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TITLE: The STRONG STAR Multidisciplinary PTSD Research Consortium

PRINCIPAL INVESTIGATOR: John D. Roache, Ph.D.

CONTRACTING ORGANIZATION: University of Texas Health Science Center  
San Antonio, TX 78229

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |                                 |                                             | <b>5b. GRANT NUMBER</b><br>W81XWH-08-2-0117                   |                                                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |                                 |                                             | <b>5c. PROGRAM ELEMENT NUMBER</b>                             |                                                   |
| <b>6. AUTHOR(S)</b><br>John D. Roache, Ph.D.<br><br>E-Mail: roache@uthscsa.edu                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                         |                                 |                                             | <b>5d. PROJECT NUMBER</b>                                     |                                                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |                                 |                                             | <b>5e. TASK NUMBER</b>                                        |                                                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |                                 |                                             | <b>5f. WORK UNIT NUMBER</b>                                   |                                                   |
| <b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b><br>University of Texas Health Science Center<br>San Antonio, TX 78229                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |                                 |                                             | <b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>               |                                                   |
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| <b>13. SUPPLEMENTARY NOTES</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                         |                                 |                                             |                                                               |                                                   |
| <b>14. ABSTRACT</b><br>The proposed study seeking to identify predictors of differential response to SSRI's is significant given the widespread use of SSRI's. With CDMRP approval, we have revised the aims of the second study to include only an analysis of STRONG STAR Repository data. We have finally begun to recruit subjects in the first study, though the rate of accrual is still not where it needs to be. Protocols and study SOP's have been developed and regulatory approvals have been achieved. STVHCS staff have been trained, though CTVHCS lost staff and need new hires to replace those losses.                                                                                                                                                                                                                                                                                                                                  |                         |                                 |                                             |                                                               |                                                   |
| <b>15. SUBJECT TERMS</b><br>SSRI Antidepressants, Regulatory Approval Delays, Pending Study Enrollment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                         |                                 |                                             |                                                               |                                                   |
| <b>16. SECURITY CLASSIFICATION OF:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                         |                                 | <b>17. LIMITATION OF ABSTRACT</b><br><br>UU | <b>18. NUMBER OF PAGES</b><br><br>10                          | <b>19a. NAME OF RESPONSIBLE PERSON</b><br>USAMRMC |
| <b>a. REPORT</b><br>U                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>b. ABSTRACT</b><br>U | <b>c. THIS PAGE</b><br>U        |                                             |                                                               | <b>19b. TELEPHONE NUMBER (include area code)</b>  |

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## INTRODUCTION:

There are two components to this project. The first is a study of the assessment and treatment of alcohol use disorder comorbidity among separated veterans who have PTSD and were exposed to deployment-related trauma. A particularly important aspect of this study is an evaluation of the hypothesis that there are subgroups of patients who have different phenomenological presentations of alcohol use related comorbidity; and further that these subgroups have fundamental differences in their serotonin biology that cause them to respond differently to medication treatment with selective serotonin reuptake inhibitors (SSRI's). These objectives are being approached in two different ways. First, we are conducting a randomized clinical trial evaluating the efficacy of sertraline (an SSRI) in the treatment of PTSD-Alcohol Use Disorder Dual Diagnosis patients who are previously-deployed veterans seeking treatment in the Texas Veterans Health Care System. This is a two-site trial involving both the South Texas and Central Texas Veterans Health Care Systems and it involves dual diagnosis psychotherapy (using the COPE manual) as well as randomized treatment with sertraline vs. placebo.

The second component of the project, involves extending the generality of observations that SSRI's can differentially alter the outcome of treatment for PTSD in different patient subgroups. The original plan was to perform a cluster analysis of patients in treatment in a separate Fluoxetine treatment trial. However, progress on that trial has not been forthcoming. In consultation with DoD Project Officer, Kim DelCarmen, it was determined to satisfy this objective instead through an analysis of the STRONG STAR data repository. Demographic and psychological disturbance information obtained at baseline will assess the phenomenological characteristics of active-duty military personnel receiving treatment for psychiatric symptoms at Fort Hood. These data will be used to perform a cluster analysis of phenomenological types of patients. Subsequent analyses will determine how SSRI use and assessed drinking behaviors may modulate treatment outcome and whether or not the cluster types predict this outcome.

