

Consent to Participate in a Research Study

TITLE OF STUDY

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

You are being invited to take part in a research study about _____. You are being invited to take part in this research study because _____ (If there is a condition or circumstance that makes the person eligible for the study, specify this information. This statement may not be applicable for some social science studies.). If you volunteer to take part in this study, you will be one of about _____ people to do so. (If applicable, you may add "...one of about _____ people to do so nationally, and one of _____ at the University of Memphis".)

WHO IS DOING THE STUDY?

The person in charge of this study is _____ (Lead Investigator, LI) of Southwest Tennessee Community College Department of _____ (list department) (If the LI is a student, add the following sentence: He/She is being guided in this research by _____ [Advisor].) There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

Describe, in lay terms, the purpose of the study.

By doing this study, we hope to learn _____.

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, such as 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 review of records or by the decision of an attending physician. Include those events/conditions of which the potential subject would ordinarily be aware.

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

The research procedures will be conducted at _____ (state the general facility such as the UM Psychological Services Center, Memphis City Schools, etc.). You will need to come to _____ (state the site where the research will be conducted, including the room if possible) XXX times during the study. Each of those visits will take about XXX (state in minutes or hours). The total amount of time you will be asked to volunteer for this study is XXX over the next XXX (state in days, months or years).

WHAT WILL YOU BE ASKED TO DO?

Tell the subject what to expect. Describe all procedures in lay language, using 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.

Answer the following questions for the subject: What is being performed as part of the research? If applicable, what is being performed as part of the care or services the subject would normally receive? Any procedures that are experimental must be clearly identified.

Prepare a time-line chart or schema to accompany descriptions of procedures and tests for studies that require more than 1 or 2 steps/visits.

Provide a lay description of the randomization procedures, if applicable, and describe the chances of being assigned to any one group. Define randomization in simple language such as "by chance."

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

If the research involves minimal risk to the subject, include the following statement:

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.

If the research involves any procedures which could cause possible physical harm, describe the risks in lay terms and any ramifications that could result should an unanticipated problem or adverse event occur.

If the research involves any procedures which could cause possible emotional or mental harm, include the following statement:

You may find some questions we ask you (or some procedures we ask you to do) to be upsetting or stressful. 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.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. However, some people have experienced _____ when _____. Your willingness to take part, however, may, in the future, help society as a whole better understand this research topic.

OR

You will not get any personal benefit from taking part in this study.

DO YOU HAVE TO TAKE PART IN THE STUDY?

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. (Add the following, if applicable: If you decide not to take part in this study, your decision will have no effect on the quality of care, services, etc., you receive). Add the following for student volunteers: As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or grade in the class.

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

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

OR

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study.

OR

(Describe any costs the subject may incur as a result of participating in the study. For example: You may have to pay for the cost of getting to the study site and a parking fee.)

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive _____ for taking part in this study. (If this is a monetary reward/payment, explain how this will be pro-rated should the subject choose to withdraw early. If this is not a cash payment then the IRB strongly suggests that the reward be given to the subjects regardless of the completion of the study. This information should be explained here.) (If applicable, provide a statement: if you earn \$600 or above by participating in research, it is potentially reportable for tax purposes).

OR

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

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep private all research records that identify you to the extent allowed by law.

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. *(If you are collecting social security numbers, inform subjects of this fact. Tell subjects whether they can withhold their social security number and still participate.)*

[IF THE STUDY IS ANONYMOUS:] *(There can be absolutely no link to identifiers anywhere, nor any code lists)*

(If data is going to be collected and/or stored electronically, please provide Confidentiality and Data Security for Electronic Data procedures.)

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.

