

# Final Progress Report for Research Projects Funded by Health Research Grants

Instructions: Please complete all of the items as instructed. Do not delete instructions. Do not leave any items blank; responses must be provided for all items. If your response to an item is “None”, please specify “None” as your response. “Not applicable” is not an acceptable response for any of the items. There is no limit to the length of your response to any question. Responses should be single-spaced, no smaller than 12-point type. The report **must be completed using MS Word**. Submitted reports must be Word documents; they should not be converted to pdf format. Questions? Contact Health Research Program staff at 717-783-2548.

1. **Grantee Institution:** Temple University – of the Commonwealth System of Higher Education
2. **Reporting Period (start and end date of grant award period):** 1/01/2009 – 12/31/2012
3. **Grant Contact Person (First Name, M.I., Last Name, Degrees):** Germaine A Calicat
4. **Grant Contact Person’s Telephone Number:** 215.204.7655
5. **Grant SAP Number:** 4100047651
6. **Project Number and Title of Research Project:** 10 - Data Analysis of Cognitive-Behavioral Therapy as an Augmentation Strategy for Social Anxiety Disorder
7. **Start and End Date of Research Project:** 7/1/2009 – 6/30/2011
8. **Name of Principal Investigator for the Research Project:** Richard G. Heimberg, Ph.D.
9. **Research Project Expenses.**

9(A) Please provide the amount of health research grant funds spent on this project for the entire duration of the grant, including any interest earned that was spent:

\$65,295 (direct costs), \$78,964 (total costs)

9(B) Provide the last names (include first initial if multiple individuals with the same last name are listed) of **all** persons who worked on this research project and were supported with health research funds. Include position titles (Principal Investigator, Graduate Assistant, Post-doctoral Fellow, etc.), percent of effort on project and total health research funds expended for the position. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project	Cost
Scott	Project Coordinator	100 (40 hrs) (6/15/09–6/30/10)	\$32,169+fringe
Jørstad-Stein	Graduate Rsch Assistant	100 (20 hrs) (9/1/09 – 5/31/10)	\$15,810+fringe
Wong	Graduate Rsch Assistant	100 (20 hrs) (August, 2009)	\$1,736+fringe*
Gordon	Graduate Rsch Assistant	100 (20 hrs) (August, 2009)	\$1,736+fringe*

9(C) Provide the names of **all** persons who worked on this research project, but who *were not* supported with health research funds. Include position titles (Research Assistant, Administrative Assistant, etc.) and percent of effort on project. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project
Heimberg	Principal Investigator	5%
Blanco	Co-Investigator	5%
Chen	Statistician	5% Yr 1 only
Marcus	Statistician	5% Yr 2 partial
Schmidt	Data Manager	5% Yr 1 only
Lin	Statistician/Data Manager	5% Yr 2 partial
Liu	Statistician/Data Manager	5% Yr 2 remainder

9(D) Provide a list of **all** scientific equipment purchased as part of this research grant, a short description of the value (benefit) derived by the institution from this equipment, and the cost of the equipment.

Type of Scientific Equipment	Value Derived	Cost
None		

**10. Co-funding of Research Project during Health Research Grant Award Period.** Did this research project receive funding from any other source during the project period when it was supported by the health research grant?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, please indicate the source and amount of other funds:

**11. Leveraging of Additional Funds**

11(A) As a result of the health research funds provided for this research project, were you able to apply for and/or obtain funding from other sources to continue or expand the research?

Yes x \_\_\_\_\_ No \_\_\_\_\_

If yes, please list the applications submitted (column A), the funding agency (National Institutes of Health—NIH, or other source in column B), the month and year when the application was submitted (column C), and the amount of funds requested (column D). If you have received a notice that the grant will be funded, please indicate the amount of funds to be awarded (column E). If the grant was not funded, insert “not funded” in column E.

Do not include funding from your own institution or from CURE (tobacco settlement funds). Do not include grants submitted prior to the start date of the grant as shown in Question 2. If you list grants submitted within 1-6 months of the start date of this grant, add a statement below the table indicating how the data/results from this project were used to secure that grant.

A. Title of research project on grant application	B. Funding agency (check those that apply)	C. Month and Year Submitted	D. Amount of funds requested:	E. Amount of funds to be awarded:
<i>Mirtazapine &amp; CBT Augmentation of SSRI Treatment for Social Anxiety Disorder</i>	<input checked="" type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify:____) <input type="checkbox"/> Nonfederal source (specify:_)	11/2009	\$1,500,000 (total costs)	\$ Not funded
<i>Integrated MET-CBT for Social Anxiety Disorder with Alcohol Misuse</i>	<input checked="" type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify:____) <input type="checkbox"/> Nonfederal source (specify:_)	3/2010	\$685,500 (total costs)	\$ Not funded
<i>Integrated MET-CBT for Social Anxiety and Marijuana Use Disorders</i>	<input checked="" type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify:____) <input type="checkbox"/> Nonfederal source (specify:_)	6/2010	\$\$689,250 (total costs)	\$ Not funded
<i>A Computer-Based Cognitive Bias Modification Program to Treat Aggression</i>	<input checked="" type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify:____) <input type="checkbox"/> Nonfederal source (specify:_)	2/2011	\$688,500 (total costs)	\$ Not funded
<i>Novel Personalized Treatment for Dually Diagnosed Anxious Marijuana Users</i>	<input checked="" type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify:____) <input type="checkbox"/> Nonfederal source (specify:_)	3/2011	\$689,250 (total costs)	\$ Under review

The grant application “*Mirtazapine & CBT Augmentation of SSRI Treatment for Social Anxiety Disorder*” was submitted within the first six months of the project period. Preliminary data analysis conducted with the support of this grant were included in the preliminary studies section of that application.

11(B) Are you planning to apply for additional funding in the future to continue or expand the research?

Yes  No

If yes, please describe your plans:

We continue to pursue funding in support of research that will allow the development of new treatment approaches for social anxiety disorder in populations with additional concerns. Further pursuit of funding as this relates to cannabis depends on the outcome of the review of the last of the listed applications above. It is likely that we will submit another application concerning social anxiety disorder and alcohol use in the fall of 2011. We also are considering a revised submission of the unfunded proposal “*A Computer-Based Cognitive Bias Modification Program to Treat Aggression*” listed in the table above.

**12. Future of Research Project.** What are the future plans for this research project?

The specific research project for which this grant was originally intended will continue in the data analysis phase until the primary outcome paper is published. Other papers from the larger database, concerning both the psychopathology of social anxiety disorder and aspects of its treatment, will continue to be developed well into the future.

**13. New Investigator Training and Development.** Did students participate in project supported internships or graduate or post-graduate training for at least one semester or one summer?

Yes  No

If yes, how many students? Please specify in the tables below:

	Undergraduate	Masters	Pre-doc	Post-doc
Male				
Female				
Unknown				
<b>Total</b>				

	Undergraduate	Masters	Pre-doc	Post-doc
Hispanic				
Non-Hispanic				
Unknown				
<b>Total</b>				

	Undergraduate	Masters	Pre-doc	Post-doc
White				
Black				
Asian				
Other				
Unknown				
<b>Total</b>				

**14. Recruitment of Out-of-State Researchers.** Did you bring researchers into Pennsylvania to carry out this research project?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, please list the name and degree of each researcher and his/her previous affiliation:

**15. Impact on Research Capacity and Quality.** Did the health research project enhance the quality and/or capacity of research at your institution?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, describe how improvements in infrastructure, the addition of new investigators, and other resources have led to more and better research.

