Full Application

Title of Proposed Ancillary Study Influence of Explicit and Implicit Weight Bias on Dietary Compliance, and Stress Response in Treatment Seeking Overweight and Obese Adults.

Principal Investigator for Ancillary Study Andrea Gorman; Charles Sachs

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Abstract Overweight and obesity has gained much attention as a growing health concern and researchers are now seeking to better understand the mind-body relationship. The mechanism of this relationship remains uncertain, however weight bias impacts quality of life, stress, and perhaps compliance with dietary interventions. There is a well-recognized potential for psychological variables to influence dietary intake. The objective of this study is to assess explicit weight bias towards oneself and implicit weight bias toward others in a treatment seeking adult population. A novel composite of these two psychological elements may enhance prediction of weight loss and weight loss maintenance success as well as shape potential interventions for bias reduction. A relationship between weight stigma and greater biochemical stress, independent of level of adiposity will also be tested. The study will also seek additional insight as to whether a 10-15% weight reduction and successful maintenance of this weight loss may affect a change in weight bias.

PROPOSED BUDGET

Personnel		Tim	Time/Effort		\$ Amount Requested		
Name	Project position title	%	Hours per week	Salary	Fringe benefits	Salary + Fringe	
	Research Assistant			\$2000			
Supplies (itemize, expand any boxe		total of perse	onnel costs				
iPad Keyboards (2)					Su	btotal=\$3	
Patient care costs (itemize) None							
					Subto	Subtotal=	
Other expenses (itemize) IAT hosting and data trans							

Total Budget=\$9,535

BIOGRAPHICAL SKETCH

Provide the following information for the Principal Investigator. DO NOT EXCEED FOUR PAGES

Andrea Gorman, PhD, MS, RD, LDN Charles J. Sachs, PhD, M.Phil, MS, MA						
EDUCATION/TRAINING (Begin with baccalaureate or other ini training if applicable.)	itial professional education, s	such as nursing, ir	nclude postdoctoral training and residency			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY			
University of Rhode Island	BS	05/94	Dietetics			
University of New Haven	MS	01/00	Human Nutrition Science			
Boston University	PhD	09/11	Medical Nutrition Science			

Stony Brook University Columbia University	BA MA MS MPhil PhD	8/80 10/88 2/90 10/90 10/96	Psychology Developmental Psychology Clinical Psychology Psychology Psychology
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A. Personal Statement

Briefly describe why your experience and qualifications make you particularly well-suited for your role as Principal Investigator on the proposed ancillary project. In the section, if appropriate, you also may explain how your expertise might contribute to the parent project.

I have spent several years working as a clinical dietetics professional assisting adults and adolescents struggling with overweight and obesity. I have worked with several bariatric surgery services providing both inpatient and outpatients services. This has included work with multidisciplinary professionals to provide comprehensive, patient-centered programs that are certified as centers for excellence in the field. My doctoral dissertation was related to the topic of obesity as it relates to periodontal disease and nutrition quality. I am currently the instructor for the graduate level course at Framingham State University NUTR/NUED 924 Obesity and Weight Management. I am also trained by the Academy of Nutrition and Dietetics in Level I Adult Weight Management. – Andrea Gorman

My training and practice in clinical psychology broadly includes health psychology. I was the consulting psychologist to a bariatric surgery program. I have been involved in multiple grant funded studies, starting in graduate school. I am currently an Assistant Professor at Framingham State University where I teach undergraduate research methods courses, among other courses. – Charles Sachs

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors.

