INFORMED CONSENT DOCUMENT

David Grant USAF Medical Center
101 Bodin Circle
Travis Air Force Base CA 94535

TITLE OF STUDY

"Effectiveness of a Group Lifestyle Balance class in a Military Population"

CONTACT INFORMATION

Role	Name	Dept	Phone#
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PURPOSE OF STUDY

You are being asked to participate in a research study at David Grant Medical Center (DGMC), sponsored by TriService Nursing Research Program (TSNRP), entitled "Effectiveness of a Group Lifestyle Balance Class in an Military Population" because you are an active duty member of the U.S. Air Force and have a Body Mass Index (BMI) or an abdominal circumference that puts you in a higher risk category for chronic disease.

The purpose of the study is to examine the effects of Group Lifestyle Balance™ (GLB) program on participants' individual physical fitness, risk of developing chronic disease and how they feel about their state of health. An additional purpose is to compare the GLB class to the on-line Fitness Improvement Program (FIP) and to the Better Body Better Life (BBBL) program. Lastly, the purpose is to obtain feedback about the usefulness of the GLB, FIP, and BBBL programs to active duty personnel. The GLB program has been shown to be effective in helping people lose weight and in reducing the risk of developing diabetes in civilian populations who are pre-diabetic.

Participating in research is voluntary which means you can choose whether or not to participate. If you decide not to take part in the study there will be no loss of benefits to which you are entitled. You have the right to know about the procedures, risks, and benefits of the research study. If you decide to take part, you can change your mind later and leave the study. To participate in this study, you will need to give your written consent by signing this form. A member of the study team will talk to you about the research study, and they will give you this consent form to read. Please take your time to read it carefully to make your decision. You may want to discuss it with your family, friends, and caregivers. You will be asked to sign this form and you will receive a signed copy.

This study will enroll 131 participants over a period of 18 months from David Grant Medical Center. This is a randomized study; there is a 1 in 3 chance that you will be in any one of the three groups. Approximately, 44 participants will be enrolled into the GLB group, 44 will be enrolled into the FIP group and 44 will be enrolled into the BBBL group.

This study involves the use of the in-person GLB program, the on-line FIP, or the in-person BBBL program. The GLB class consists of 16 one-hour group classes over the course of 6 months (12 weekly, 2 every other

week, and 2 monthly classes) during which participants learn about ways to change their eating and exercise habits in order to lose weight and decrease risk of future disease. The FIP involves viewing a course on-line that provides information about nutrition, exercise and emotional well-being. The FIP takes approximately 90 minutes to complete and can be done in more than one sitting. The BBBL consists of five 2-hour long group classes (1 class each week for 5 weeks) during which participants learn about important aspects of nutrition, physical activity and healthy behaviors.

You are eligible to participate in this study if you are an active duty member of the U.S. Air Force, have a Body Mass Index over 25 kg/m2 or have an abdominal circumference over 35 inches for men or 31.5 inches for women, and are willing to commit to weekly 1 hour classes for 12 weeks and monthly classes for an additional 3 months.

You are NOT eligible to participate if you are pregnant or breastfeeding, if you are within 8 months of a PCS or deployment, are restricted from participating in moderate activity equivalent to a brisk walk, are taking medications to lower your blood sugar, have started on a new medication or new dose of the same medication to lower your cholesterol, or cannot have a calorie-restricted diet for medical reasons.

PROCEDURES

This is a randomized study. If you are eligible to participate, then you will be assigned by chance to one of three groups described below. "Randomized" means that you are put into a group by a selection similar to flipping a coin. You will have a one in three chance of being assigned to any of the groups.