**16. Collaboration, business and community involvement.**

16(A) Did the health research funds lead to collaboration with research partners outside of your institution (e.g., entire university, entire hospital system)?

Yes X \_\_\_\_\_ No \_\_\_\_\_

If yes, please describe the collaborations:

The research project that was the initial focus of this grant was the outgrowth of a collaboration between the Principal Investigator (Heimberg) and psychiatric and statistical professionals at the New York State Psychiatric Institute and the Department of Psychiatry of Columbia University (Carlos Blanco, MD, PhD, is a Co-Investigator on this grant). Later grant applications listed in the table above that concerned social anxiety disorder and alcohol or marijuana use were the outgrowth of a collaboration between Heimberg and Julia Buckner, PhD, of the Department of Psychology of Louisiana State University.

16(B) Did the research project result in commercial development of any research products?

Yes \_\_\_\_\_ No  X

If yes, please describe commercial development activities that resulted from the research project:

16(C) Did the research lead to new involvement with the community?

Yes \_\_\_\_\_ No  X

If yes, please describe involvement with community groups that resulted from the research project:

**17. Progress in Achieving Research Goals, Objectives and Aims.**

List the project goals, objectives and specific aims (as contained in the grant application’s strategic plan). Summarize the progress made in achieving these goals, objectives and aims for the entire grant award period. Indicate whether or not each goal/objective/aim was achieved; if something was not achieved, note the reasons why. Describe the methods used. If changes were made to the research goals/objectives/aims, methods, design or timeline since the original grant application was submitted, please describe the changes. Provide detailed results of the project. Include evidence of the data that was generated and analyzed, and provide tables, graphs, and figures of the data. List published abstracts, poster presentations and scientific meeting presentations at the end of the summary of progress; peer-reviewed publications should be listed under item 20.

This response should be a DETAILED report of the methods and findings. It is not sufficient to state that the work was completed. Insufficient information may result in an unfavorable performance review, which may jeopardize future funding. If research findings are pending publication you must still include enough detail for the expert peer reviewers to evaluate the progress during the course of the project.

Health research grants funded under the Tobacco Settlement Act will be evaluated via a performance review by an expert panel of researchers and clinicians who will assess project work using this Final Progress Report, all project Annual Reports and the project’s strategic plan. After the final performance review of each project is complete, approximately 12-16 months after the end of the grant, this Final Progress Report, as well as the Final Performance Review Report containing the comments of the expert review panel, and the grantee’s written response to the Final Performance Review Report, will be posted on the CURE Web site.

**There is no limit to the length of your response. Responses must be single-spaced below, no smaller than 12-point type. If you cut and paste text from a publication, be sure symbols print properly, e.g., the Greek symbol for alpha ( $\alpha$ ) and beta ( $\beta$ ) should not print as boxes (□) and include the appropriate citation(s). DO NOT DELETE THESE INSTRUCTIONS.**

Completion of all research was hampered by the loss of the project statistician, who was replaced, and the data manager, who has been replaced twice. However, we were unable to retain a replacement statistician for several months, which slowed progress toward our goals.

One of the specific aims of this project was the completion of a grant application to the NIMH that would further examine the nature and utility of augmentation treatments for social anxiety disorder. Despite the obstacles noted above, this was accomplished (first entry in table under item 11). This application “*Mirtazapine and CBT Augmentation of SSRI Treatment for Social Anxiety Disorder*” was submitted to the NIMH in November, 2009, deadline. The data analysis that were conducted and reported in that grant application are presented here:

This recent study assessed the efficacy of two treatments assigned at random for SAD patients who showed at least minimal response after an Acute Treatment Phase of 12 weeks of open treatment with paroxetine: (1) paroxetine continued as monotherapy or (2) paroxetine continuation augmented by individual cognitive-behavioral therapy (CBT) for 16 weeks. After the 16-week Augmentation/Continuation Phase, all treatments were discontinued and patients were followed up 24 weeks later (Follow-up Phase). The analyses reported herein are limited to primary continuous and categorical outcome measures for patients who entered and completed the Acute and Augmentation/Continuation Phases (or dropped out prematurely).

Patients. 150 patients (94 New York State Psychiatric Institute, NY; 56 Temple) who entered the study are the subject of this analysis.

Acute Treatment Phase Results. Analyses of acute outcomes were based on the intent-to-treat (ITT) sample, defined as patients who signed consent and provided data on the relevant measures during the Week 0 baseline assessment (with the exception of Clinical Global Impression Improvement Scores, CGI-I, which requires that at least one further assessment be administered after baseline for admission to the ITT sample, and for which the numbers are necessarily lower).

CGI-I scores were available for 122 patients. Of these patients, 79 (64.8%) were classified as responders (CGI-I score of 1 or 2). Twenty-nine of these patients (23.8% of the total) received a CGI-I score of 1. Twenty-seven (22.1%) patients received a score of 3. Sixteen (13.1%) patients received a score of 4 or higher.

We also examined changes achieved by patients in open paroxetine treatment on the clinician-administered Liebowitz Social Anxiety Scale (LSAS) and CGI-Severity Scale, as well as several self-rating measures. Significant changes were noted in the ITT sample for all of these measures.

Progression from Acute Phase to Augmentation vs. Continuation Treatment Phase. To progress to this phase, patients had to complete Phase I with at least 10% improvement on the LSAS. Fifty-two patients dropped out during Phase I, and 6 more patients dropped out when notified of their randomization (3 in each

condition). We were most interested in the treatment of partial responders, and so we also excluded from the analyses to follow patients who met criteria for remission ( $n=23$ , 15.3%). Our criterion for this was a Week 12 CGI-I score of 1 and an LSAS score of less than 30. This cut-off score was found in our previous research (see Mennin et al, 2002) as the score that best discriminated between patients with SAD and normal controls in a receiver operating characteristics analysis (ROC). The ITT sample for Phase II included 29 patients who received paroxetine continuation and 32 who received paroxetine continuation augmented by CBT.

Augmentation vs. Continuation Treatment Phase Results. We looked at CGI-Improvement scores in two ways. First, we examined the proportion of patients in each randomized treatment who achieved remission, defined for this analysis as a CGI-Improvement score of 1 (we considered the Mennin et al. cut-off criterion to be appropriate in selection of patients for Phase II because it assured that patients with remaining symptoms would be included; however, we consider it to be too conservative for assessing outcome in Phase II, as its ROC analysis had compared patients to controls who could not meet criteria for any mental disorder, a “supernormal” group). Among partially responding patients who were continued on paroxetine alone, 3 of 29 (10.3%) were classified as remitters at Week 28. The corresponding number for the group receiving paroxetine augmented by CBT was 11 of 32 (34.4%), also significant, Fisher’s Exact Test,  $p = .034$ .

Second, we conducted the traditional responder-nonresponder analysis, in which a score of 1 or 2 denoted responder status. Among patients who were continued on paroxetine alone, 17 of 29 (58.6%) were classified as responders at Week 28. The corresponding number for the group receiving paroxetine augmented by CBT was 28 of 32 (87.5%), and the difference between groups was significant, Fisher’s Exact Test,  $p = .018$ .