## BODY:

- Preparation and Review of the Research Proposal for Multiple IRB Approvals. See Regulatory Action and Milestone Excel spreadsheet for this project.

| PI     | Organization | Regulatory Action                                             | Submission Date | Approval Date | Date Approval Received | Comments                                                                                                                                                                                            |
|--------|--------------|---------------------------------------------------------------|-----------------|---------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Roache | UTHSCSA IRB  | New Protocol-Administrative Pre-review                        | 1/25/2009       | 5/8/2009      |                        |                                                                                                                                                                                                     |
| Roache | STVHCS       | New Protocol Submission                                       | 2/2/2009        | 4/26/2010     |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | New Protocol-Full-board Review                                | 2/12/2009       | 5/8/2009      |                        |                                                                                                                                                                                                     |
| Roache | STVHCS       | Response to Pre-Review                                        | 3/4/2009        | 4/26/2010     |                        |                                                                                                                                                                                                     |
| Roache | STVHCS       | Response to Stipulations                                      | 4/21/2009       | 4/26/2010     |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | New Protocol-Response to Full-board Review                    | 4/30/2009       | 5/8/2009      |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | New Protocol-Response to Full-board Review (Additional Stips) | 5/11/2009       | 5/8/2009      |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Amendment #1                                                  | 5/29/2009       | 6/12/2009     |                        | see #1 HSC20090236H Human Amendment Form (Protocol and Consent Changes)                                                                                                                             |
| Roache | STVHCS       | Response to Stipulations                                      | 6/9/2009        | 4/26/2010     |                        |                                                                                                                                                                                                     |
| Roache | HRPO         | Second Level Review                                           | 8/14/2009       | 11/3/2010     |                        | see entire packet at \\lecho\strongstarregulatory\STRONG STAR Protocols\Roache Protocol\HRPO\Second Level Review\HRPO packet, Roache, 08-14-09                                                      |
| Roache | DSMB         | DSMB Initial Review                                           | 8/20/2009       | 3/28/2011     |                        | Reviewed Version 2 February 12, 2009                                                                                                                                                                |
| Roache | BRU          | New Protocol Submission                                       | 10/2/2009       | N/A           |                        |                                                                                                                                                                                                     |
| Roache | STVHCS       | Response to Stipulations                                      | 1/7/2010        | 4/26/2010     |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Amendment #2                                                  | 1/7/2010        | 1/29/2010     | 2/2/2010               | #2 Amendment, removed remove Trisha Benson, Crystal Pearson, Christie Ybarra, and Shawn Jones. Added Mascarenas, Gujardo, Murff, polanco, and Hammack. Updated                                      |
| Roache | BRU          | New Protocol Submission                                       | 1/14/2010       | N/A           |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Progress Report-Continuing Review 2010                        | 1/20/2010       | 3/12/2010     | 2/23/2010              |                                                                                                                                                                                                     |
| Roache | CTVHCS IRB   | Protocol Review-Initial                                       | Feb-10          | 5/12/2010     |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Progress Report-Continuing Review 2010 (response to stips)    | 3/5/2010        | 3/12/2010     | 2/23/2010              |                                                                                                                                                                                                     |
| Roache | HRPO         | Second Level Review                                           | 3/23/2010       | 11/3/2010     |                        |                                                                                                                                                                                                     |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 3/31/2010       | 11/3/2010     |                        |                                                                                                                                                                                                     |
