

## Example of Responses to The Questions Asked in an IRB Application

### ❖ **Example of a Response to Question # 1:**

Recent literature suggests that, while people tend to perform behavior for which they are rewarded, external rewards (e.g., money) can undercut “intrinsic” or enjoyment-for-its-own-sake motivation. As a professor of public health funded under a PSC-CUNY award, Dr. G., also a certified kinesiologist (kinesiology is the science of human movement), intends to test whether the extrinsic vs intrinsic reward effect holds for exercise for 100 previously inactive (in the last six months) students, ages 18-24, cleared by their physicians, who sign up for guided exercise during Fall semester 2010 that can be performed at home but requires one guided session at the Brookdale campus gymnasium on a weeknight 6-7 p.m.. A randomly chosen half will receive an instruction booklet and video with advice on exercise maintenance directing them to pay attention to gradual increases in their flexibility, strength, stamina and mood while half will receive identical materials with their exercise maintenance advice directing them to reward themselves with small gifts or experiences (e.g., a shopping trip) for their efforts. After consent and six months after receiving exercise training, both groups will be tested using standard measures of strength, endurance and flexibility as well as weight, height and Body Mass Index (BMI)) and a published paper/pencil test of mood commonly used with normal populations (see attached data collection forms). These measures will take about 15 minutes (stretch and reach box, vertical jump, sphygmometer reading as a stand-in for endurance, height/weight, and the 5-8minute mood checklist). Although the results may surprise us, we expect intrinsic motivation to lead to greater fitness gains. Given the epidemic of inactivity in the US, we hope to contribute in professional publications and presentations to an important literature on self-maintenance of exercise habits.

### ❖ **Example of a Response to Question # 2:**

The reward study includes both young men and women students, 18-24, self-reported as exercising less than 30 minutes a week during the last six months, enrolled at Hunter, who have access to the Brookdale gym on a weeknight 6-7p.m. Fall 2010. The age limitation follows the work of Dr. Q. whose studies found that 18-24 represented the critical “transition to inactivity” phase of late adolescence. The study will be advertised by flyer (attached) posted by elevators and stairwells throughout Hunter’s four campuses (art, arts and sciences, health sciences, social work). Those responding to the listed e-mail and phone will receive a brief screening interview (script attached) by a master’s student in kinesiology. Those who are ineligible, or reply after recruitment has closed, will be directed to a safe exercise guidance site maintained by the International Society of Kinesiologists, while those eligible will be asked to provide their IDs for use of exercise facilities (requiring a physician waiver) prior to a private appointment for informed

consent and weigh-in/pretests; those that do not have IDs will be e-mailed procedures for getting them through Hunter's health/wellness center. The student wellness center has been informed of the potential for extra requests.

❖ **Example of a Response to Question # 3:**

After receipt of IDs certifying fitness for exercise, participants will complete informed consent in a private office at the Brookdale campus scheduled during the four weeks before the initial study activity meeting; weigh in and fitness measures will also take place at that time in a private office adjacent to the Brookdale gym and having a separate entrance. The initial study activity meeting will take place in groups of 20, one group per weeknight, at the Brookdale campus gymnasium. The participants will each receive a booklet and video, describing and illustrating, three 30 minute "work-outs" based on the "inactive" fitness entry level of the Texas Board of Governors Physical Fitness program developed by the Health and Leisure Department of the University of Houston (outline of activities attached). Booklets and videos, however, will differ in the extrinsic vs intrinsic motivational advice given at the end of each session (motivational scripts attached). Although the first "work-out," led by Dr. G. and 4 circulating master's level kinesiologists, will take place at the Brookdale gym to assure correct performance of exercises, the exercises are designed for use anywhere, at home, in dorm rooms, etc. The "work-out" includes graduated warm-up, stretches, activities, stretches and cool-down in each session as recommended by the American Association of Exercise Physiologists. In harmony both with current exercise principles and human subjects protections, participants will be instructed that they can perform exercises in slow or skip exercises.

The final "weigh-out" and fitness (strength, flexibility, endurance, BMI) and mood measures will also occur at the Brookdale gym, but with individually scheduled appointments with a master's level kinesiologists in a private room off of the gymnasium as described in #2.