We next looked at response to several other measures. There were no significant differences between treatment conditions at Week 12 with the exception of the Brief Fear of Negative Evaluation Scale,  $t(57) = -2.23$ ,  $p = .03$ , with higher scores reported by those patients reported by patients randomized to received paroxetine continuation ( $M = 34.72$ ,  $SD = 7.92$ ) versus those randomized to receive paroxetine augmented by CBT ( $M = 30.47$ ,  $SD = 6.74$ ). For each measure, we then conducted an analysis of covariance, using the Week 12 score on the measure as the covariate, to examine whether there were differences between groups in residual change from Week 12 to Week 28. There were no significant differences between groups on the LSAS, Liebowitz Self-Rated Disability Scale, or Beck Depression Inventory. However, group differences were significant on the Social Phobia Scale,  $F(1,58) = 5.62$ ,  $p = .021$ , and the Brief Fear of Negative Evaluation Scale,  $F(1,58) = 4.24$ ,  $p = .044$ . The difference between groups approached significance on CGI-Severity,  $F(1,58) = 3.39$ ,  $p = .071$ , and the Social Interaction Anxiety Scale,  $F(1,58) = 3.36$ ,  $p = .072$ . In each case, differences favored the group receiving paroxetine augmented by CBT.

Finally, we examined within-group change for each treatment in Weeks 12-28. Statistical significance suggests further improvements during Phase II, whereas lack of significance reflects maintenance of gains for the specific group as a whole (individuals, of course, could get better or worse). Table 1 presents these data for the group receiving paroxetine alone and shows that patients in this group generally maintained their gains across measures, without further improvement. Table 2 presents the data for the group receiving paroxetine augmented by CBT; this group demonstrated additional change in Phase II on five of seven measures. Tables appear at the end of the response to item 17.

Summary of Findings. Open label treatment with paroxetine (Phase I) resulted in a high rate of response and significant changes from Week 0 to Week 12 on all measures. In Phase II, which focused on partial responders to Phase I treatment, continuation of paroxetine alone resulted in maintenance of gains, both on categorical measures of response and continuous clinician-administered and self-rated measures. However, there was little evidence for further change over the course of Phase II for these patients.

During Phase II, augmentation of paroxetine treatment with CBT was associated with further improvement. Improvement was significantly greater than for paroxetine alone for two measures and nearly so for two more. Further, this group improved significantly from Week 12 to Week 28 on 5 of 7 continuous measures, suggesting the efficacy of combined paroxetine/CBT for partial responders to an initial trial of paroxetine alone.

This was an A1 application, which means that no further revisions of that application would be accepted for review. After consultation with our Program Officer and the Branch Chief, we concluded that further pursuit of this line of research funding would not be advisable, and no further applications in this line have been submitted. However, we have remained active in the pursuit of external funding of research that would examine treatments for social anxiety disorder, especially among those whose distress and impairment is not typically reduced by first-line or standard treatments. We did so by submitting several applications to the National Institute of Mental Health and the National Institute of Drug Abuse to fund the development and evaluation treatments for persons with social anxiety disorder who use either alcohol or cannabis to self-medicate their distress and who further complicate their lives in the process. We also submitted an additional application during the current reporting period, based on the premise that many of the biased views of social interactions evident in social anxiety disorder (the modification of which leads to clinically significant change) are also evident among persons with problems with aggression. See the table under item 11. Dr. Heimberg was principal investigator (PI) or one of multiple PI's on all of these applications.

The second specific aim of this project was the development of the final dataset for the original project, the conduct of the final analyses of outcomes of the treatments examined in that study, and the submission of the resultant paper to a top-tier journal in the field of mental health treatment. This goal has not been accomplished at this writing although work continues in that direction, and we hope to be able to complete our movement toward this goal in 2011. Progress

toward that goal has been hindered by continuing staff turnover at the NY sister site of the original project, such that we have been unable to completely enter, clean, and certify the data at all time points in the study. In that study, comprehensive assessment of social anxiety disorder symptoms and related impairment took place at Week 0 (baseline), Week 12 (after open-label treatment with the selective serotonin reuptake inhibitor paroxetine), Week 28 (after a 16 week period of continued treatment with paroxetine with or without CBT, randomly determined), and at follow-ups at Week 40 and Week 52. Less comprehensive assessments were also conducted at Weeks 4, 8, and 20.

Although we have not been able to complete the work on the full dataset, we have accomplished the bulk of the work for the Week 0 assessment and for the major outcome measures at Weeks 4, 8, and 12. This allowed us to pursue other projects working from this database that are related to the nature of social anxiety disorder or moderation of attrition from or response to treatment with paroxetine, which we see as related to the overarching goals of our research program and consistent with the goals of this specific project. These projects have resulted in two presentations at professional meetings and three manuscripts which are currently under review for publication. The results of these studies are described in the remainder of this report, and the submitted manuscripts are appended.

#### *Fear of Positive Evaluation in Patients with Social Anxiety Disorder*

We designed the Fear of Positive Evaluation Scale (FPES) in previous research to assess *fear of positive evaluation*. Most research on social anxiety disorder has come to the conclusion that social anxiety is related to fear of negative evaluation, and the support for that contention is robust. However, evolutionary theory suggests that fear of positive evaluation (FPE), which we define as the sense of dread associated with being evaluated *favorably* and *publicly*, which begs a direct social comparison of the self to others and therefore causes a person to feel conspicuous and “in the spotlight” is a type of cognition which may be substantially related to social anxiety. Although previous findings on the psychometric properties of the FPES have been highly encouraging, only one previous study has examined the psychometric profile of the FPES in a sample of patients with social anxiety disorder. In the current study, we examined the psychometric profile of the FPES in 226 patients with a principal diagnosis of social anxiety disorder and 42 non-anxious controls. The FPES demonstrated strong internal consistency ( $\alpha = .85$ ) and test-retest reliability ( $r = .80$ ) in the clinical sample, and patients ( $M = 39.60$ ,  $SD = 14.92$ ) scored significantly higher than controls ( $M = 13.07$ ,  $SD = 10.99$ ),  $F(1, 266) = 120.52$ ,  $p < .001$ ,  $d = 2.02$ . Patients’ FPES scores correlated between .27-.50 with measures of symptom severity and impairment (all  $ps < .01$ ). FPES scores were also significantly more strongly related to scores on measures of social anxiety than to scores on the Beck Depression Inventory II. Hierarchical regression analyses revealed that FPES scores accounted for significant variance in social anxiety scores after controlling for scores on a measure of fear of negative evaluation (see Table 3). A comparison of patients who received CBT compared to those randomized to a waiting list revealed greater FPES change in the CBT group ( $M = -17.41$ ,  $SD = 16.36$ ) than the wait list group ( $M = 1.41$ ,  $SD = 10.10$ ),  $F(1, 54) = 26.35$ ,  $p < .001$ ,  $d = 1.38$ . This study provided encouraging support of the psychometric characteristics of the FPES and the clinical validity of the construct of fear of positive evaluation.

### Perfectionism and Social Anxiety Disorder

Perfectionism is a trait with adaptive and maladaptive components that has been linked to several psychological disorders, including social anxiety disorder. Extant assessments of perfectionism are based on different theories, and the extent of convergence across these assessments remains unclear. The present study clarifies the core dimensions assessed by leading perfectionism measures and tests them across groups, including a clinical sample of persons with social anxiety disorder. Multiple perfectionism measures were used for an exploratory factor analysis in an undergraduate sample and a confirmatory factor analysis in a larger sample of individuals with social anxiety disorder. Consistent with prior research, findings suggest that some of the most frequently utilized perfectionism measures converge on two factors: (a) maladaptive and (b) adaptive/orderly perfectionism. We report here a subset of the findings for the patient sample only. Patients completed the Multidimensional Perfectionism Scale (MPS) and the Almost Perfect Scale Revised (APS-R), along with measures of social anxiety, depression, and quality of life. Both perfectionism factors significant and uniquely predicted depression and quality of life, in opposite directions, as expected. However, the hierarchical regression for depression scores revealed a significant interaction between maladaptive perfectionism and social anxiety, such that when maladaptive perfectionism was high, the relationship between social anxiety and depression was significantly positive ( $\beta = .57, t = 5.61, p < .001$ ), but this relationship was not significant at low levels of maladaptive perfectionism ( $\beta = .13, t = 1.34, p = .183$ ). See Figure 1.

