Author's response to reviews

Title: Targeted versus tailored multimedia patient engagement to enhance depression recognition and treatment in primary care: randomized controlled trial protocol

Authors:

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Janie Shelton (janie.shelton@gmail.com)
Richard L Kravitz (rlkravitz@ucdavis.edu)

Version: 5 Date: 21 February 2013

Author's response to reviews: see over
February 18, 2013

Dear Natalie Pafitis,

Please find enclosed a revised manuscript entitled “Targeted versus tailored multimedia patient engagement to enhance depression recognition and treatment in primary care: randomized controlled trial protocol for the AMEP2 Study”, which I am submitting for exclusive consideration of publication as a study protocol in BMC Health Services Research and which adheres to your journal’s suggested guidelines, including those from the CONSORT group. This is a protocol for a multi-site randomized control trial of two interventions designed to improve the recognition and treatment of depression in primary care settings. The trial name is an acronym for Activating Messages to Enhance Primary Care Practice, a randomized controlled trial that was sponsored by the National Institute of Mental Health as a major component of the investigator-initiated research that included the development of the two experimental interventions being evaluated by the trial (R01 MH 079387 01Al, PI: Kavitz). The AMEP2 trial enrolled 867 patients that will be included in the final analysis. Enrollment has already been completed at the study sites, all of whose institutional review boards granted ethical approval of the study protocol.

This revised manuscript addresses some “pre-review revisions” concerns that Armee Valencia in the BMC Journal Editorial Office brought to our attention on January 11, 2013 when reviewing our original submission dated December 31, 2012. Although we attempted to address these concerns on January 14, 2013, I understand from corresponding with Ms. Valencia today that there were some technical issues that prevented the submitted computer files from being opened. This revision address all of Ms. Valencia’s concerns: Specifically, we have

1. Verified that the Trial Registration Number from the ClinicalTrials.gov entry for our study is included in the Abstract
2. Hereby notify you that no other journal articles based on the AMEP2 trial have been submitted to your journal or any other journal
3. Include the names of the institutional review boards that approved the study in the text of the manuscript
4. Attach evidence to the cover letter that the National Institutes of Mental Health sponsored the study and that it has received IRB approval. Most of those documents are included within this document, in the pages following my signature. There you will find the NIH/NIMH Award Notice and approval letters from 4 of the 5 relevant IRBs. The document from the fifth IRB (Kaiser) had to be submitted as a separate PDF file within the “Confidential Comments to the Editor” section of the BMC Health Service Research Manuscript Submission Webpages because it was password protected by the Kaiser IRB. Please note that the NIMH Award Notice includes the amounts of the award for the overall project for each year.

5. In addition to the revisions that were requested, I also made some slight corrections to the text of the manuscript (to aid clarity and to correct typos), to the Tables (to reformat the race variable so that it matches how this variable was used for randomization) and to the figures (to correct a typo and to convert the font to Arial)

Thank you very much for consideration of this study protocol. If you have any questions or concerns, please feel free to contact me as the corresponding author at my email address (djtancredi@ucdavis.edu), via telephone (916.734.3293) or at my postal address.

Sincerely,

Daniel J. Tancredi, PhD
Assistant Professor
Grant Number: 1R01MH079387-01A1

Principal Investigator(s):
RICHARD L KRAVITZ, MD

Project Title: Targeted and Tailored Messages to Enhance Depression Care

Contracts and Grants Officer
Regents of the University of California
1850 Research Park Drive, Suite 300
Davis, CA 95618

Award e-mailed to: vcresearch@ucdavis.edu


Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $605,208 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to Regents of the University of California in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the “Terms and Conditions” is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as “The project described was supported by Grant Number R01MH079387 from the National Institute Of Mental Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute Of Mental Health or the National Institutes of Health.”