❖ **Example of a Response to Question # 4:**

After receipt of IDs certifying fitness for exercise, participants will complete informed consent in a private office at the Brookdale campus scheduled during the four weeks before the initial study activity meeting; weigh in and fitness measures will also take place at that time in a private office adjacent to the Brookdale gym and having a separate entrance. The initial study activity meeting will take place in groups of 20, one group per weeknight, at the Brookdale campus gymnasium. The participants will each receive a booklet and video, describing and illustrating, three 30 minute "work-outs" based on the "inactive" fitness entry level of the Texas Board of Governors Physical

Fitness program developed by the Health and Leisure Department of the University of Houston (outline of activities attached). Booklets and videos, however, will differ in the extrinsic vs intrinsic motivational advice given at the end of each session (motivational scripts attached). Although the first “work-out,” led by Dr. G. and 4 circulating master’s level kinesiologists, will take place at the Brookdale gym to assure correct performance of exercises, the exercises are designed for use anywhere, at home, in dorm rooms, etc. The “work-out” includes graduated warm-up, stretches, activities, stretches and cool-down in each session as recommended by the American Association of Exercise Physiologists. In harmony both with current exercise principles and human subjects protections, participants will be instructed that they can perform exercises in slow or skip exercises.

The final “weigh-out” and fitness (strength, flexibility, endurance, BMI) and mood measures will also occur at the Brookdale gym, but with individually scheduled appointments with a master’s level kinesiologists in a private room off of the gymnasium as described in #2. There are no direct benefits to participants however, they will each receive an exercise program with the potential to benefit individual fitness.

This study poses minimal risks, such as those that may be experienced in daily student life. However, some participants may reflect on negative mood states while answering questions about mood, and some may be embarrassed to exercise in front of others at the initial meeting. There is some risk of sore muscles. Others may be upset by being “out of shape” or by having made “little progress” at weigh-out.

In informed consent documents, participants will be reminded that they may decide to leave the study, skip measures or items on measures, and skip or scale down exercise activities without penalty or loss of benefits. The mood measure—the Profile of Mood States—focuses on a normal range of mood and includes positive as well as negative feelings. All participants will be given a referral list for emotional/mental as well as physical health (see attached). Dr. G., who also holds a master’s in counseling, will make appropriate referrals should anyone be upset while completing this measure. The setting of the initial activity meeting and exercises will have been described in the consent document (attached). Those who appear or feel ill at ease in this setting may exercise “in the back” where they are less likely to be seen by others, but can still have observation that exercises are being performed correctly. The initial meeting and the written and video materials will advise about the treatment of sore muscles and on how to differentiate strains and sprains from soreness with recommended actions and resources for treatment (see referral list attached and Dr. G’s certification in first aid).

Finally, at “weigh-out” and final data collection sessions, master’s level kinesiologists will give feedback on fitness gains and give every participant an individualized hand-out on “next steps,” derived from the Texas fitness program. The kinesiologists have been trained in providing encouragement even for those who have made few gains. Dr. G. will be available by beeper to handle unlikely but potential cases of physical injury or emotional upset during these final meetings. Respondents will also be debriefed on the motivational hypothesis of the study. If study results indicate superiority of extrinsic or intrinsic reward, all participants will be informed and given the material demonstrated to be more motivating.

❖ **Example of a Response to Question # 5**

The study is not anonymous. Consent forms will be stored separate from the data collected. All data collected will be kept in a locked cabinet in Dr. Q’s Office. Only Dr. Q will have access to the data. Data will be kept for a minimum of three years. During the three year period all data be kept confidential.

❖ **Example of a Response to Question # 6:**

This study will involve no deception.

❖ **Example of a Response to Question # 7:**

After receipt of IDs certifying fitness for exercise, participants will be asked to come to a private office at the Brookdale campus to complete informed consent during the four weeks before the initial study activity meeting. Participants will sign two consent forms. They will be given a copy of the consent form for their records. The attached consent form will be used.

❖ **Example of a Response to Question # 8:**

N/A