### Childhood Maltreatment: Implications for Symptom Severity and Response to Pharmacotherapy

Childhood maltreatment has been associated with severity of symptoms, reduced quality of life, impaired functioning, and reduced resilience in individuals with social anxiety disorder. No study has investigated the possible link between specific types of childhood maltreatment and outcome of treatment for social anxiety disorder. However, several studies suggest a link between childhood maltreatment and response to pharmacotherapy or cognitive-behavioral therapy for depression. We replicated previous work on the effects of childhood maltreatment in social anxiety disorder and examined its impact on response to pharmacotherapy. One hundred fifty-six individuals seeking treatment for social anxiety disorder completed the Childhood Trauma Questionnaire, which includes subscales measuring physical abuse and neglect, emotional abuse and neglect, and sexual abuse, along with measures of severity of social anxiety, quality of life, and disability. Data from the subset of 127 patients enrolled in the paroxetine trial were analyzed to gauge the impact of childhood maltreatment on attrition and response. Except for physical and sexual abuse, all types of maltreatment were related to greater symptom severity. Emotional abuse and neglect were related to greater disability, and emotional abuse, emotional neglect, and physical abuse were related to decreased quality of life (Table 4). Attrition from pharmacotherapy was significantly predicted by emotional abuse and physical abuse (Table 5); however, only the effect of emotional abuse remained robust after controlling for severity of social anxiety symptoms. A time by emotional abuse interaction ( $p < .012$ ) suggests that, for those who completed the full trial of paroxetine, the impact of emotional abuse on severity of social anxiety weakened significantly over time. In sum, emotional maltreatment was most strongly linked to dysfunction in social anxiety disorder. Individuals with a history of emotional abuse were more likely to dropout from pharmacotherapy for social anxiety disorder;

however, if they stayed the course, their outcomes were similar to those without a history of emotional abuse, findings that may have important implications for treatment providers.

Presentations at professional meetings based on preliminary versions of the above:

Shumaker, E.A., Rodebaugh, T.L., Heimberg, R.G., Blanco, C., Schneier, F.R., & Liebowitz, M. (2009, November). *A confirmatory factor analysis using two perfectionism measures: Maladaptive and adaptive perfectionism in a social anxiety disorder sample*. Poster presented at the annual meeting of the Association for Behavioral and Cognitive Therapies, New York, NY.

Sorensen, L.C., Heimberg, R.G., Blanco, C., Schneier, F.R., & Liebowitz, M.R. (2011, March). *Childhood maltreatment and social anxiety disorder: Implications for symptom severity and response to pharmacotherapy*. Paper presented at the annual meeting of the Anxiety Disorders Association of America, New Orleans, LA.

*Table 1. Week 12 to Week 28 Change on Measures of Social Anxiety, Depression, and Disability Among Patients Receiving Paroxetine Alone*

Measure	Wk 12 Mean	Wk 12 SD	Wk 28 Mean	Wk 28 SD	<i>t</i>	<i>df</i>	<i>p</i>
CGI Severity	4.00	0.77	3.85	1.27	0.66	27	.515
Liebowitz Social Anxiety Scale	49.45	19.23	44.86	20.75	1.24	28	.225
Brief Fear of Negative Evaluation Scale	34.72	7.92	33.07	8.43	1.48	28	.150
Social Interaction Anxiety Scale	39.31	12.97	37.03	12.70	1.47	28	.153
Social Phobia Scale	21.31	13.00	20.72	14.72	0.38	28	.707
Liebowitz Self-Rated Disability Scale	8.18	5.49	7.73	5.28	0.89	28	.381
Beck Depression Inventory	10.38	9.71	11.28	10.57	-1.2	28	.233

*Table 2. Week 12 to Week 28 Change on Measures of Social Anxiety, Depression, and Disability Among Patients Receiving Paroxetine Augmented by CBT*

Measure	Wk 12 Mean	Wk 12 SD	Wk 28 Mean	Wk 28 SD	<i>t</i>	<i>df</i>	<i>p</i>
CGI Severity	4.00	1.06	3.35	1.11	3.42	30	.002
Liebowitz Social Anxiety Scale	44.63	13.60	38.19	15.54	2.33	31	.026
Brief Fear of Negative Evaluation Scale	30.47	6.74	27.20	5.94	3.04	29	.005
Social Interaction Anxiety Scale	36.44	12.80	30.88	11.82	2.72	31	.011
Social Phobia Scale	17.25	10.52	12.78	8.69	3.16	31	.003
Liebowitz Self-Rated Disability Scale	6.55	4.34	6.72	4.25	-.35	31	.728
Beck Depression Inventory	7.97	7.30	8.30	8.53	-.25	29	.804

Table 3. Regression Weights from Hierarchical Regression Analyses Examining the Unique Variance in Social Anxiety Measures accounted for by Measures of Fear of Positive and Negative Evaluation.

Variable	<i>B</i>	<i>SE B</i>	Beta
Liebowitz Social Anxiety Scale			
Step 1:			
BFNE-S	1.00	.26	.18
Step 2:			
BFNE-S	.67	.25	.18
FPES	.51	.09	.38
Social Interaction Anxiety Scale – Straightforward			
Step 1:			
BFNE-S	1.09	.12	.45
Step 2:			
BFNE-S	.92	.12	.45
FPES	.23	.04	.31
Social Phobia Scale			
Step 1:			
BFNE-S	1.26	.21	.43
Step 2:			
BFNE-S	1.00	.21	.43
FPES	.30	.09	.31

Notes: FPES = Fear of Positive Evaluation Scale; BFNE-S = Brief Fear of Negative Evaluation Scale-Straightforward. All overall adjusted  $R^2$ s > .20, all *SE*s < 18.21; all  $R^2$   $\Delta$ s > .08, all *F*s > 11.26, all *p*s < .001.

*Table 4. Impact of Different Types of Childhood Maltreatment (CTQ subscale scores) on Social Anxiety Symptom Severity (LSAS), Quality of Life (QOLI), and Disability (LSRDS)*

Variable	<u>LSAS</u>	<u>QOLI</u>	<u>LSRDS</u>
	$\beta$ (SE)	$\beta$ (SE)	$\beta$ (SE)
Childhood Physical Neglect	.20 (1.76)*	-.09 (.09)	.12 (.48)
Childhood Physical Abuse	.16 (1.78)	-.21 (.08)*	.06 (.48)
Childhood Sexual Abuse	.07 (1.78)	.01 (.09)	-.01 (.48)
Childhood Emotional Neglect	.20 (1.77)*	-.27 (.08)**	.22 (.48)**
Childhood Emotional Abuse	.24 (1.77)**	-.33 (.08)**	.26 (.46)**

LSAS, Liebowitz Social Anxiety Scale; QOLI, Quality of Life Inventory; LSRDS, Liebowitz Self-Rated Disability Scale.

