made to decrease risk to subject(s)?

   | ✗ | YES |
   | □ | NO  |

4. The potential research benefits justify the risk to subject(s)?

   | ✗ | YES |
   | □ | NO  |

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: (a) the research can’t be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) If an incompetent subject resist, he/she sill not have to participate; d) If there exists any question about the subject’s competency, the basis for decision on competency has been fully described.

   | ✗ | YES |
   | □ | NO  |

6. If the subject is paid, the payment is reasonable and commensurate with the subject’s contribution.

   | ✗ | YES |
   | □ | NO  |
   | □ | NA  |

7. Members of minority groups and women have been included in the study population whenever possible and scientifically desirable.

   | ✗ | YES |
   | □ | NO  |

8. Comments: (Indicate if Expedited Review)

   2009-070508 - NEW STUDY WITH VA CONSENT FORM

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**RECOMMENDATION:**

☑ APPROVED  ☐ DISAPPROVED/REVISE

**SIGNATURE OF CHAIRPERSON**

Carol A. Kauffman, MD

**DATE**

8/17/09
MEMORANDUM

VA Ann Arbor
Healthcare System

Date: August 27, 2009
To: Lowery, Julie, PhD
From: Ann Arbor VA Research Service (11R), Subcommittee on Human Studies
       (FWA# IRB00000264) of the VA Ann Arbor Healthcare System (FWA00000348)
Subj: Project review at the 8/13/2009 meeting, Item #3.02.

3.02
7/29/09
Lowery, Julie, PhD    Coaching Veterans to Healthy Weights and Wellness
The purpose of this research study is to set up a 3-month initial weight-loss coaching intervention program for delivery via phone or on-site group visits, with a 9-month phone follow-up, called ASPIRE. The study will include a weight loss program that coaches participants to set small and attainable dietary and/or physical activity goals and use problem-solving strategies to overcome obstacles. The objectives of this study are to determine: (1) whether ASPIRE will result in significantly more weight loss than the “usual care” MOVE! Program; and (2) whether telephone-based coaching is more effective than group visit coaching. ASPIRE has 4 key features: (1) lifestyle coaches encourage small but cumulative steps; (2) simplified “Stoplight” diet precludes having to log calories; (3) enhanced pedometers log daily step-counts; and (4) program is integrated with VAMC clinical processes.

Sites and Settings: The Ann Arbor VAMC and the Louis Stokes VAMC (Cleveland, OH)
Identify and Recruit Participants: The research assistant (RA) will work with MOVE! program staff to help market the MOVE! Program, because referral to MOVE! constitutes the pipeline of potential participants for this study. The RA will work with the MOVE! team to determine the most effective way to put the RA in touch with patients who may be interested in MOVE!.
Research Procedures: All research procedures will be conducted as part of outpatient care.
a) Participants will receive an Omron pedometer and a log, blood draw at baseline.
b) Baseline questionnaire, 6-minute walk test, assign lifestyle coach and randomize to 1 of 3 arms: Usual care MOVE!; Phone-based ASPIRE; On-site ASPIRE.
c) A purposive sample of participants will be invited to participate in up to two semi-structured interviews over the phone. In addition, all participants will be invited to participate in a focus group at the end of the study.
Research Risks: musculoskeletal injury, loss of privacy, possible loss of confidentiality [VA Consent Form] (156 subj)

8/13/09
(Julie Lowery was not present during the discussion and vote.)

PROTOCOL DISCUSSION
1) The investigators indicate they may conduct a survey of persons who refuse to participate in the study. The investigators did not submit the survey.
2) The Committee reminded the investigators that all surveys, questionnaires, recruitment materials, etc must be reviewed and approved by the VA IRB.

VA CONSENT FORM CORRECTIONS
Description:
->It may be difficult for some persons to imagine a “three-sided” coin. An alternate explanation could be “randomly assigned by a computer”.
->In the paragraph that starts with “(2) If you are assigned to telephone ASPIRE-VA”, revise as shown: “for the first 12 weeks, then every other week for the next 6 months”

Page 2:
->In the paragraph that starts with “(3) If you are assigned to group ASPIRE-VA”, revise as shown: “the group visits will continue every other week for 6 months and then”
->In the paragraph that starts with “You may be asked”, revise as shown: “interviews with one of the researchers.”
->In the paragraph that starts with “Research staff”, revise as shown: “your VA medical records during”.
Request for Patient Authorization:
-> Item 5, revise as shown: "The authorization will expire at the end of the research study."

ACTIONS TAKEN:
APPROVED, VA Consent Form (up to 156 subj)
APPROVED, Dr. Kauffman to review revised VA Consent Form with requested corrections
The risks are reasonable in relation to benefits to subjects and the knowledge to be gained.
The risks of the study have been minimized to the extent possible.
Continued Approval Status (Months, Exp Date, Risk) 12 8/12/2010 LOW
(7=for, 0=opposed, 0=abstain, 2=not present) [JL] [BN]

8/21/09 Leah Gillon (study coordinator) submitted a revised VA Consent Form with the requested corrections.