| Roache | STVHCS       | Response to Stipulations                                      | 4/6/2010        | 4/26/2010     |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Amendment #3                                                  | 4/6/2010        | 4/20/2010     | 4/21/2010              | add Dr. Flynn as VA investigator                                                                                                                                                                    |
| Roache | STVHCS       | Amendment #1                                                  | 4/27/2010       | 4/28/2010     |                        | #1 Amendment, added VA audio consent.                                                                                                                                                               |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 4/28/2010       | 11/3/2010     |                        |                                                                                                                                                                                                     |
| Roache | CTVHCS R&D   | Protocol Review-Initial                                       | May-10          | 5/25/2010     |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Amendment #4                                                  | 5/27/2010       | 6/10/2010     | 6/14/2010              | Add Kenny and Crystal as IE                                                                                                                                                                         |
| Roache | STVHCS       | Amendment #2                                                  | 6/1/2010        |               |                        | #2 Amendment, revised study personnel list. Added Belinfante and Mendoza.                                                                                                                           |
| Roache | BRU          | New Protocol Submission                                       | 6/29/2010       | N/A           |                        |                                                                                                                                                                                                     |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 7/16/2010       | 11/3/2010     |                        |                                                                                                                                                                                                     |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 7/27/2010       | 11/3/2010     |                        |                                                                                                                                                                                                     |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 8/24/2010       | 11/3/2010     |                        | resent on 8/25/10 to update protocol page numbers                                                                                                                                                   |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 8/25/2010       | 11/3/2010     |                        | previous copy had tracked changes from our last response to stips-revised to include                                                                                                                |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 9/1/2010        | 11/3/2010     |                        |                                                                                                                                                                                                     |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 9/20/2010       | 11/3/2010     |                        |                                                                                                                                                                                                     |
| Roache | STVHCS       | Amendment #3                                                  | 10/4/2010       | 10/22/2010    |                        | #3 Amendment, updated VA personnel list (corresponds with UTHSCSA amendment                                                                                                                         |
| Roache | UTHSCSA IRB  | Amendment #5                                                  | 10/4/2010       | 10/22/2010    | 10/26/2010             | Response to HRPO stips                                                                                                                                                                              |
| Roache | STVHCS       | Amendment #4                                                  | 10/19/2010      | pending       |                        | #4 Amendment, revised VA audio consent. added Dr. Peterson and Dr. Kloczek as                                                                                                                       |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 10/26/2010      | 11/3/2010     |                        |                                                                                                                                                                                                     |
| Roache | CTVHCS IRB   | Amendment #1                                                  | Nov-10          | 11/17/2010    |                        |                                                                                                                                                                                                     |
| Roache | CTVHCS IRB   | Amendment #1, response to stips                               | Nov-10          | 11/17/2010    |                        |                                                                                                                                                                                                     |
