

Protocol Number:

Approval Date:

Expiration Date:

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY

- 1. WHO IS DOING THE STUDY?**
- 2. WHAT IS THE PURPOSE OF THE STUDY?**
- 3. WHAT WILL YOU BE ASKED TO DO?**
- 4. WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?**
- 5. WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**
- 6. WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?**
- 7. DO YOU HAVE TO TAKE PART IN THE STUDY?**
- 8. CAN YOUR TAKING PART IN THE STUDY END EARLY?**
- 9. IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**
- 10. WILL YOU RECEIVE ANY REWARDS OR PAYMENT FOR TAKING PART IN THIS STUDY?**
- 11. WHO WILL SEE THE INFORMATION THAT YOU GIVE?**
- 12. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS OR COMPLAINTS?**

My signature below indicates my willingness to participate in this research study.

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Participant printed name

Participant signature

Date

Advising Investigator printed name

Advising Investigator Signature

Date

I witnessed the participant's signature to this document.

Witness printed name

Witness Signature

Date

ADDITIONAL SECTIONS THAT CAN BE ADDED AS NECESSARY

13. WHAT IF WE LEARN ABOUT MORE RISKS OR PROBLEMS AFTER YOU AGREE TO TAKE PART IN THE STUDY?

14. WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

15. ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

16. WHAT WILL IT COST YOU TO PARTICIPATE?

**17. FOR RESEARCH INVOLVING MORE THAN MINIMAL RISK:
WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?**

Section-by-Section Investigator Instructions for Developing an Informed Consent Document

1. WHO IS DOING THIS STUDY?

- a. Include the name, department, organization and telephone number of the Principal Investigator (PI).
- b. Include information for a medical monitor if one is required.
- c. Do not list ranks/grades of investigators; Dr. or PhD is acceptable.

2. WHAT IS THE PURPOSE OF THE STUDY?

Describe the purpose of your study in terms easy for your subjects to understand. Use simple terms and short sentences.

3. WHAT WILL YOU BE ASKED TO DO?

- a. Tell the subject what to expect in second person (i.e., you will...).
- b. Describe all procedures in terms easy for your subjects to understand. Use simple terms and short sentences. If the study involves numerous procedures and/or visits, give a time-line description of the procedures that will be performed.
- c. Answer the following questions for the subject: What is being performed as part of the research? If applicable, explain what is being performed as part of the care of services the subject would normally receive, making clear that these are not part of the research. Any procedures that are experimental must be clearly identified.
- d. Prepare a time-line chart of schema to accompany descriptions of procedures and tests for studies that require more than 1 or 2 steps/visits.
- e. Include the total number of subjects expected to participate, please include the following template language:

If you volunteer to take part in this study, you will be one of about _____ people to do so.

- f. If you are grouping subjects randomly, please include the following template language:

As a participant, you will be assigned to one of _____ (number) groups described above by a process similar to flipping a coin. You will have a(n) _____ (equal, 1 in 2, etc.) chance of being assigned to any of the groups.

4. WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

Please use the following template language:

You will need to come to _____ (state the site where the research will be conducted, including the room) _____ (number) times during the study. Each of those visits will take about _____ (state in minutes or hours). The total amount of time you will be asked to volunteer for this study is _____ over the next _____ (state in days, months or years).

5. WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

a. If the research involves minimal risk to the subject, include the following template language:

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

b. If the research involves any procedures which could cause possible physical harm, describe in terms easy for your subjects to understand, both the risks and any ramifications that could result should an unanticipated problem or adverse event occur. Use simple terms and short sentences. Make some estimate of the frequency or severity of the risk, if known. Add the following template language:

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

c. If the research involves any procedures which could cause possible emotional or mental harm include the following template language:

You may find some questions we ask you (or some procedures we ask you to do) to be upsetting or stressful. If the researcher is prepared to offer referrals to appropriate support services add: If so, we can tell you about some people who may be able to help you with these feelings.

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

6. WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

a. Include only benefits where the research participant will personally gain something from the study itself (e.g., a possible cure to a disease or body fat test that costs money at a gym). If the benefit is available without participating in the study, state how and where it can be obtained (e.g., submerged body fat measurements can be obtained at Gold's Gym for an average cost of ...)

b. If there are no benefits please use the following template language:

You will not receive any personal benefit from participating in this study.

7. DO YOU HAVE TO TAKE PART IN THE STUDY?

Please use the following template language:

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. Your choice to participate will not affect your military or Air Force Academy career.