Award recipients are strongly encouraged to submit to PubMed Central (PMC), upon acceptance for publication, an electronic version of peer-reviewed, original research publications, resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author’s final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Joy R. Knipple
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows
SECTION I – AWARD DATA – 1R01MH079387-01A1

Award Calculation (U.S. Dollars)

<table>
<thead>
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<th>Amount</th>
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<tr>
<td>Fringe Benefits</td>
<td>$31,976</td>
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<tr>
<td>Consultant Services</td>
<td>$49,800</td>
</tr>
<tr>
<td>Supplies</td>
<td>$8,814</td>
</tr>
<tr>
<td>Travel Costs</td>
<td>$7,800</td>
</tr>
<tr>
<td>Other Costs</td>
<td>$26,377</td>
</tr>
<tr>
<td>Consortium/Contractual Cost</td>
<td>$130,145</td>
</tr>
</tbody>
</table>

Federal Direct Costs            | $431,038 |
Federal F&A Costs               | $174,170 |
Approved Budget                 | $605,208 |
Federal Share                   | $605,208 |

TOTAL FEDERAL AWARD AMOUNT      | $605,208 |

AMOUNT OF THIS ACTION (FEDERAL SHARE) | $605,208

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<tr>
<th>SUMMARY TOTALS FOR ALL YEARS</th>
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<tr>
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Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

Fiscal Information:
CFDA Number: 93.242
EIN: 1946036494A1
Document Number: RMH079387A
Fiscal Year: 2007

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Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

NIH Administrative Data:
PCC: 82-SEDR / OC: 414A / Processed: KNIPPLEJO 09/24/2007

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01MH079387-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 1R01MH079387-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to the award.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.
This grant is awarded under the terms and conditions of the Federal Demonstration Partnership Phase IV.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

**Treatment of Program Income:**
**Additional Costs**

SECTION IV – MH Special Terms and Conditions – 1R01MH079387-01A1

RESTRICTION - HUMAN SUBJECTS:
This award is issued subject to the following special condition:

NOTICE: Under governing regulations, Federal funds administered by the Department of Health and Human Services shall not be expended for and individuals shall not be enrolled in research unless the institution has an approved Assurance of Compliance with 45 CFR 46 on file in the Office for Human Research Protections (OHRP) and the project has been reviewed and approved by the Institutional Review Board (IRB) in accordance with the requirements in 45 CFR 46.

The present award is being made without currently valid certification of IRB approval for this project with the following restriction: Only activities which do not directly involve human subjects (i.e., are clearly severable and independent from those activities that do involve human subjects) may be conducted pending acceptance by the National Institute of Mental Health (NIMH) of certification of IRB approval. The certification of IRB approval must be received no later than October 31, 2007, to the Grants Management Specialist (GMS), NIMH, Neuroscience Bldg, 6001 Executive Boulevard, Room 6115, MSC 9605, Bethesda, MD 20892-9605 (for overnight courier, use Rockville, MD 20852).

If the certification of IRB approval has not been received and accepted by the NIMH before October 31, 2007, the award may be suspended and/or terminated. No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects in this project until NIMH has accepted the certification of IRB.

AWARDED AMOUNT:
This award is based on the IRG recommendations as noted on the Summary Statement (with arithmetic errors corrected, grant policies applied as appropriate, direct salaries and associated fringe benefits adjusted to comply with the salary cap, and no more than 3% cost of living factor used to calculate the level of support recommended for each future budget period-see Summary Statement Budget Recommendations). In addition, in order to meet Institute program objectives within Fiscal Year 2007 budget constraints as described in the NIMH FY 2007 Operating Guidelines, which can be found at the NIMH Website (http://www.nimh.nih.gov/grants/FYpolicy.cfm), grants may be administratively reduced below the level recommended by peer review. Future year committed levels have been determined by applying the same administrative reduction to the corrected recommended level for each budget category for all years of the project period. Future year total cost commitments appearing on the award notice under "Recommended Future Year Total Cost Support" have been calculated by applying the negotiated facilities and administrative cost rate(s) in effect at the time of this competitive award to the committed total direct cost level for each future year.

BUDGET/PROJECT PERIOD ADJUSTMENT:
This grant has been selected under the NIMH plan to redistribute grant workloads more evenly throughout the year. Consequently, the initial budget period reflects a 07/31/2008 end date. Subsequent budget periods will begin on August 1, and will be for a 12-month duration. Although this grant will have a slightly shorter budget period this year, it is awarded the full 12-month level of funds for the budget period. Additional time may be requested at the end of the project period if needed.
CHANGE IN SCOPE OF WORK:
This award approves the proposed change in scope of work as outlined in the grantees email dated July 27, 2007.