\*\*  $p > .01$

\*  $p > .05$

*Table 5. Univariate Logistic Regression of Maltreatment Variables with Completer Status<sup>a</sup>*

Variable	OR	(95% CI)
Childhood Physical Neglect	1.13	(0.83, 1.54)
Childhood Physical Abuse	0.73	(0.57, 0.93)*
Childhood Sexual Abuse	1.03	(0.77, 1.38)
Childhood Emotional Neglect	1.10	(0.82, 1.47)
Childhood Emotional Abuse	0.73	(0.56, 0.96)*

<sup>a</sup> Completer status dichotomized into completer vs. non-completer of 12 weeks of paroxetine treatment

\*  $p > .05$

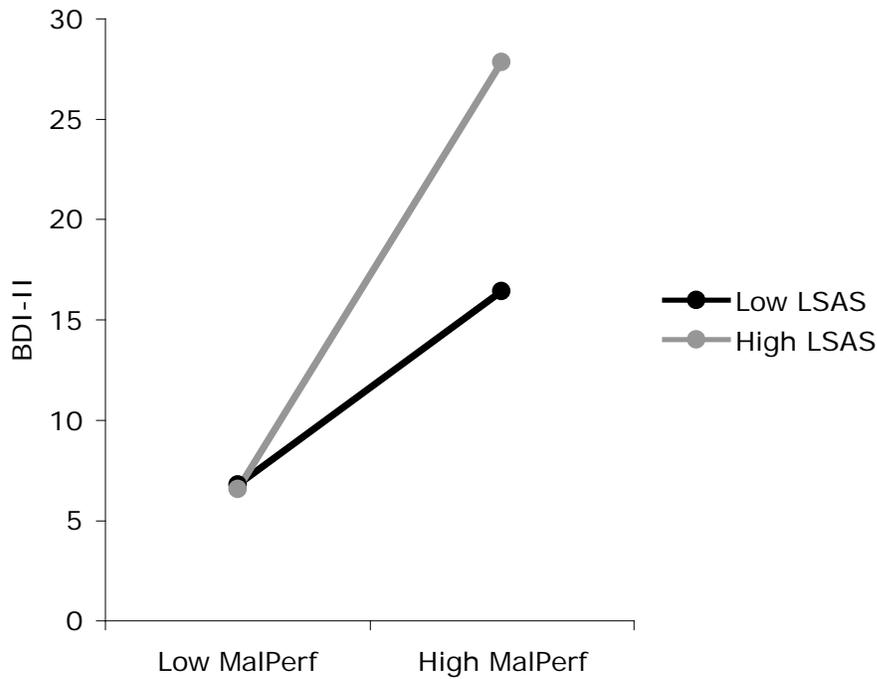


Figure 1. Interaction of Maladaptive Perfectionism (MalPerf) and Liebowitz Social Anxiety Scale (LSAS) scores in predicting Beck Depression Inventory-II (BDI-II) scores. *High* = +1 SD; *Low* = -1 SD.

**18. Extent of Clinical Activities Initiated and Completed.** Items 18(A) and 18(B) should be completed for all research projects. If the project was restricted to secondary analysis of clinical data or data analysis of clinical research, then responses to 18(A) and 18(B) should be “No.”

18(A) Did you initiate a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

Yes  
 No

18(B) Did you complete a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

Yes  
 No

**If “Yes” to either 18(A) or 18(B), items 18(C) – (F) must also be completed.** (Do NOT complete 18(C-F) if 18(A) and 18(B) are both “No.”)

18(C) How many hospital and health care professionals were involved in the research project?

\_\_\_\_\_ Number of hospital and health care professionals involved in the research project

18(D) How many subjects were included in the study compared to targeted goals?

\_\_\_\_\_ Number of subjects originally targeted to be included in the study  
\_\_\_\_\_ Number of subjects enrolled in the study

**Note:** Studies that fall dramatically short on recruitment are encouraged to provide the details of their recruitment efforts in Item 17, Progress in Achieving Research Goals, Objectives and Aims. For example, the number of eligible subjects approached, the number that refused to participate and the reasons for refusal. Without this information it is difficult to discern whether eligibility criteria were too restrictive or the study simply did not appeal to subjects.

18(E) How many subjects were enrolled in the study by gender, ethnicity and race?

Gender:

\_\_\_\_\_ Males  
\_\_\_\_\_ Females  
\_\_\_\_\_ Unknown

Ethnicity:

\_\_\_\_\_ Latinos or Hispanics  
\_\_\_\_\_ Not Latinos or Hispanics  
\_\_\_\_\_ Unknown

Race:

\_\_\_\_\_ American Indian or Alaska Native  
\_\_\_\_\_ Asian  
\_\_\_\_\_ Blacks or African American  
\_\_\_\_\_ Native Hawaiian or Other Pacific Islander  
\_\_\_\_\_ White  
\_\_\_\_\_ Other, specify: \_\_\_\_\_  
\_\_\_\_\_ Unknown

18(F) Where was the research study conducted? (List the county where the research study was conducted. If the treatment, prevention and diagnostic tests were offered in more than one county, list all of the counties where the research study was conducted.)

**19. Human Embryonic Stem Cell Research.** Item 19(A) should be completed for all research projects. If the research project involved human embryonic stem cells, items 19(B) and 19(C) must also be completed.

19(A) Did this project involve, in any capacity, human embryonic stem cells?

Yes  
 No

19(B) Were these stem cell lines NIH-approved lines that were derived outside of Pennsylvania?

Yes  
 No

19(C) Please describe how this project involved human embryonic stem cells:

**20. Articles Submitted to Peer-Reviewed Publications.**

20(A) Identify all publications that resulted from the research performed during the funding period and that have been submitted to peer-reviewed publications. Do not list journal abstracts or presentations at professional meetings; abstract and meeting presentations should be listed at the end of item 17. **Include only those publications that acknowledge the Pennsylvania Department of Health as a funding source** (as required in the grant agreement). List the title of the journal article, the authors, the name of the peer-reviewed publication, the month and year when it was submitted, and the status of publication (submitted for publication, accepted for publication or published.). Submit an electronic copy of each publication, listed in the table, in a PDF version 5.0.5 format, 1,200 dpi. Filenames for each publication should include the number of the research project, the last name of the PI, the number of the publication and an abbreviated research project title. For example, if you submit two publications for PI Smith for the “Cognition and MRI in Older Adults” research project (Project 1), and two publications for PI Zhang for the “Lung Cancer” research project (Project 3), the filenames should be:

Project 1 – Smith – Publication 1 – Cognition and MRI

Project 1 – Smith – Publication 2 – Cognition and MRI

Project 3 – Zhang – Publication 1 – Lung Cancer

Project 3 – Zhang – Publication 2 – Lung Cancer

If the publication is not available electronically, provide 5 paper copies of the publication.

**Note:** The grant agreement requires that recipients acknowledge the Pennsylvania Department of Health funding in all publications. Please ensure that all publications listed acknowledge the Department of Health funding. If a publication does not acknowledge the funding from the Commonwealth, do not list the publication.

Title of Journal Article:	Authors:	Name of Peer-reviewed Publication:	Month and Year Submitted:	Publication Status (check appropriate box below):
1. Psychometric Evaluation of the Fear of Positive Evaluation Scale in Patients With Social Anxiety Disorder	Justin W. Weeks, Richard G. Heimberg, Thomas L. Rodebaugh, Philippe R. Goldin, James J. Gross	<i>Psychological Assessment</i>	April 2011 (revision)	<input type="checkbox"/> Submitted <input type="checkbox"/> Accepted <input checked="" type="checkbox"/> Published
2. Perfectionism Factors Across Measures Using Exploratory and Confirmatory Factor Analysis in Social Anxiety Disorder and Non-clinical Samples	Erik A. Shumaker, Thomas L. Rodebaugh, Richard G. Heimberg, Carlos Blanco, Franklin R. Schneier, Michael R. Liebowitz	<i>Psychological Assessment</i>	April 2011	<input checked="" type="checkbox"/> Submitted <input type="checkbox"/> Accepted <input type="checkbox"/> Published
3. Childhood Maltreatment and Social Anxiety Disorder: Implications for Symptom Severity and Response to Pharmacotherapy	Laura C. Bruce, Richard G. Heimberg, Carlos Blanco, Franklin R. Schneier, Michael R. Liebowitz	<i>Depression and Anxiety</i>	July 2011	<input type="checkbox"/> Submitted <input type="checkbox"/> Accepted <input checked="" type="checkbox"/> Published

20(B) Based on this project, are you planning to submit articles to peer-reviewed publications in the future?