<u>Andrea Gorman</u>

Assistant Professor - Framingham State University Sept 2013-Present

Clinical Nutrition Manager - Rhode Island Hospital & Hasbro Children's Hospital *June 2009-July 2013*

Adjunct Faculty- Johnson & Wales University, Providence, RI Sept 2012-Aug 2013

Research Assistant - Department of Veterans Affairs, Boston Healthcare System *Sept 2008 – Sept 2012* *System Director-Clinical Nutrition - Morrison Healthcare Foodservice -* St. Vincent & MetroWest Hospitals, Worcester, Framingham and Natick, MA *Feb 2004 – May 2009*

Adjunct Faculty - Framingham State College, Framingham, MA Spring '08

Nutrition Educator- Rhode Island Pilates Studio & The State Ballet of Rhode Island, Lincoln, RI July 1999 - present

Assistant Director Patient Services; Chief Clinical Dietitian - Landmark Medical Center & Rehabilitation Hospital of RI, Woonsocket, RI Oct. 2001 – Feb. 2004

Assistant Director Patient Services; Chief Clinical Dietitian - ARAMARK at Massachusetts Hospital School, Canton, MA Sept. 1996 – Oct. 2001

Clinical Dietitian - HealthSouth Rehabilitation Hospital, Toms River, NJ June 1995–Aug.1996

Recipient of the Rhode Island Dietetic Association's Recognized Young Dietitian of the Year - 2005 Recipient of ARAMARK's Outstanding Clinical Leadership award – 2001 Recipient of the Commonwealth Citation for Outstanding Performance – 2000

Charles Sachs

Framingham State College Assistant Professor, Department of Psychology and Philosophy [8/11 to present]. Visiting Lecturer in Psychology: [9/8 to 5/11]

MetroWest Medical Center Staff Psychologist 1/98 to 11/2010

The Justice Resource Institute, Butler Residential Treatment Center Assistant Clinical Director 3/96 to 1/98

Children's Services of Roxbury Clinical Director Lifeskills Residential Treatment Center and Building Communities Initiative 1/95 to 2/96

Children's Hospital-Boston, Department of Medicine (Half-time) *Fellow in Pediatric Psychology* 9/93 to 8/94

Judge Baker Children's Center, Manville School (Half-time) *Fellow in Developmental Clinical Psychology 9/93 to 8/94*

Beth Israel Hospital-Boston, Department of Psychiatry *Staff Psychotherapist* (7/92 to 6/97); *Psychology Fellow* (7/90 to 6/92)

Infant Health and Development Program-Boston Site Child Assessor 10/92 to 6/93

New York University, Department of Community Psychology, Adolescent Pathways Project 9/89 to 6/90

Mt. Sinai Hospital (New York), Departments of Psychiatry and Geriatrics 7/87 to 6/90

Barnard College, Adolescent Risk Project 10/85 to 10/86

C. Selected Peer-reviewed Publications

Limit the list of selected peer-reviewed publications, or manuscripts in press, to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed ancillary study or parent project.

Overweight and obesity predict time to periodontal disease progression in men.

Gorman A, Kaye EK, Apovian C, Fung TT, Nunn M, Garcia RI. *J Clin Periodontol.* 2012 Feb; 39(2): 107-14.

Changes in body weight and adiposity predict periodontitis progression in men.

Gorman A, Kaye EK, Nunn M, Garcia RI. J Dent Res. 2012 Oct; 91(10): 921-926.

- Fillit, H., Howe, J.L., Fulop, G., Sachs, C., Sell, L., Siegel, P., Miller, M., Butler, R.N. (1992) Studies of hospital social stays in the frail elderly and their relationship to the intensity of social work intervention. Social Work and Health Care, <u>18</u> (1), 1-22.
- Fields, S., Fulop, G., Sachs, C.J., Strain, J., Fillit, H. (1992) Usefulness of the Neurobehavioral Cognitive Status Exam in the hospitalized elderly. International Psychogeriatrics, <u>4</u>(1), 93-102.
- Strain, J.J., Lyons, J.S., Hammer, J.S., Fahs, M., Lebovits, A., Paddison, P.L., Snyder, S., Strauss, E., Burton, R., Nuber, G., Nordlie, J., Sachs, C.J. (1991) Cost offset from a psychiatric consultation-liaison intervention with elderly hip-fracture patients. American Journal of Psychiatry, <u>148</u>, 1044-1049.

D. Research Support

List selected ongoing and completed research projects for the past five years. Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and your responsibilities.

DISCLOSURES

Title of Proposed Ancillary Study Influence of Weight Bias on Self-efficacy, Dietary Compliance, and Stress Response in Treatment Seeking Overweight and Obese Adults.