If you volunteer to participate in this study, we will ask you to undergo the following procedures according to the group you are randomized:

Table of Procedures/Visits:

	GLB	FIP	BBBL
Visit 1	▪ Sign consent form ▪ Demographic Questionnaire ▪ RAND SF-36 Questionnaire ▪ weight measurement ▪ abdominal circumference ▪ Physical activity questionnaire ▪ Modifiable Activity Questionnaire ▪ blood work ordered (to be obtained after fasting for 12 hours) ▪ pregnancy test for women as indicated ▪ Scheduled for GLB class	▪ Sign consent form ▪ Demographic Questionnaire ▪ RAND SF-36 Questionnaire ▪ Physical activity questionnaire ▪ Modifiable Activity Questionnaire ▪ weight measurement ▪ abdominal circumference ▪ blood work ordered (to be obtained after fasting for 12 hours) ▪ pregnancy test for women as indicated	▪ Sign consent form ▪ Demographic Questionnaire ▪ RAND SF-36 Questionnaire ▪ Physical activity questionnaire ▪ Modifiable Activity Questionnaire ▪ weight measurement ▪ abdominal circumference ▪ blood work ordered (to be obtained after fasting for 12 hours) ▪ pregnancy test for women as indicated ▪ Scheduled for BBBL class

		▪ Instructions for taking FIP on-line and printing certificate	
Visit 2	Attend 1st weekly GLB class	▪ Occurs 12-14 weeks after visit 1 ▪ Turn in FIP certificate of completion ▪ Weight measurement ▪ Abdominal circumference ▪ RAND SF-36 Questionnaire ▪ Physical activity questionnaire	Attend 1st BBBL class
Visit 3	Attend 2d weekly GLB class	▪ Occurs 6 months after visit 1 ▪ Weight measurement ▪ Abdominal circumference ▪ RAND SF-36 Questionnaire ▪ Physical activity questionnaire ▪ Modifiable Activity Questionnaire ▪ Intervention Feedback Questionnaire ▪ Blood work ordered (to be obtained after fasting for 12 hours) **STUDY COMPLETE ONCE BLOODWORK DONE**	Attend 2d BBBL class
Visit 4	Attend 3rd GLB class		Attend 3rd BBBL class
Visit 5	Attend 4th GLB class		Attend 4th BBBL class
Visit 6	Attend 5th GLB class		Attend 5th BBBL class
Visit 7	Attend 5th GLB class		▪ Occurs 12-14 weeks after visit 1 ▪ Weight measurement ▪ Abdominal circumference ▪ RAND SF-36 Questionnaire ▪ Physical activity questionnaire
Visit 8	Attend 7th GLB class		▪ Occurs 6 months after visit 1 ▪ Weight measurement ▪ Abdominal circumference ▪ RAND SF-36 Questionnaire ▪ Physical activity questionnaire ▪ Modifiable Activity Questionnaire ▪ Intervention Feedback Questionnaire ▪ Blood work ordered (to be obtained after fasting for 12 hours)

			STUDY COMPLETE ONCE BLOODWORK DONE
Visits 9-13	Attend 8th-12th GLB classes		
Visit 14	▪ Occurs 12-14 weeks after visit 1 ▪ Weight measurement ▪ Abdominal circumference ▪ RAND SF-36 Questionnaire ▪ Physical activity questionnaire		
Visits 15-18	Attend bi-monthly then monthly GLB classes		
Visit 19	▪ Occurs approximately 6 months after visit 1 ▪ Weight measurement ▪ Abdominal circumference ▪ RAND SF-36 Questionnaire ▪ Physical activity questionnaire ▪ Modifiable Activity Questionnaire ▪ Intervention Feedback Questionnaire ▪ Blood work ordered (to be obtained after fasting for 12 hours) **STUDY COMPLETE ONCE BLOODWORK DONE**		

Details of Procedures/Visits:

GLB GROUP

Each of the 16 GLB sessions lasts approximately one hour, as well as the final meeting with the investigator.

Visit 1: A research study coordinator will explain the study in detail, obtain your written consent to participate, ask you to complete four short questionnaires, and obtain your weight and abdominal circumference measurement. The first questionnaire consists of demographic questions such as age, gender, race, rank, unit, years of service, presence of any chronic medical conditions, and use of any regular medications. The second questionnaire, called the RAND SF-36, consists of 36 short questions that ask you to rank your overall physical and mental health, ability to complete daily work and social tasks, and the amount of pain, fatigue and energy you had over the past four weeks. The third questionnaire consists of 3 short questions about your typical physical activity in the past 4 weeks. The fourth questionnaire consists of eight questions about the amount of time you spend doing physical activities during work and leisure time. Lastly, the research coordinator will ask you to go to the DGMC clinical laboratory after fasting for 12 hours to have blood work done to check your cholesterol panel and your hemoglobin A1C (a measure of glucose metabolism). The lab will collect tubes of blood which equals about two tablespoons of blood for research purposes only, however the results from the blood tests will become part of your medical record. These blood tests are the same type of tests you might have during a routine physical exam. Females will be asked to provide a urine sample for a pregnancy test.