8/27/09 The revised document was reviewed and the approval letter was signed by Dr. Kauffman.

Human Studies Committee regulations require investigators to follow these procedures:
1) Always use copies of the VA IRB-approved Consent Form with the VA logo and date of approval & expiration.
2) Transfer digital images of VA Consent Forms into Research Enrollment Notes in VA CPRS (for > Minimal risk studies)
3) Submit a "Request for Continued Approval of Human Use" at least 10 days before the expiration date.
4) Submit changes or deviations from the research protocol or consent form for review by the convened VA IRB.
5) Report Unanticipated Problems that occurs to research subjects or others within 7 calendar days
See the VA IRB UPR Reporting Policy at "http://www1.va.gov/aaavaresearch/page.cfm?pg=3"

VA Human Studies IRB Coordinator = Douglas Feldman (734) 845-3440 e-mail = doug.feldman@med.va.gov
R&D FAX = (734) 845-3244 VA Research Web Site = http://www1.va.gov/aaavaresearch

Sincerely,

Carol Kauffman, M.D.
VA Human Studies Chairperson
COMMITTEE FINDINGS:

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2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances.

3. Every effort has been made to decrease risk to subject(s)?

4. The potential research benefits justify the risk to subject(s)?

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) if an incompetent subject resists, he will not have to participate; d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described.

6. If the subject is paid the payment is reasonable and commensurate with the subject's contribution.

7. Comments: (Indicate if Expedited Review)

8. Annual Review, Modifications:

RECOMMENDATIONS: □ APPROVE □ DISAPPROVE/REVISE

SIGNATURE OF CHAIRMAN

DATE 11-18-09
Date: October 21, 2009

From: ACOS, Research Service, Roger J. Grekin, MD

Subj: Research Proposal Final Approval - 2009-070508

To: Julie C. Lowery, MHSA, PhD (IIH)

1. On September 2, 2009, the Ann Arbor Research and Development Committee gave **final approval** to your study, entitled *ASPIRE: Coaching Veterans to Healthy Weights and Wellness*. The study was approved by the Ann Arbor Human Studies Committee on August 13, 2009 and the Biosafety Subcommittee on August 20, 2009.

2. The Human Subject risk level is **low risk**. The Human Studies approval period is for **one-year**. The Human Studies approval period expires on **August 12, 2010**. Renewal notices for continued approval will be emailed to you approximately 12 weeks prior to the expiration date. In order to avoid any interruptions in your study, continued approvals must be submitted to the IRB Coordinator at least six weeks before the expiration date.

3. Approval carries with it the understanding that:

   a. You will make no modification to this study without prior approval by the Ann Arbor Human Studies Committee and the R&D Committee, and all advertisements and supplemental materials will be submitted for approval prior to their use.
   
   b. You will inform the Ann Arbor Human Studies Committee of any unanticipated problems that occur to subjects or others.
   
   c. You will submit documents for continuation approval at least once annually or more often if requested.
   
   d. **If a VA Consent Form is required, you must use copies that include the VA IRB logo date stamp on the bottom of each page.** If any research consent form is required, you must place a signed form in the patient’s hospital medical chart in CPRS, will flag the chart and will enter a progress note stating the patient is entered in the study (study title) and will include the name and phone number of the investigator to contact for further information.

4. Any material submitted for publication that is generated from this study must be submitted for review by the R&D Committee. You must also acknowledge the VA on any published materials generated from this study. For further clarification, the policy is located at: [http://www.va.gov/publ/direc/health/handbook/1200.19hk.pdf](http://www.va.gov/publ/direc/health/handbook/1200.19hk.pdf)
5. Thank you for your cooperation in helping us adhere to the rules and regulations of the Research and Development Office of the Department of Veterans Affairs in protecting the rights and welfare of human subjects involved in medical research.

Roger J. Grekin, MD
12/1/2009

Dr. Kirsh,

Congratulations, your study entitled “ASPIRE-VA: Coaching veterans to healthy weights and wellness” has obtained the following Louis Stokes Cleveland VAMC approvals:

☐ Final Research & Development Committee Approval on: 12/1/2009
☐ Institutional Review Board Approval on: 11/18/2009
☐ Subcommittee on Research Safety Approval on: 10/14/2009

Now that you have all Committee and Subcommittee approvals, you may begin your study. Please remember that within 1 year, or sooner if required by specific subcommittee(s), of the approval dates, you must submit continuing renewals. If you should need anything in the interim, please do not hesitate to contact the Research Office.

Best Regards,

Neal S. Peachey, Ph.D.
Associate Chief of Staff for Research (ACOS/R)

Sherry L. Ball, Ph.D.
Member, Research & Development Committee