Principal Investigator for Ancillary Study Andrea Gorman; Charles Sachs

Please report relationships that were present during the 36 months prior to submission of your full application.

Section 1. Work Under Consideration for Funding

Do you anticipate receiving receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the proposed work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes X No

Section 2. Relevant Financial Activities Outside of the Work Under Consideration for Funding

Do you have financial relationships (regardless of amount of compensation) with entities such as a government agency, foundation, commercial sponsor, or academic institution (other than Framingham State University)?

The relationship may be in the form of **1**) a grant, **2**) personal fees (monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony, employment, or other affiliations), **3**) non-financial support (examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, or administrative support), or **4**) other.

Are there any relevant conflicts of interest?	' 🗌 Yes 🗶 No	lf yes,
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lf yes,	please	list k	below.
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Name of Entity	Grant?	Personal Fees?	Non-financial	Other?	Comments
		rees	Support?		

Section 3. Intellectual Property – Patents and Copyrights

Do you have any patents (planned, pending or issued) broadly relevant to the proposed work?
Yes X No

Section 4. Relationships Not Covered Above

Are there other relationships or activities that could be perceive to influence, or that give the appearance of potentially influencing, how you conduct the proposed ancillary study?

Yes, the following relationships/conditions/circumstances are present (explain below):

X No other relationships/conditions/circumstances that present a potential conflict of interest

RESEARCH PLAN

This study distinguishes between explicit weight bias and implicit weight bias. Explicit weight bias refers to an openly expressed negative attitude toward those who are overweight. Implicit weight bias refers to a negative attitude toward those who are overweight when the negative attitude is *not* openly expressed.

Individuals' explicit and implicit weight bias status may not be concordant. While these attitudes are generally conceptualized as continuous, a simplified version of how the two attitudes may combine is shown below.

Explicit Weight Bias

	High	High Bias (+)		w Bias (-)
High Bias (+)	+/+		11	+/-
Low Bias (-)	+/-		IV	-/-

Implicit Weight Bias

These constructs can be represented in multiple ways, as described below. Explicit weight bias and implicit weight bias thus may combine to define weight bias profiles. For example, one profile could describe individuals with neither an explicit nor an implicit bias (cell IV, above), while an alternative profile could describe individuals with no explicit weight bias, who at the same time have an implicit weight bias (cell II, above).

The purpose of this study is to explore the impact that select psychological and physiological factors may have on compliance with a weight loss protocol. First, it is predicted that all participants will evidence both explicit and implicit weight bias at baseline. It is also predicted that participants with higher scores of explicit weight bias will evidence greater compliance than participants with lower explicit weight bias. Further, it is predicted that this will be true regardless of whether the explicit weight bias is framed in terms of attitudes toward others or attitudes toward the self. It is also predicted that participants with higher implicit weight bias will show greater compliance compared with participants who have lower implicit weight bias. Additionally, it is predicted that participants will demonstrate a change in weight bias from baseline to completion of the test phase.

Finally, it is predicted that participants characterized by the combination of low explicit weight bias together with implicit weight bias will be more compliant than all other participants (cell II). Again, we predict that this will be the case regardless of whether the overt component of weight bias is framed as attitudes toward others or toward the self. It is also predicted that these relations will themselves relate to cortisol level. It is predicted that participants with higher explicit weight bias, but no implicit bias will have higher cortisol levels. This is consistent with the idea that this form of dissonance causes stress and therefore, correlated with elevated cortisol.