Yes  No

If yes, please describe your plans:

The primary outcome paper will be submitted in the months to come, and other papers based on the original dataset will also be submitted for review.

**21. Changes in Outcome, Impact and Effectiveness Attributable to the Research Project.**

Describe the outcome, impact, and effectiveness of the research project by summarizing its impact on the incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of outcome, impact or effectiveness of the research project. If there were no changes, insert “None”; do not use “Not applicable.” Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

None at this time, as the primary and secondary analyses have yet to reach the publication stage.

**22. Major Discoveries, New Drugs, and New Approaches for Prevention Diagnosis and Treatment.** Describe major discoveries, new drugs, and new approaches for prevention, diagnosis and treatment that are attributable to the completed research project. If there were no major discoveries, drugs or approaches, insert “None”; do not use “Not applicable.” Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

None.

**23. Inventions, Patents and Commercial Development Opportunities.**

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 of the United States Code, conceived or first actually reduced to practice in the performance of work under this health research grant? Yes \_\_\_\_\_ No  X

If “Yes” to 23(A), complete items a – g below for each invention. (Do NOT complete items a - g if 23(A) is “No.”)

- a. Title of Invention:
- b. Name of Inventor(s):
- c. Technical Description of Invention (describe nature, purpose, operation and physical, chemical, biological or electrical characteristics of the invention):
- d. Was a patent filed for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?  
Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, indicate date patent was filed:

- e. Was a patent issued for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?  
Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, indicate number of patent, title and date issued:  
Patent number:  
Title of patent:  
Date issued:
- f. Were any licenses granted for the patent obtained as a result of work performed under this health research grant? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, how many licenses were granted? \_\_\_\_\_

- g. Were any commercial development activities taken to develop the invention into a commercial product or service for manufacture or sale? Yes \_\_\_ No \_\_\_

If yes, describe the commercial development activities:

23(B) Based on the results of this project, are you planning to file for any licenses or patents, or undertake any commercial development opportunities in the future?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, please describe your plans:

**24. Key Investigator Qualifications.** Briefly describe the education, research interests and experience and professional commitments of the Principal Investigator and all other key investigators. In place of narrative you may insert the NIH biosketch form here; however, please limit each biosketch to 1-2 pages. *For Nonformula grants only – include information for only those key investigators whose biosketches were not included in the original grant application.*

Following are abbreviated biosketches Principal Investigator Heimberg, Co-Investigator Blanco, current Statistician Marcus, and current Data Manager Liu.

## BIOGRAPHICAL SKETCH

NAME Richard G. Heimberg		POSITION TITLE Principal Investigator	
eRA COMMONS USER NAME (credential, e.g., agency login) GERSON728			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of Tennessee, Knoxville, TN	B.S.	06/72	Psychology
Florida State University, Tallahassee, FL	M.S.	08/74	Clinical Psychology
West Virginia University School of Medicine, Morgantown, WV (Internship)		9/76-8/77	Clinical Psychology
Florida State University, Tallahassee, FL	Ph.D.	08/77	Clinical Psychology

### **Positions and Employment**

1977-1978	Lecturer, Department of Psychology, Florida State University, Tallahassee, FL
1978-1996	Professor (various ranks), Psychology Department, State University of New York at Albany
1996-	Professor, Department of Psychology, Temple University
1996-	Director, Adult Anxiety Clinic of Temple University
2002-2007	Director of Clinical Training, Department of Psychology, Temple University

### **Other Experience and Professional Memberships**

1980-1984	Consulting Editor, <i>Journal of Consulting &amp; Clinical Psychology</i> (also 1997-2002)
1982-1995	Consulting Editor, <i>Cognitive Therapy and Research</i> (also 2000-present)
1984-1986	Consulting Editor, <i>Behavior Therapy</i> (also 1989-1990, 1998-2005, 2010-present)
1987-	Consulting Editor, <i>Journal of Cognitive Psychotherapy: An International Quarterly</i>
1993-	Consulting Editor, <i>Behaviour Research and Therapy</i>
1995-	Consulting Editor, <i>Journal of Anxiety Disorders</i>
1995-2000	Consulting Editor, <i>Journal of Abnormal Psychology</i>
1995-2000	Associate Editor, <i>Cognitive Therapy and Research</i>
1996-1997	Consulting Editor, <i>Psychological Assessment</i>
1997-	Consulting Editor, <i>Clinical Psychology: Science and Practice</i>
1997-1999	Member, Board of Directors, Association for Advancement of Behavior Therapy
1997-	Fellow, Association for Psychological Science
1998-	Consulting Editor, <i>Cognitive and Behavioral Practice</i>
1999-	Member, Scientific Advisory Board, Anxiety Disorders Association of America
1999-	Founding Fellow, Academy of Cognitive Therapy
2000-2001	President-Elect, Association for Behavioral and Cognitive Therapies
2001-2002	President, Association for Behavioral and Cognitive Therapies
2002-2003	Past President, Association for Behavioral and Cognitive Therapies
2004-	Consulting Editor, <i>Depression and Anxiety</i>
2006-2009	Editor, <i>Behavior Therapy</i>
2007-	Consulting Editor, <i>International Journal of Cognitive Therapy</i>
2011	President-Elect, Society for a Science of Clinical Psychology

## Honors

- 2001 Aaron T. Beck Award for Significant and Enduring Contributions to Cognitive Therapy, Academy of Cognitive Therapy
- 2004 David Kipnis Distinguished Faculty Fellow in Psychology, Temple University
- 2005 Paul Eberman Award for Outstanding Research, Temple University
- 2005 Doctoral Graduate of Distinction, Psychology Department, Florida State Univ.
- 2006 Outstanding Mentor Award, Association for Behavioral and Cognitive Therapies

## **Selected Recent Peer-reviewed Publications** (Publications selected from approx. 200+ peer-reviewed publications; 341 total articles & chapters; 11 books)

- Brozovich, F., & **Heimberg, R.G.** (2008). An analysis of post-event processing in social anxiety disorder. *Clinical Psychology Review, 28*, 891-903.
- Hayes, S.A., Hope, D.A., & **Heimberg, R.G.** (2008). The pattern of subjective anxiety during in-session exposures across therapy for clients with social anxiety disorder. *Behavior Therapy, 39*, 286-299.
- Ledley, D.R., **Heimberg, R.G.**, Hope, D.A., Hayes, S.A., Zaider, T.I., Van Dyke, M., et al. (2009). Efficacy of a manualized and workbook-driven individual treatment for social anxiety disorder. *Behavior Therapy, 40*, 414-424.
- Blanco, C., **Heimberg, R.G.**, Schneier, F.R., Fresco, D.M., Chen, H., Turk, C.L., et al. (2010). A placebo-controlled trial of phenelzine, cognitive behavioral group therapy and their combination for social anxiety disorder. *Archives of General Psychiatry, 67*, 286-295.
- Zaider, T.I., **Heimberg, R.G.**, & Iida, M. (2010). Anxiety disorders and intimate relationships: A study of daily processes in couples. *Journal of Abnormal Psychology, 119*, 163-173.
- Schneier, F., Foose, T., Hasin, D.S., **Heimberg, R.G.**, Liu, S.-M., Grant, B., & Blanco, C. (2010). Social anxiety disorder and alcohol use disorder: Comorbidity in the National Epidemiologic Survey on Alcohol and Related Conditions. *Psychological Medicine, 40*, 977-988.
- Brozovich, F., & **Heimberg, R.G.** (2011). The relationship of post-event processing to self-evaluation of performance in social anxiety. *Behavior Therapy, 42*, 224-235.