8. CAN YOUR TAKING PART IN THE STUDY END EARLY?

a. Please use the following template language:

If you decide to take part in the study, you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

b. If appropriate please use the following template language:

The individuals conducting the study may need to withdraw you from the study. This may occur (1) if you are not able to follow the directions they give you, (2) if they find that your being in the study is more risk than benefit to you, or (3) if the agency funding the study decides to stop the study early for a variety of scientific reasons.

c. Information regarding any consequences of withdrawing (e.g., reduced extra-credit points) should be included along with any procedures necessary for withdrawing.

9. IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

a. Please use the following template language:

Choosing not to participate is an alternative to participating in this study. There are no alternative procedures that would be advantageous to you.

b. If you are using the DFBL Participant Pool, you **must** replace the second sentence above with the following statement:

Your course syllabus or instructor will have information on how to receive extra credit without taking part in a research study.

OR

If you do not want to take part in the study, there are other choices such as _____ . (Describe what other procedures the subject could participate in to receive the same level of benefit or receive the same reward).

10. WILL YOU RECEIVE ANY REWARDS OR PAYMENT FOR TAKING PART IN THIS STUDY?

Please use the following template language:

You will receive _____ for taking part in this study. (Insert what the subject will receive. If this is payment, explain how it will be pro-rated should the subject choose to

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withdraw early. If using the DFBL Participant Pool, insert: *extra-credit points in your BS110/310 course as it is stated in your syllabus.*

OR

You will not receive any rewards or payment for taking part in the study.

11. WHO WILL SEE THE INFORMATION THAT YOU GIVE?

a. If the study is anonymous, please use the following template language: *There can be absolutely no link to identifiers anywhere, including any code lists)*

This study is anonymous. That means that no one, not even members of the research team, will know that the information you give came from you.

b. If the study is not anonymous, please use the following template language:

We will make every effort to keep confidential all research records that identify you to the extent allowed by law. However, 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 information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

Include a clear statement as to what will be done with the identifiable information about the participant: who will have access to such information, how will it be stored, how long will it be maintained.

If the study involves the collection of photographs, videos, or audiotapes, describe how confidentiality of the subject will be maintained.

If this is a multisite study, include names of institutions that will have access to the data.

c. Please use the following template language for all studies:

USAF Surgeon General's Research Oversight and Compliance Division (AFMSA/SGE-C) and other DoD personnel may inspect your study records.

12. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS OR COMPLAINTS?

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Please use the following template language:

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, PI name at PI contact information. If you have questions about your rights as a volunteer in this research or believe you were harmed as a result of participation, contact the USAFA IRB Administrator between the hours of 7:30 am and 3pm at 719.333.6593 or usafa.irb@usafa.edu. We will give you a signed copy of this consent form to take with you.

ADDITIONAL SECTIONS THAT CAN BE ADDED AS NECESSARY

13. WHAT IF WE LEARN ABOUT MORE RISKS OR PROBLEMS AFTER YOU AGREE TO TAKE PART IN THE STUDY?

Please use the following template language:

If more risks are found or problems occur while you are taking part in the study, you will be informed immediately. Add if appropriate: 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.

14. WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

If there is a condition or circumstance that makes the person eligible for the study and others not, please use the following template language and specify the requirement (e.g., you are a rated pilot):

You are being invited to take part in this research study because _____

15. ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

State in basic lay language reasons a subject could be excluded from volunteering (e.g., being a smoker, being under 18 years of age, being pregnant, etc.) Include only those events/conditions which would not be pre-determined by a screening procedure. Include those events/conditions of which the potential subject would ordinarily be aware.

16. WHAT WILL IT COST YOU TO PARTICIPATE?

Describe any costs the subject may incur as a result of participating in the study (e.g., you may have to pay for the cost of getting to the study site and a parking fee.)

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**FOR RESEARCH INVOLVING MORE THAN MINIMAL RISK:
17. WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?**

Please use the following template language:

If you believe you are hurt or if you get sick because of something that is due to the study, you should call (insert PI and/or medical monitor name) at (insert PI and/or medical monitor contact information) immediately. For contact information, provide a dedicated pager or cell phone number or other reliable 24-hour contact option.

(insert PI and/or medical monitor name) will determine what type of treatment, if any, that is best for you at that time.

It is important for you to understand that USAFA does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, USAFA will not pay for any wages you may lose if you are harmed by this study. Medical costs that result will be your responsibility or may be paid by your insurer if you are insured by a health insurance company and all deductibles and co-payments will be your responsibility.