Background

Weight bias, or stigma, is a term encompassing negative weight-related attitudes towards overweight and obese individuals. This bias may be *explicit* (overt, conscious, expressed openly). Further, the literature has made distinctions between explicit weight bias as directed towards others (Allison 1991; Puhl 2005) or towards the self (Durso 2008). Overweight and obese individuals often internalize explicit weight bias and thereby view themselves in a negative light. Others have conceptualized bias as *implicit* (covert, subconscious, not expressed openly), and have operationalized this construct using a methodology that can be applied to various content areas including weight bias (Greenwald, McGhee, & Schwartz, 1998). This latter construct refers to attitudes that are not openly expressed, and that may not be evident to those who have that bias

Previous studies have produced inconsistent findings regarding the impact of weight bias. On one hand, weight bias *internalization* (i.e., self-directed weight stigma) has been associated with psychological maladjustment, compromised physical health, and eating disturbances (Carels, 2010; Pearl, 2014). Further, Carels et al. found that implicit or explicit weight bias was directly associated with higher attrition, greater energy intake, lower levels of physical activity, and less weight loss among treatment-seeking overweight and obese adults (Carels, 2009). When evaluating outcomes among bariatric surgery patients, Lent et al. reported less weight loss 12 months after surgery among patients who expressed higher weight bias internalization prior to surgery (Lent, 2014).

However, others have found positive outcomes associated with greater weight bias experience. Latner, Wilson, Jackson, and Stunkard (2009) noted that a history of weight-stigmatizing experience predicted greater weight loss in a longitudinal analysis of patients in a group treatment program. In a more recent paper Carels et al. found that greater weight bias may facilitate weight loss and compliance with a weight loss program (Carels, 2014). Clearly, more research is warranted to determine how weight bias affects treatment outcomes.

The mechanisms by which weight bias may affect adherence to dietary interventions are unknown and likely complex. When discussing the results of previous intervention studies (Carels, 2009; Latner et al., 2009; Lent, 2014), research teams have speculated mediation by variables related to psychosocial functioning including motivation. However, the link between psychosocial and physiological variables has received relatively little attention. In an intriguing review article, Tokiyama (2014) recently proposed a conceptual model in which stress induced by weight bias elicits a cortisol response, leading to a vicious cycle of more weight gain, additional weight bias, and escalating stress. Based on inconsistent previous findings, it may be that individuals who express implicit bias but profess no explicit bias may experience greater motivation leading to better compliance and outcomes. However, it may also be the case that these individuals experience more emotional stress due to dissonance between covert and overt bias. According to the model, weight loss may be one means by which to exit this cycle, and weight loss maintenance may prevent re-entry.

Cortisol, a key component of the aforementioned model, is a steroid hormone released from the adrenal glands in response to stress or low blood glucose level. Consistent with the model, Tokiyama et al. found that frequency of exposure to weight-stigmatizing situations and consciousness of weight stigma were positively related to fasting serum cortisol level, independent of adiposity (Tokiyama et al., 2014). Previous dietary intervention studies indicate that macronutrient composition, independent of body weight, affects cortisol metabolism and suggest that very-low-carbohydrate diets may cause greater physiological stress, possibly due to low blood glucose level (Ebbeling 2012; Stimson 2007). High cortisol levels may promote not only weight gain but also insulin resistance and cardiovascular disease, based on epidemiological research (Adam 2010; Holt 2007; Purnell 2009; Vogelzangs 2010). However, whether weight bias interacts with dietary macronutrient

composition to influence cortisol, energy balance, and risk factors for chronic disease has not been studied to date.

In an ancillary study to our ongoing trial, we will assess implicit, explicit, and internalized weight bias and conduct exploratory analyses to address the questions listed below. Our findings will provide hypothesis-generating data to inform the design of future studies.

<u>Baseline</u>

- Do the study participants express explicit and/or implicit weight bias at baseline?
- Is there an association between weight bias profile and physiological stress, as assessed by 24-hour urinary cortisol at baseline?

End of Run-in Phase

- Does baseline weight bias influence weight loss and attrition during the run-in phase?
- Does weight bias change among participants during the run-in phase?

End of Test Phase

- Does weight bias modify the effect of dietary interventions on 24-hour urinary cortisol?
- Does weight bias change among participants during the test phase?