## **Recently Completed Selected Research Support**

R34 MH070682 Heimberg (PI) 6/1/2006-5/31/2010  
National Institute of Mental Health  
"Emotion Regulation Therapy for Generalized Anxiety"

The major goal of this project is to develop a new approach to the treatment of generalized anxiety disorder (GAD) that integrates cognitive-behavioral therapy with components of treatment hypothesized to be important based on the principal investigator's theoretical model of deficits in emotion regulation in GAD and to test this treatment in both open and randomized clinical trials.

R01 MH64481 Heimberg (PI) 8/15/2003-5/31/2008  
National Institute of Mental Health  
"CBT Augmentation of Paroxetine Treatment for Social Anxiety"

The major goal of this project was to determine whether cognitive-behavioral therapy (CBT) can serve to augment the gains achieved by patients with social anxiety disorder who have been partially responsive to initial treatment with paroxetine and whether the addition of CBT to continued paroxetine treatment will result in better maintenance of gains after the discontinuation of treatment.

## BIOGRAPHICAL SKETCH

NAME Carlos Blanco, M.D., Ph.D., M.S., M.S.	POSITION TITLE Co-Investigator
eRA COMMONS USER NAME Blancoc	

EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(S)	FIELD OF STUDY
Autonóma University, Madrid, Spain	M.D.	1986	Medicine
Autonóma University, Madrid, Spain	Ph.D.	1992	Neurochemistry
New School University, New York, NY	M.S.	1996	Health Resources Management
Columbia University, New York, NY	M.S.	2004	Biostatistics

### **Professional Positions**

1997-1998 Chair, Members-In-Training Committee, American Psychiatric Association  
 1997-1998 Member, Assembly Executive Committee, American Psychiatric Association  
 2000- Ontario Problem Gambling Research Center Grant Review Panel  
 2001-2010 Associate Professor of Clinical Psychiatry, Columbia University  
 1999 - 2001 Member, Board of Directors, Hispanic Association of Mental Health Professionals  
 2001 Reviewer, Center for Substance Abuse Treatment  
 2004- Member, Editorial Board, Journal of Gambling Studies  
 2007- Member, Editorial Board, American Journal of Addictions  
 2007-2009 Member, NIDA Health Services Initial Grant Review Group (NIDA-F)  
 2008- Assistant Editor, Addiction  
 2009- American Cancer Society Psychosocial and Behavioral Review Committee  
 2010- Member, NIH Health Services Organization and Delivery Initial Review Group  
 2010- Member, Advisory Council, NYS Office of Alcoholism and Substance Abuse Services (position requiring NYS Senate confirmation)  
 2010- Professor of Clinical Psychiatry, Columbia University

### **Selected Recent Peer-reviewed Publications:**

Vesga-López O, **Blanco C**, Keyes KM, Olfson M, Grant BF, Hasin DS. Psychiatric disorders in pregnant and postpartum women in the United States: Results from National Epidemiological Survey on Alcohol and Related Conditions. Arch Gen Psychiatry 2008;65: 805-815.

**Blanco C**, Ogburn E, Perez de Los Cobos J, Lujan J, Nunes EV, Grant B, Liu SM, Hasin DS: DSM-IV criteria-based clinical subtypes of cannabis use disorders: Results from the National Epidemiological Survey on Alcohol and Related Conditions (NESARC). Drug Alcohol Depend 2008;96:136-144.

**Blanco C**, Alderson D, Ogburn E, Grant B, Nunes E, Hatzenbuehler ML, Hasin D: Changes in the prevalence of non-medical prescription drug use and drug use disorders in the United States; 1991-1992 and 2001-2002. Drug Alcohol Depend 2007;90:252-260.

- Blanco C**, Okuda M, Wright C, Hasin DS, Grant BF, Liu SM, Olfson M: Mental health of college students and their non-college-attending peers: Results from the National Epidemiologic Study on Alcohol and Related Conditions. *Arch Gen Psychiatry* 2008;65:1429-1437.
- Blanco C**, Olfson M, Goodwin RD, Ogburn E, Liebowitz MR, Nunes EV, Hasin DS: Generalizability of clinical trial results for major depression to community samples. *J Clin Psychiatry* 2008;69:1276-1280.
- Blanco C**, Olfson M, Okuda M, Nunes EV, Liu SM, Hasin DS: Generalizability of clinical trials for alcohol dependence to community samples. *Drug Alcohol Depend* 2008;98:123-128.
- Keyes KM, Martins SS, **Blanco C**, Hasin DS. Telescoping and gender differences in alcohol dependence: New evidence from two national surveys. *Am J Psychiatry* 2010;167:969-976.
- Blanco C**, Heimberg RG, Schneier F, Fresco DM, Chen H, Turk C, Vermes D, Erwin BA, Schmidt A, Juster HR, Campeas R, Liebowitz M: A placebo-controlled trial of phenelzine, cognitive behavioral group therapy and their combination for social anxiety disorder. *Arch Gen Psychiatry* 2010;67:286-295.

### **Selected Recent Research Support**

K02 DA 023200 (PI: Blanco)

Bridging Efficacy and Effectiveness in Drug Abuse Treatment  
NIDA

2/1/08 – 1/30/13

The goal of this this proposal is to support the continuing development of the applicant as an independent research psychiatrist in the field of interventions development for drug abuse treatment.

R01 MH076051 (PI: Blanco)

NIMH

Improving the Effectiveness of Treatment for Depression in Hispanics

To test the efficacy of an intervention to improve retention of depressed Hispanics in outpatient treatment that is based on combined treatment with antidepressants and telephone-administered interpersonal psychotherapy.

2/1/08 – 1/30/13

R01 CA133050 (PI: Blanco)

NCI

Interpersonal Psychotherapy for Depression in Breast Cancer

The goal of this study is to examine to examine the short-term efficacy of IPT delivered face to face in the treatment of breast cancer survivors with MDD.

9/24/09-11/30/14

R01 MH078056 (PI: Blanco)

NIMH

Cognitive-Motivational Behavior Therapy for Pathological Gamblers

The goal of this study is to test the efficacy of a novel intervention based on CBT and motivational interviewing for the treatment of outpatients with pathological gambling.

8/20/09-4/30/13

R01 DA023973 (PI: Blanco)

NIDA

Substance Use Comorbidity Care: Evidence-Based Stepped Strategies

The goal of this study is to test the efficacy of a novel intervention based motivational interviewing and pharmacological algorithms for the treatment of depressed substance abuse patients.