| Roache | BRU          | Amendment-UTHSCSA Amendment #5                                | 11/4/2010       | N/A           |                        | #5 Amendment, Version 4 dated 10-4-10 updated study staff, updated inclusion exclusion criteria. Updated recruitment, recruitment material, screening and consent procedures. Added Relief Drinking |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 11/17/2010      | 11/23/2010    |                        | Supporting documents for CTVHCS approval                                                                                                                                                            |
| Roache | HRPO         | Second Level Review-Response to Stipulations                  | 11/22/2010      | 11/23/2010    |                        | Supporting documents for CTVHCS approval                                                                                                                                                            |
| Roache | UTHSCSA IRB  | Amendment #6                                                  | 1/7/2011        | 2/14/2011     | 2/15/2011              | updated recruitment material                                                                                                                                                                        |
| Roache | UTHSCSA IRB  | Progress Report-Continuing Review 2011                        | 1/12/2011       | 2/22/2011     | 2/23/2011              |                                                                                                                                                                                                     |
| Roache | STVHCS       | Continuing Review 2011                                        | 1/19/2011       | pending       |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Progress Report-Continuing Review 2011, response to stips     | 1/20/2011       | 2/22/2011     | 2/23/2011              |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Amendment #6 (response to stips)                              | 2/1/2011        | 2/14/2011     | 2/15/2011              | The VA had been removed from the ads as a site location, and they asked us to put it                                                                                                                |
| Roache | UTHSCSA IRB  | Amendment #7                                                  | 3/14/2011       | 4/1/2011      | 4/6/2011               | Clarify stopping medications prior to enrollment, revised inc/exc criteria, and clarified                                                                                                           |
| Roache | DSMB         | DSMB Initial Review, Response to Stips                        | 3/24/2011       | 3/28/2011     | 4/20/2011              |                                                                                                                                                                                                     |
| Roache | HRPO         | Continuing Review for UTHSCSA 2011                            | 4/7/2011        | 7/18/2011     | 7/18/2011              |                                                                                                                                                                                                     |
| Roache | CTVHCS IRB   | Continuing Review 2011                                        | 4/7/2011        | 6/8/2011      |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Amendment #8                                                  | 4/26/2011       | 5/3/2011      | 5/9/2011               | Add Malach and Hernandez                                                                                                                                                                            |
| Roache | STVHCS       | Amendment #5                                                  | 4/26/2011       | 5/2/2011      | 5/2/2011               | Add Ann Marie Hernandez and Steffany Malach as therapists at the VA (UTHSCSA                                                                                                                        |
| Roache | UTHSCSA IRB  | Amendment #9                                                  | 5/5/2011        | 6/20/2011     | 6/20/2011              | TV ads                                                                                                                                                                                              |
| Roache | CTVHCS IRB   | Continuing Review 2011, response to stips                     | 5/18/2011       | 6/8/2011      |                        |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Amendment #9, response to stips                               | 6/1/2011        | 6/20/2011     | 6/20/2011              | revised TV spot per STVHCS Office of Public Affairs                                                                                                                                                 |
| Roache | HRPO         | Continuing Review for CTVHCS 2011                             | 6/16/2011       | 7/18/2011     | 7/18/2011              |                                                                                                                                                                                                     |
| Roache | UTHSCSA IRB  | Amendment #10                                                 | 8/4/2011        |               |                        | Update Inc/Exc criteria (changed min age from 18 to 21, changed heavy drinking days required to 30%, changed alcohol dependence to alcohol use disorder, changed                                    |
| Roache | UTHSCSA IRB  | Amendment #10 Re-Submitted                                    | 8/8/2011        |               |                        |                                                                                                                                                                                                     |