Visits 2-13: A trained GLB instructor will function as a lifestyle coach during these GLB classes. The GLB class is a group class for military beneficiaries. You will be weighed and given instruction on how to make changes to your eating and exercise habits in order to lose weight and eat a healthy diet. The class takes place for one hour a week for 12 weeks.

Visit 14: This visit will be scheduled after completing the first 12 classes of the GLB. The study coordinator will obtain your weight and abdominal circumference, ask you to fill out the RAND SF-36 questionnaire and the physical activity questionnaire.

Visits 15-18: These visits will be for the remaining GLB classes and will occur twice per month or monthly, rather than weekly.

Visit 19: This visit will be scheduled within 1-2 weeks of completing the GLB program with a research study coordinator who will again obtain your weight and abdominal circumference measurement and ask you to complete the RAND SF-36 questionnaire, the physical activity questionnaire, and the Modifiable Activity Questionnaire. In addition the study coordinator will ask you to complete another short questionnaire to provide feedback about the program. At this time you will be asked again to go to the DGMC clinical laboratory within 1 week of the visit to obtain fasting blood work for a cholesterol panel and hemoglobin A1C. This will complete your participation in this study.

FIP GROUP

Visit 1: A research study coordinator will explain the study in detail, obtain your written consent to participate, ask you to complete four short questionnaires, and obtain your weight and abdominal circumference measurement. The questionnaires consist of demographic questions such as age, gender, race, rank, unit, years of service, presence of any chronic medical conditions, and use of any regular medications. The second questionnaire, called the RAND SF-36, consists of 36 short questions that ask you to rank your overall physical and mental health, ability to complete daily work and social tasks, and the amount of pain, fatigue and energy you had over the past 4 weeks. The third questionnaire consists of 3 short questions about your typical physical activity in the past 4 weeks. The fourth questionnaire consists of eight questions about the amount of time you spend doing physical activities during work and leisure time. Lastly, the research coordinator will ask you to go to the DGMC clinical laboratory after fasting for 12 hours to have blood work done to check your cholesterol panel and your hemoglobin A1C (a measure of glucose metabolism). The lab will collect tubes of blood which equals about two tablespoons of blood, for research purposes only, however the results from the blood tests will become part of your medical record. These blood tests are the same type of tests you might have during a routine physical exam. Females will be asked to provide a urine sample for a pregnancy test.

You will be asked to complete the on-line FIP on your own, within 4 weeks of visit 1. You will need to print the certificate of completion to give to the research coordinator on or before visit 2.

Visit 2: This visit will be scheduled within 12-14 weeks after Visit 1. You will meet with a research study coordinator who will again obtain your weight and abdominal circumference measurement, ask you to complete

the RAND SF-36 questionnaire and the physical activity questionnaire. The research coordinator will ask you to provide a copy of FIP certificate of completion.

Visit 3: This visit will be scheduled within 6 months of starting the FIP program with a research study coordinator who will again obtain your weight and abdominal circumference measurement, ask you to complete the RAND SF-36 questionnaire, the physical activity questionnaire, and the Modifiable Activity Questionnaire. In addition the study coordinator will ask you to complete a short questionnaire to provide feedback about the program. At this time you will be asked again to go to the DGMC laboratory within 1 week of the visit to obtain fasting blood work for a cholesterol panel and hemoglobin A1C. This will complete your participation in this study.

