

SOUTHWEST

TENNESSEE COMMUNITY COLLEGE

Parental Permission for Your Child to Participate in a Research Study

TITLE OF STUDY

WHY IS YOUR CHILD BEING INVITED TO TAKE PART IN THIS RESEARCH?

Your child is being invited to take part in a research study about _____. Your child is 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 your child takes part in this study, your child will be one of about _____ children to do so. (If applicable, your child may add "...one of about _____ children to do so nationally, and one of _____ at the Southwest Tennessee Community College".)

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 YOUR CHILD 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.). Your child 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 your child will be asked to volunteer for this study is XXX over the next XXX (state in days, months or years).

WHAT WILL YOUR CHILD BE ASKED TO DO?

Tell the parent 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.

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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 your child will be doing have no more risk of harm than your child 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:

Your child may find some questions we ask your child (or some procedures we ask your child to do) to be upsetting or stressful. If so, we can tell your child about some people who may be able to help your child with these feelings.

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

WILL YOUR CHILD BENEFIT FROM TAKING PART IN THIS STUDY?

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

OR

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

DOES YOUR CHILD HAVE TO TAKE PART IN THE STUDY?

If you decide to allow your child take part in the study, it should be because your child really wants to volunteer. Your child will not lose any benefits or rights your child would normally have if your child chooses not to volunteer. Your child can stop at any time during the study and still keep the benefits and rights your child had before volunteering. *(Add the following, if applicable: If you or your child decides not to take part in this study, your child's decision will have no effect on the quality of care, services, etc., your child receives). Add the following for student volunteers: As a student, if your child decides not to take part in this study, your child's choice will have no effect on your child's academic status or grade in the class.*

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

If your child does 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 your child does 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 FOR YOUR CHILD 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: Your child may have to pay for the cost of getting to the study site and a parking fee.)

WILL YOUR CHILD RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

Your child 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 your child earns \$600 or above by participating in research, it is potentially reportable for tax purposes).*

OR

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

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WHO WILL SEE THE INFORMATION THAT YOUR CHILD PROVIDES?

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

Your child's information will be combined with information from other children 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. Your child will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your child's 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 your child give came from your child.

[IF THE STUDY IS NOT ANONYMOUS:]

We will make every effort to prevent anyone who is not on the research team from knowing that your child 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 your child to the extent allowed by law. However, there are some circumstances in which we may have to show your child's 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 child's information to a court [IF APPLICABLE: or to tell authorities if your child report information about a child being abused or if your child pose a danger to your child or someone else. Also, we may be required to show information which identifies your child 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 CHILD'S TAKING PART IN THE STUDY END EARLY?

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

The individuals conducting the study may need to withdraw your child from the study. This may occur if your child are not able to follow the directions they give your child, if they find that your child's being in the study is more risk than benefit to your child, 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 YOUR CHILD PARTICIPATING OR CAN YOUR CHILD 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 child's subject at risk)

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

WHAT HAPPENS IF YOUR CHILD 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 your child believe your child is hurt or if your child gets sick because of something that is due to the study, your child should call _____ (LI's or medical supervisor's name) at _____ immediately. [For **greater than**

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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 child's 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, is best for your child at that time.

It is important for your child 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 your child get hurt or sick while taking part in this study. Also, the Southwest Tennessee Community College will not pay for any wages your child may lose if your child 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 child's care and treatment because of research related harm (*add study specific language by selecting appropriate options... e.g.*), will be you 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 child's failure to follow the sponsor's directions or the investigator's failure to follow the sponsor's directions. **or**

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

may be paid by Medicare or Medicaid if your child 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 child's insurer or Medicare/Medicaid even if your child's insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be substantial.

Your child does not give up your child's legal rights by signing this form.

WHAT IF YOUR CHILD HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation for your child 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 child's 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 permission form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR CHILD'S 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 for your child to stay in this study, the information will be provided to you. You may be asked to sign a new permission form if the information is provided to you after your child has joined the study.

WHAT ELSE DOES YOUR CHILD 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.*)

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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

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