- Hiring and Training of Research Staff. Dr. Roache has developed the study procedures for the treatment protocol and Dr. Javors has done so for the biological assessments required for the study. Mr. Jonathon Polanco is the Study Coordinator in conjunction with Mr. Bill Murff who is overseeing the two-site coordination. Dr. John Kloczek is the site PI at the PTSD Center of Excellence at the CTVHCS and Dr. Jennifer Guajardo is the PI at the STVHCS. Drs. Kloczek, Guajardo, and Jeslina Raj, Psy.D., have been trained to provide psychotherapy as have two

STRONG STAR Post-Doctoral Fellows and one fellow at the STVHCS. Dr. Klocek will oversee additional and continued Psychologist training for fidelity to the COPE manual. All STVHCS personnel have been trained and are implementing the protocol. The training study coordinator at CTVHCS has terminated employment which has delayed the start of the study at that site.

- Two Site Coordination. Mr. Murff at UTHSCSA is coordinating the two study sites. Dr. Roache, Mr. Murff, and Mr Polanco have all visited the CTVHCS site in Waco to deliver study materials and identify any site needs. For the multisite coordination, we have:
  - o Determined how UTHSCSA accounts could be used to compensate subjects in Waco.
  - o Provided CTVHCS with study supplies.
  - o Provided blood collection and processing equipment and supplies.
  - o Arranged for a contract pharmacy to provide compounded, blinded medication to the CTVHCS.
  - o Arranged for a blood collection, processing, and shipment protocol to enable the CTVHCS personnel to send specimen samples to San Antonio.
- Participant Recruitment, Therapy, Participant Evaluation. To date six Veterans have been consented and two have been randomized. Because of the difficulty identifying and recruiting eligible OIF/OEF Veterans into this study, several protocol amendments have been implemented to facilitate recruitments, and Dr. Roache and his study team have been visiting VA clinics and distributing study newsletter information to gain clinical patient referrals. In consultation with Dr. del Carmen and Dr. Murray Raskind of the EAB, approved protocol amendments include: a) dropping the OEF/OIF requirement allowing combat veterans from other deployments; and b) dropping the alcohol dependence requirement, allowing alcohol use disorder; and c) direct recruitment of combat veterans from the community. Dr. Roache and his study team have identified 17 clinics within the STVHCS from which potential patients may be referred. We have presented the study at staff meetings, distributed study brochure information, and sent providers a series of Study Newsletter information about dual diagnosis issues within the VA.
- Database, Data Entry, and Data Analysis. The STRONG STAR Data Core has developed our subject enrollment and randomization database, and provided a draft version of the study database. At the time of this report, the final study database programming is being completed and a sample shipping database is being developed.
- Administrative Tasks. Dr. Roache participated in weekly STRONG STAR teleconferences and in monthly calls with Dr. Kim del Carmen. In response to an EAB request to specify subject recruitment milestones, Dr. Roache identified two recent reports (Kranzler et al. 2011a,b) of a study showing differential efficacy of sertraline in the treatment of primary alcohol dependence. Based upon these data, we were able to conduct a new power analysis which suggested the need for much smaller samples than previously proposed. From these analyses, a sample size of n=34 would be required to satisfy Aim #1, and n=100 would be required to satisfy Aim #2.

### **Key Research Accomplishments**

- We have finally begun recruitment and randomization but there have not been other accomplishments.

### **Reportable Outcomes**

- There were no reportable outcomes in the past year.

## **Conclusion**

- The study is actively recruiting in San Antonio and approved for recruitment in Waco. The Center of Excellence in Waco is working with Dr. Klocek to support the study so that patient recruitment and accrual can begin there soon. With the consultation and agreement of Dr. del Carmen and consultant Dr. Raskind, the protocol has been modified to relax the subject Inclusion/Exclusion criteria. Minimum necessary recruitment goals have been specified based upon a new power analysis suggested much smaller sample sizes are required.

## **References**

Kranzler H, et al. (2011a) Comparison of alcoholism subtypes as moderators of the response to sertraline treatment. *Alc Clin Exp Res, in press (privileged communication)*.

Kranzler H, et al. (2011b) Post-Treatment outcomes in a double-blind randomized trial of sertraline for alcohol dependence. *Alc Clin Exp Res, in press (privileged communication)*.

## **Appendices**

See Attached Regulatory Action and Milestone Chart

## **Supporting Data**

none





|                            |  |   |   |   |   |   |   |   |    |  |  |  |  |
|----------------------------|--|---|---|---|---|---|---|---|----|--|--|--|--|
| Participants Contacted     |  | 1 | 3 | 7 | 5 | 0 | 0 | 6 | 20 |  |  |  |  |
| Participants Screened      |  | 1 | 2 | 4 | 6 | 0 | 0 | 5 | 14 |  |  |  |  |
| Participants Consented     |  | 0 | 0 | 0 | 1 | 1 | 0 | 2 | 2  |  |  |  |  |
| Excluded After Consent     |  | 0 | 0 | 0 | 0 | 2 | 0 | 1 | 0  |  |  |  |  |
| Participants Withdrawn     |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0  |  |  |  |  |
| Dual Enrolled              |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2  |  |  |  |  |
| Actual Cumulative Enrolled |  | 0 | 0 | 0 | 1 | 2 | 2 | 4 | 6  |  |  |  |  |

|  |                             |
|--|-----------------------------|
|  | Date Submitted: Nov.2, 2011 |
|  | Date Approved               |