BBBL GROUP

Visit 1: A research study coordinator will explain the study in detail, obtain your written consent to participate, ask you to complete four short questionnaires, and obtain your weight and abdominal circumference measurement. The questionnaires consist of demographic questions such as age, gender, race, rank, unit, years of service, presence of any chronic medical conditions, and use of any regular medications. The second questionnaire, called the RAND SF-36, consists of 36 short questions that ask you to rank your overall physical and mental health, ability to complete daily work and social tasks, and the amount of pain, fatigue and energy you had over the past 4 weeks. The third questionnaire consists of 3 short questions about your typical physical activity in the past 4 weeks. The fourth questionnaire consists of eight questions about the amount of time you spend doing physical activities during work and leisure time. Lastly, the research coordinator will ask you to go to the DGMC laboratory after fasting for 12 hours to have blood work done to check your cholesterol panel and your hemoglobin A1C (a measure of glucose metabolism). The lab will collect tubes of blood which equals about two tablespoons of blood, for research purposes only, however the results from the blood tests will become part of your medical record. These blood tests are the same type of tests you might have during a routine physical exam. Females will be asked to provide a urine sample for a pregnancy test.

Visits 2-6: These visits will be with a trained BBBL instructor. The BBBL class is a group class for military beneficiaries during which you will be weighed and given instruction on how to make changes to your eating and exercise habits in order to lose weight and eat a healthy diet. The class takes place for two hours each week for five weeks.

Visit 7: This visit will be scheduled within 12-14 weeks after Visit 1 with a research study coordinator who will again obtain your weight and abdominal circumference measurement, ask you to complete the RAND SF-36 questionnaire and the physical activity questionnaire.

Visit 8: This visit will be scheduled within 6 months of starting the BBBL program with a research study coordinator who will again obtain your weight and abdominal circumference measurement, ask you to complete the RAND SF-36 questionnaire, the physical activity questionnaire, and the Modifiable Activity Questionnaire. In addition the study coordinator will ask you to complete a short questionnaire to provide feedback about the program. The research coordinator will again ask you to go to the DGMC laboratory within 1 week of the visit

to obtain fasting blood work for a cholesterol panel and hemoglobin A1C. This will complete your participation in this study.

Any lab results obtained for the purposes of this study that are abnormal will be reported to you and to your Primary Care Manager.

RISKS/INCONVENIENCES

Risks of blood draw: Approximately 2-3 teaspoons of blood will be taken from your arm intravenously (IV). You may experience mild pain and swelling where the needle enters the skin and vein, bruising, infection and possible fainting.

Risks of loss of confidentiality: There is always a small risk that information from your data could be leaked. To minimize this risk, all information collected for the research study will be kept in locked cabinets in locked offices or on intranet directories that are CAC and password protected and only the researchers will have access to the information. In addition, your information will be de-identified prior to data analysis. Lastly your personally identifiable information will not be released unless required by law and will not be used in any published reports or papers resulting from this research.

Risks of GLB, FIP and BBBL interventions:
The GLB intervention involves learning about changing eating habits which should not cause harm and may benefit you. The GLB intervention also involves doing physical activity up to 150 minutes per week. This activity will be at a level no more than what is typically required for unit physical training. The GLB intervention does require attending 16 1-hour classes over the course of 6 months which could cause a minor inconvenience.

There are minimal risks to the FIP intervention as it provides information only and is an intervention that is already available to Airmen to take on their own.

The BBBL is an in-person class that provides information about nutrition, exercise and healthy behaviors. It does require attending five weekly 2-hour classes which could cause a minor inconvenience.

If you are pregnant or breastfeeding, this treatment will not be offered. If it is possible that you may be pregnant, a pregnancy test will be performed. If you are sexually active, you should take precautions to avoid the possibility of becoming pregnant. You are advised to use an effective contraceptive method including abstinence, since it is not known how the GLB or FIP interventions could affect a pregnancy. If you become pregnant or feel you might be pregnant, contact your provider and the study investigator.

Risk of Incidental Findings
There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

The research team will be obtaining blood work to measure your lipids (cholesterol) and HbA1c (measure of glucose metabolism). A qualified person will review these results just as it would be if you were having these procedures as part of your routine medical care. If the results were found to be abnormal, this would be an incidental finding.

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you of the condition at the point it is detected.

You do not have an option to decline information about an incidental finding.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. As a TRICARE beneficiary, you will have access to care through standard TRICARE providers

BENEFITS
You may or may not benefit directly from this study. Potential direct benefits are that you may experience weight loss and a reduction in risk of chronic disease. However, there is no guarantee that you will benefit from this study. The primary benefit will be to increase the general understanding of how the GLB class may help improve the health and well-being of active duty personnel.