Assessment of Weight Bias

IAT: The Implicit Associations Test is a widely used measure of implicit attitudes toward several potential prejudices. We will invite participants to complete the IAT online (<u>http://www.uconnruddcenter.org/weight-bias-stigma-tools-for-researchers</u>) at baseline, at the end of the run-in, and again at the end of the test phases of the study. The IAT involves matching target category labels (e.g. fat people, thin people) with attribute labels (e.g. good, bad, lazy, motivated) in a timed test scenario. We will instruct participants to complete the tasks as quickly as possible without making a judgment about "correctness." A score will be calculated by measuring differential response times. Through a timed word association, the IAT will provide unconscious attitudes towards individuals with overweight or obesity, which can be at odds with conscious attitudes. The IAT test will take each participant approximately 10-15 minutes to complete.

WBIS: The Weight Bias Internalization Scale (Durso 2008) consists of an 11-item self-report measure to evaluate explicit beliefs about negative societal stereotypes and how self-statements about individuals with overweight and obesity applies to oneself. The content areas include acceptance/rejection of weight status, desire for change, effect of perceived weight status on mood, perceived personal value, ease of life, public appearance and social interaction, and recognition of the existence and unfairness of weight stigma. Respondents rate their agreement with items on a scale of 1 (strongly disagree) to 7 (strongly agree). Participants shall complete a baseline and follow-up WBIS test at end of study. Each test session may add approximately 10-15 minutes of testing time per participant.

OPTS: The Obese Persons Trait Survey (Puhl 2005) assesses explicit weight bias directed toward others using a 20-item measure that asks participants to estimate the percentage (0-100%) of obese persons who possess each trait on a list of stereotypical traits. Traits include 10 negative traits (e.g. undisciplined, lazy, unhealthy) and 10 positive characteristics (e.g. intelligent, sociable, productive). Higher scores indicate stronger negative and positive traits on the OPTS subscales, respectively. The OPTS test will take each participant approximately 5-10 minutes to complete.

BAOP: The Beliefs About Obese Persons Scale (Allison 1991) is an 8-item Likert rating survey that assesses explicit beliefs about causes of obesity. Each question asks respondents rate their extent of agreement on a scale of -3 (strongly disagree) to +3 (strongly agree) with statements about causes of obesity and assesses 'stereotypical' perceptions of the controllability of obesity, such as "Obesity is really caused by a lack of

willpower." Higher scores indicated beliefs that obesity is not controllable. The BAOP test will take each participant approximately 5-10 minutes to complete.

Statistics:

To evaluate the hypothesis that all participants will evidence explicit and implicit weight bias at baseline *t*-tests will be used. Next, continuous weight bias scores will be converted to categorical variables by median split. Thus, participants will thus be categorized as having either high or low weight bias as measured by the instruments described above. A 2(explicit weight bias: high, low) x 2(implicit weight bias; high, low) ANOVA will be conducted with weight loss used as the dependent variable. This will make it possible to test hypotheses regarding the impact of explicit and implicit weight bias alone, and their joint impact on protocol compliance. Similarly, a 2(explicit weight bias: high, low) x 2(implicit weight bias; high, low) ANOVA will be conducted with cortisol level used as the dependent variable. This will make it possible to test the hypothesized relation between weight bias profile and stress. A one-way ANOVA will be used to evaluate the hypothesis regarding change in weight bias over the course of the study.

Limitations:

The sample of volunteer participants is highly committed to weight reduction efforts. In assessing dietary compliance, the subjective method of relying on oral or written self-reports creates an assumption of honesty and accuracy in participant reporting. Weight bias surveys will also rely on participant honesty in responses. Repeated administration of the IAT may contribute to a decline in effect magnitude, however, utilizing the D scoring algorithm will reduce the influence of this factor. Additionally, the IAT was designed to measure associations, not beliefs, however this test may provide indirect evidence for the presence of beliefs. The WBIS assesses negative weight-based feelings about oneself that could, in turn, generalize to attitudes about overweight or obese people as a whole.

REFERENCES

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Vogelzangs N, Beekman AT, Milaneschi Y, Bandinelli S, Ferrucci L, Penninx BW. Urinary cortisol and six-year risk of all-cause and cardiovascular mortality. *J Clin Endocrinol Metab.* 2010;95(11):4959-4964.