PARTICIPANT RECRUITMENT - MILESTONES:
Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as detailed in the grantee's letter dated 9/18/2007. It is expected that 20 of the 1183 total projected participants will be recruited by April 1, 2008. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phaseout of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at http://www.nimh.nih.gov/researchfunding/nimhrecruitmentpolicy.cfm.

PERSONNEL COSTS:
As detailed in the NIH Guide Notice dated February 22, 2007 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-051.html), for FY 2007, Public Law 110-005 extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY2007. Therefore none of the funds appropriated for the National Institutes of Health shall be used to pay the salary of an individual, through a grant or other extramural mechanism, as a rate in excess of $186,600 per year for FY2007 awards.

Salaries requested in the application at a rate in excess of $186,600 per year have been reduced and future years have been adjusted accordingly, including 3% escalation. No salary increases will be provided on this grant for the remainder of this project period in the event of future salary cap level changes.

CONSORTIUM/CONTRACTUAL COSTS:
This award includes funds for consortium activity with the University of California, San Francisco, awarded in the amount of $8,029 ($5,207 direct costs and $2,824 F&A costs); University of Texas at Austin, awarded in the amount of $113,066 ($78,677 direct costs and $34,389 F&A costs); and University of Rochester, awarded in the amount of $9,050 ($7,021 direct costs and $2,029 F&A costs). Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement dated December 2003. No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

NON-COMPETING RENEWAL:
Future year non-competing progress reports and other documents applicable to this grant should be submitted to:

Division of Extramural Activities Support,
OER National Institutes of Health
6705 Rockledge Drive, Room 2207, MSC 7987
Bethesda, MD 20892-7987 (for regular or US Postal Service Express mail) Bethesda, MD 20817 (for other courier/express mail delivery only)

PRIOR APPROVAL REQUESTS:
Any prior approval request should be directed to the Grants Management Office and may be sent by email, fax, or mail:

Grants Management Branch, NIMH
6001 Executive Blvd.
Room 6115, MSC 9605
Bethesda, MD 20892-9605 (Express Mail: Rockville, MD 20852)
Fax: (301) 443-6885

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.
Grants Management Specialist: Betty Nkansah  
Email: bn30m@nih.gov  Phone: 301-443-7638  Fax: 301-443-6885

Program Official: David A Chambers  
Email: dchamber@mail.nih.gov  Phone: 301-443-3747  Fax: 301-443-4045

SPREADSHEET SUMMARY

GRANT NUMBER: 1R01MH079387-01A1

INSTITUTION: Regents of the University of California

<table>
<thead>
<tr>
<th>Budget</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
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<td>$151,143</td>
<td>$87,224</td>
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<tr>
<td>TOTAL F&amp;A</td>
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<td>$605,214</td>
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<tr>
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<th>Year 3</th>
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<td>$166,505</td>
<td>$151,143</td>
<td>$87,224</td>
<td>$132,565</td>
</tr>
</tbody>
</table>
INSTITUTIONAL REVIEW BOARD
University of California, Davis

PROTECTION OF HUMAN SUBJECTS - DECLARATION / ASSURANCE OF IRB APPROVAL

The following research study has been determined to meet the definition of human subjects research as defined by Federal Regulations and UC Davis IRB Policy and has been reviewed by the IRB in accordance with the Common Rule and any other governing regulations:

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Protocol No.</th>
<th>Approval Period</th>
<th>Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>(214193-5) Activating Messages for Enhancing Primary Care Practice (AME-P2)</td>
<td>214193-5</td>
<td>January 11, 2012 through January 10, 2013</td>
<td>Minimal Risk</td>
</tr>
</tbody>
</table>

As Principal Investigator for the above-referenced project, you assume certain responsibilities, including, but not limited to:

1. You will conduct the study according to the protocol approved by the IRB. As the PI you are ultimately responsible for the conduct of the research and the protection of rights and welfare of the human subjects. You will ensure, at all times, that you have the appropriate resources and facilities to conduct this study. You will ensure that all research personnel involved in the conduct of the study have been appropriately trained on the protection of human subjects, in addition to the study procedures.

2. Any unanticipated problems involving risks to participants or others will be reported within 5 days to the IRB or in accordance with IRB Standard Operating Procedures (SOPs).

3. Any changes in your research plan (including but not limited to advertisements) must be submitted to the IRB for review and approval prior to implementation of the change, except when necessary to eliminate immediate hazards to participants. Changes in approved research initiated without IRB approval to eliminate immediate hazards to the subject, are to be reported to the IRB in accordance with the SOP, “Reporting of Unanticipated Problems Involving Risks to Participants or Others.”