COSTS
The medical care received during this research is free of charge to Department of Defense Health care beneficiaries. There are no associated costs to participate in this study.

PAYMENT
You will receive a $20 gift card after the initial blood draw and a $50 gift card after the second blood draw. You will not receive any other compensation for participating in this study.

ALTERNATIVES
Choosing not to participate is an alternative to participating in this study. You may speak with your provider about alternative treatments available.

If you are in the military and are on active duty, you must have your supervisor's approval to participate in this study due to the potential to miss duty time.

EVENT OF INJURY

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations. If you have questions about your rights or if you believe you have received a research-related injury, you may contact the Director of the Clinical Investigation Facility Lt Col Leonardo Tato at **(707) 423-7400** the Patient Advocate at **(707) 423-2388**, or the study investigator, Dr. Mary Nelson, at **(707) 424-0058.**

It is important that you tell your study investigator, Dr. Mary Nelson, if you feel that you have been injured because of taking part in this study. You can tell the study investigator in person or call her at (707) 424-0058.

OCCURRENCE OF UNANTICIPATED ADVERSE EVENT

If an unanticipated event occurs during your participation in this study, you will be informed immediately. If you are not competent at the time to understand the nature of the event, such information will be brought to the attention of your next of kin, or your medical agent who has legal authority to make medical decisions on your behalf. If you wish to specify a medical agent, you should provide a medical power of attorney, a document which appoints an agent. Contact the Office of the Medical Law Consultant at 707-423-7836 if you have questions about a medical power of attorney.

WITHDRAWAL

The study investigator may decide to withdraw you from the study if he or she believes it is in your best interest. You may also withdraw at any time without penalty or loss of benefits. If you decide to discontinue the study, contact the Primary Investigator or your provider for instructions on how to do so safely. Your data will be kept for analysis after withdrawal.

PRIVACY AND CONFIDENTIALITY

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Data collected will be kept on a government computer assigned to the PI in a locked Clinical Investigation Facility office. The computer is password/CAC-card protected, and the system is firewalled protected. There are no planned linkages with external databases. Any data transmitted for collaborative will be de-identified and encrypted prior to transmission. Following completion of the study the data will be stored and destroyed in compliance with policies implemented by the DGMC Institutional Review Board.
Upon the close of the study all records will be transferred to the Clinical Investigations Facility for storage for at least six years.

Note: Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), the Air Force, the DoD, the David Grant Medical Center Institutional Review Board, the Uniformed Services University of the Health Sciences, Bethesda, MD and other Federal agencies that provide oversight for human subject protection.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Records of your participation in this study may only be disclosed according to Federal law, including the Federal Privacy Act, 5 U.S.C. 552a; the Health Insurance Portability and Accountability Act (HIPAA); and the Freedom of Information Act, 5 U.S.C. Sec 522, and their applicable regulations.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

DECISION TO PARTICIPATE

The decision to participate in this study is completely voluntary on your part. Refusal to participate in the research study will involve no penalty or loss of benefits. No one has coerced or intimidated you into participating in this program. You are participating because you want to. Your investigator(s) has adequately answered any and all questions you have about this study, your participation, and the procedures involved. You understand that the investigator will be available to answer any questions concerning procedures throughout this study. You understand that if significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed. You further understand that you may withdraw this consent at any time and discontinue further participation in this study without prejudice to your entitlement to care. You also understand that the investigator of this study may terminate your participation in this study at any time if the investigator feels this to be in your best interest. You will be provided a copy of this consent form. Your signature below indicates your willingness to participate in this research study and serves as your consent to release your protected health information.

CONSENT FOR ADULT PARTICIPANTS

Research Participant:
I have read this consent form and have been given the chance to ask questions. I agree to participate in the research described above, entitled: Effectiveness of GLB class in an AD Population

Printed Name: _____

Signature: _____ Date: _____

Principal Investigator (or Associate Investigator, or IRB-Approved Study Coordinator):
I have given this research participant (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The participant has indicated that he or she understands the nature of the study and the risks and benefits of participating, and consents to participate.

Printed Name: _____

Signature: _____ Date: _____