8/1/09-7/31/11

## BIOGRAPHICAL SKETCH

NAME Sue M. Marcus, Ph.D.		POSITION TITLE Statistician	
eRA COMMONS USER NAME drsuemarcus			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Wellesley College, Wellesley, MA	B.A.	1972	Mathematics/Philosophy
Clark University, Worcester, MA	A.M.	1974	Mathematics
Harvard University, Cambridge, MA	M.S.	1979	Biostatistics
University of Pennsylvania, Philadelphia, PA	Ph.D.	1992	Statistics

### **Positions and Employment**

1994-1995	Faculty, Policy Research, Evaluation and Measurement, Graduate School of Education, University of Pennsylvania, Philadelphia, PA
1995-1997	Instructor, Biostatistics Section, Division of Clinical Pharmacology, Department of Medicine, Jefferson Medical College, Philadelphia, PA
1997-1998	Assistant Professor, Biostatistics Section, Division of Clinical Pharmacology, Department of Medicine, Jefferson Medical College, Philadelphia, PA
1998-2002	Assistant Professor of Biostatistics, Department of Biostatistics and Epidemiology, University of Pennsylvania School of Medicine, Philadelphia, PA
2002-2009	Assistant Professor of Psychiatry and Biomathematics, Department of Psychiatry, Mount Sinai School of Medicine, New York, NY
2009-present	Associate Professor of Biostatistics (in Psychiatry, appointment pending) and Research Scientist VIII, New York State Psychiatric Institute, Columbia University, New York NY

### **Other Experience and Professional Memberships**

1995	Statistical Consultant, Long-Term Benefits of Head Start Study, High/Scope Educational Research Foundation, Ypsilanti, Michigan
2000-Present	Research Scientist, Center for Health Statistics, University of Chicago at Illinois
2000-Present	Reviewer, Statistics in Medicine, Psychological Methods, Biostatistics, Anesthesia and Analgesia
2002-Present	Scientific Advisor to NIMH multisite trial, Treatment of Resistant Depression in Adolescents
2003-Present	NIMH Reviewer
2010-Present	Mental Health Services in Non-Specialty Settings (SRNS) Committee, National Institute of Mental Health Initial Review Group

### **Selected Recent Peer-Reviewed Publications**

Garakani, A., Martinez, J.M., **Marcus, S.**, Weaver, J., Rickels, K., Fava, M. & Hirschowitz, J. (2008). A randomized, double-blind, and placebo-controlled trial of quetiapine augmentation of fluoxetine in major depressive disorder. *International Clinical Psychopharmacology*, 23(5), 269-275.

- Marcus, S.M.**, Siddique, J., Have, T.R., Gibbons, R.D., Stuart, E. & Normand, S.L. (2008). Balancing treatment comparisons in longitudinal studies. *Psychiatric Annals*, 38(12), 805-811.
- Ten Have, T.R., Normand, S.L., **Marcus, S.M.**, Brown, C.H., Lavori, P. & Duan, N. (2008). Intent-to-treat versus non-intent-to-treat analyses under treatment non-adherence in mental health randomized trials. *Psychiatric Annals*, 38(12), 772-783.
- Marcus, S.M.**, Gorman, J., Shear, M.K., Lewin, D., Martinez, J., Ray, S., Goetz, R., Mosovich, S., Gorman, J., Barlow, D. & Woods S. (2007). A comparison of medication side effect reports by panic disorder patients with and without concomitant cognitive behavior therapy. *American Journal of Psychiatry*, 164 (2), 273-275.
- Gibbons, R.D., Brown, C.H., Hur, K., **Marcus, S.M.**, Bhaumik, D.K. & Mann, J.J. (2007). Relationship between antidepressants and suicide attempts: an analysis of the Veterans Health Administration datasets. *American Journal of Psychiatry*, 164(7), 1044-1049.
- Gibbons, R.D., Brown, C.H., Kur, H., **Marcus, S.M.**, Bhaumik, D.K., Erkens, J.A., Herings, R.M. & Mann, J.J. (2007). Early evidence on the effects of regulators' warnings on SSRI prescriptions and suicide in children and adolescents. *American Journal of Psychiatry*, 164(9), 1356-1363.
- Gibbons, R.D., Segawa, E., Karabatsos, G., Amatya, A.K., Bhaumik, D.K., Brown, C.H., Kapur, K., **Marcus, S.M.**, Hur, K. & Mann, J.J. (2008). Mixed-effects Poisson regression analysis of adverse event reports: the relationship between antidepressants and suicide. *Statistics in Medicine*, 27(11), 1814-1833.

### **Selected Recent Research Support**

1R01MH086236-01, PI: Jackson, C.  
NIMH

04/01/2009-03/31/2012

Evaluating the Impact of Clinical Alerts Generated from Medicaid Claims Data

This application proposes to use pooled Medicaid claims data from NYS and Pennsylvania (PA) to examine the impact of the "clinical alerts" generated by Medicaid claims data on continuity of care and use of psychiatric emergency services in NYC.

Role: Statistician

U01AA018111-01, PI: Hasin, D.  
NIAAA

04/15/2009-03/31/2014

Adverse childhood experiences, personality psychopathology, and alcohol disorders

The goal of this study is to clarify the relationships of childhood experiences and personality disorders to the risk for and persistence of alcohol use disorders.

Role: Statistician

1 R01 CA133050-01, PI: Blanco, C.  
NCI

09/24/2009-07/31/2014

Interpersonal Psychotherapy for Depression in Breast Cancer

The goal of this study is to examine the efficacy of IPT in the treatment of breast cancer survivors with MDD.

Role: Statistician

1 R34 MH091336-01, PI: Schneier, F  
NIMH

07/01/2010-04/30/2013

Combined Mirtazapine & SSRI Treatment of PTSD: A Placebo-Controlled Trial

To examine the efficacy and safety of augmenting SSRI with Mirtazapine vs. augmenting with placebo in patients with PTSD.

Role: Statistician

## BIOGRAPHICAL SKETCH

NAME Shang-Min Liu, M.A.	POSITION TITLE Data Manager		
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
National Taipei University, Taipei, Taiwan	B.A.	2004	Statistics
Columbia University, New York, USA	M.A.	2006	Statistics

### POSITIONS AND EMPLOYMENT

5/07 - Biostatistician, New York State Psychiatric Institute, NY, NY

### SELECTED RECENT PEER-REVIEWED PUBLICATIONS

- Blanco C, Ogburn E, Perez de Los Cobos J, Lujan J, Nunes EV, Grant B, **Liu SM**, and Hasin DS. DSM-IV criteria-based clinical subtypes of cannabis use disorders: results from the National Epidemiological Survey on Alcohol and Related Conditions (NESARC). *Drug Alcohol Depend* 2008, 96(1-2): 136-144.
- Blanco C, Okuda M, Wright C, Hasin DS, Grant BF, **Liu SM**, and Olfson M. Mental health of college students and their non-college-attending peers: results from the National Epidemiologic Study on Alcohol and Related Conditions. *Arch Gen Psychiatry* 2008, 65(12): 1429-1437.
- Blanco C, Olfson M, Okuda M, Nunes EV, **Liu SM**, and Hasin DS. Generalizability of clinical trials for alcohol dependence to community samples. *Drug Alcohol Depend* 2008, 98(1-2): 123-128.
- Blanco C, Olfson M, Okuda M, Nunes E, **Liu SM**, Hasin DS. Generalizability of Clinical Trials for Alcohol Dependence to Community Samples. *Drug Alcohol Depend*. 2008 Nov 1; 98(1-2): 123-8.
- Vesga-López O, Schneier F, Wang S, Heimberg R, **Liu SM**, Hasin DS, Blanco C. Gender Differences in Generalized Anxiety Disorder: Results from the National Epidemiological Survey on alcohol and related conditions (NESARC). *J Clin Psychiatry*. 2008; 69(10):1606-16.
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## **RESEARCH SUPPORT**

R01 DA019606 (PI:Blanco)

NIDA

9/30/06 – 6/30/11

Substance Abuse in Hispanics: A National Study

The goal of this project is to investigate the relationship between acculturation and risk of substance use disorders in a nationally representative sample of the US population.

Role: Biostatistician