4. Your protocol must be renewed prior to expiration of the study. Failure to submit renewal documents to the IRB Administration will result in a lapse in IRB approval or termination of the study by the IRB. All research involving human subjects must stop without ongoing IRB approval.

5. If you plan to collect protected health information, you are required to comply with HIPAA requirements.

6. Studies conducted at the CCRC must be reviewed and approved by the VA IRB and the Research & Development Committee prior to initiation of the study. Contact the VA Committee for submission requirements.

7. The UC Davis Health System requires that all investigational drugs be distributed through the UCDMC Pharmacy. You are required to provide a complete copy of the approved protocol to the Investigational Drug Service Pharmacy. A copy of the signed consent form must be submitted to the Pharmacy if investigational drugs are dispensed through the Outpatient Pharmacy.

8. For studies involving investigational drugs at Shriners Hospitals for Children Northern California, drugs must be distributed through Shriners Pharmacy. A copy of the signed consent form must be in the Pharmacy.

Name and Address of Institution
University of California, Davis
IRB Administration
CTSC Bldg, Suite 1400, Rm. 1429
2921 Stockton Blvd.
Sacramento, CA 95817

Institutional Administrator
Elodia Tarango
Interim Director, IRB Administration
elodia.tarango@ucdmc.ucdavis.edu
Phone No. (916) 703-9151
Fax No. (916) 703-9160

This Assurance, on file with the
Department of Health and Human
Services, covers this activity:
FWA No: 00004557
Expiration Date: January 28, 2016
IORG: 0000251

Std. December 16, 2011
Human Research Protection Program
Committee on Human Research

Notification of Expedited Review Approval

Principal Investigator
Mitchell D Feldman

Co-Principal Investigator

Type of Submission: Continuing Review Submission Form
Study Title: Activating Messages to Enhance Primary Care Practice

IRB #: 10-04236
Reference #: 041503
Committee of Record: Parnassus Panel
Study Risk Assignment: Greater than minimal

Approval Date: 03/09/2012 Expiration Date: 04/08/2013

Regulatory Determinations Pertaining to this Approval (if applicable):

IRB Comments (if applicable): This study is in data analysis and involves no greater than minimal risk for the population being studied.

All changes to a study must receive CHR approval before they are implemented. Follow the modification request instructions. The only exception to the requirement for prior CHR review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these instructions.

Expiration Notice: The iMedRIS system will generate an email notification eight weeks prior to the expiration of this study’s approval. However, it is your responsibility to ensure that an application for continuing review approval has been submitted by the required time. In addition, you are required to submit a study closeout report at the completion of the project.

Approved Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to CHR approval and follow all applicable VA and other federal requirements. The CHR website has more information.
Date: May 25, 2012

To: Andrew Hudnut, MD, Principal Investigator
From: Sutter Health Central Area Institutional Review Committee (IRC)
IRB00001813 and FWA 00001330

Study Title // [Sites]: Activating Messages to Enhance Primary Care Practices // [SMG]
RC #: 1104019
IRBNet Reference #: 226984-4

Submission Type: Continuing Review/Progress Report
Review Type: Expedited Review
Action: APPROVED
Approval Date: May 25, 2012

On May 25, 2012, your Continuing Review Report received Expedited Review by the IRC and was approved.

All research must be conducted in accordance with this approved submission, and:

- Any changes to the study or to previously approved materials must have IRC approval before implementation.
- Only current stamped IRC-approved consent forms may be used when enrolling subjects.
- All serious and unexpected adverse events must be reported to the IRC. All regulatory, sponsor or institutional reporting requirements must also be followed.
- All non-compliance issues or complaints regarding this study must be reported to the IRC office.
- This study requires IRC Continuing Review by its expiration date of May 24, 2013. Any changes in study status should be reported promptly to the IRC.
- All materials that require full committee review must be submitted by the posted deadlines.
- The study title and IRC reference number must be included in all correspondence to the IRC office.
- All research records must be retained for a minimum of 6 years.

Remember that informed consent is a process beginning with a description of the study and ensuring the subject's understanding, followed by signing the consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research subject. Each subject must be given a copy of the signed consent form.