[IF THE STUDY IS NOT ANONYMOUS:]

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. *(Insert description of procedure(s) used for protecting confidentiality of data including paper records, computer records, jump drives and portable storage device)*

We will keep private all research records that identify you to the extent allowed by law. However, there are some circumstances in which we may have to show your information to other people. *(Insert circumstances in which the subject's data could be shown or reported to others)* For example, the law may require us to show your information to a court [IF APPLICABLE: or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else. Also, we may be required to show information which identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as the Southwest Tennessee Community College [LIST ANY OTHER AGENCIES SUCH AS THE FUNDING AGENCY OR STAT/FEDERAL DEPT.].

CAN YOUR TAKING PART IN THE STUDY END EARLY?

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.

The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons. *(Any consequences of withdrawing should be included along with any procedures necessary for withdrawing.)*

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

(This section may not be applicable to social/ behavioral studies; if not applicable omit this section)

(Include this information if participating in other studies could put your subject at risk)

You may/may not (please indicate choice) take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

(This section may not be applicable to social/ behavioral studies that are less than minimal risk. For less than minimal risk studies, that are not applicable, omit this section)

If you believe you are hurt or if you get sick because of something that is due to the study, you should call _____ (LI's or medical supervisor's name) at _____ immediately. [For **greater than minimal risk** research add information for one (or a combination) of the following as a contact for subjects to use in case of illness or injury during his/her participation in the study:

1. a dedicated pager number;

2. a dedicated cell phone number;
3. other reliable 24-hour contact option at your discretion, and/or
4. as deemed necessary, in addition to one or more of the above, referral to 911 for an emergency.]

_____ (LI's or medical supervisor's 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 the Southwest Tennessee Community College 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, the Southwest Tennessee Community College will not pay for any wages you may lose if you are harmed by this study.

Medical costs that result from research related harm cannot be included as regular medical costs. Therefore, the medical costs related to your care and treatment because of research related harm *(add study specific language by selecting appropriate options... e.g.),*

will be your responsibility; **or**

will be paid by the sponsor *(only option if industry sponsored and industry trial) (insert sponsor's name here)* has agreed to pay for medical expenses incurred by treating injuries that directly result from participating in the study, with some exceptions. The exceptions are instances such as your failure to follow the sponsor's directions or the investigator's failure to follow the sponsor's directions. **or**

may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); **or**

may be paid by Medicare or Medicaid if you are covered by Medicare, or Medicaid (if you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.

A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be substantial.

You do not give up your legal rights by signing this form.

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

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, _____ at _____. If you have any questions about your rights as a volunteer in this research, contact the Institutional Review Board staff at the Southwest Tennessee Community College effectivness@southwest.tn.edu We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

(This section may not be applicable to social/ behavioral studies that have a one-time single interaction such as a survey completion, if not applicable omit this section)

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

What happens to my privacy if I participate in a focus group?

(Make it clear to focus group participants that it is important that they each keep what is said in the focus group setting private. Also, caution subjects that as the investigator you cannot ensure that participants will keep what is said private.)

What happens to my privacy if I am interviewed?

(In this section explain make it clear to subjects whether identifying information will be associated with their responses or if responses will be separated from identifying information i.e. using code numbers or pseudonyms.)

WHAT ELSE DO YOU NEED TO KNOW?

Disclose what institution(s) (such as NIH, NCI, etc.) or companies are involved in the study through funding, cooperative research, or by providing supplies or equipment. An example of such a statement would be as follows:

_____ (name of institution/company) is providing financial support and/or material for this study.

Note, if the IRB determines that disclosure of financial interest is necessary to protect the subjects' rights and welfare, you may be asked to include a statement which informs subjects of the investigator's financial interests in the study (i.e., the source of funding and funding arrangements for the conduct and review of the research, or information about a financial arrangement of the investigator and how it is being managed).

(When developing the consent form, please format to ensure the signature lines fall on a page containing text.)

Signature of person agreeing to take part in the study

Date

Printed name of person agreeing to take part in the study

Name of [authorized] person obtaining informed consent

Date

Institutional Review Board

Office of Institutional Effectiveness

Parrish Building, Suite 231

737 Union Avenue

Memphis, TN 38103

Email: effectivness@southwest.tn.edu