

20. APPENDICES

Appendix 1: Sample informed consent form for parents or guardians

<Letterhead>

INFORMED CONSENT FORM FOR PARENTS OR GUARDIANS

Dear Parent or Guardian:

Name of Middle School is involved in a research study with the Name of University. The name of the study is *Trial of Activity for Adolescent Girls (TAAG)*, and it is funded by the National Institutes of Health. Only girls who are in 8th grade during the 2004-05 year can be involved in the TAAG measurement activities. We would like your daughter to take part in the TAAG measures. This consent form explains what is involved. Please read it closely and ask any questions that you have before you decide to let your daughter take part.

PURPOSE OF THE PROJECT:

The major purpose of the TAAG project is to study the physical activity levels of girls in middle school and other items that may relate to children's health. We will do this by asking students to complete the measures described in the next section. As part of the study, we will also look at whether girls who have physical activity opportunities located near their home are more physically active than girls with fewer opportunities.

WHAT IS INVOLVED?:

Your daughter will be asked to complete the measures listed below during the spring semester of her 8th grade year. She would complete these measures during three or four classes at her school. Should other times be needed before or after school, these details would be worked out to meet her schedule.

Students involved in the measures will:

1. Wear a small activity monitor all day for seven days in a row. The activity monitor will measure only your daughter's physical activity levels. A picture of the activity monitor is attached.
2. Fill out a survey to report what physical activities she did during the last three days.
3. Fill out surveys that will measure factors related to her physical activity or exercise.
4. Have height, weight, and body fat measured.
5. Ride a stationary bike for about 10 minutes. This may be scheduled to take place outside of school hours.
6. Respond to questions about any serious injuries that may have occurred during the last three months.

REASONS WHY YOUR CHILD MAY NOT BE ALLOWED TO BE INVOLVED:

Your child should not take part in the measures listed above if she:

- Cannot read and understand the questions on the survey, which will be written in English.
- Has a physical or medical condition that might cause health problems during the bike test. These conditions are listed on the last page of this consent form.

Also, some medications may conflict with the value of the bike test. Your child may not be allowed to take part in the bike test if she is taking any of these medications.

EXPECTED RISKS AND DISCOMFORTS:

The bike test involves moderate exercise and minimal risk for healthy girls (i.e., no greater than those that would occur during physical education classes). The activity monitor will be attached to an elastic belt and worn around the waist over your daughter's clothing (see attached picture). The small size of the activity monitor makes it highly unlikely that your child will feel any discomfort when wearing it. We will ask questions that deal with sensitive health issues, such as smoking. Some students may not feel at ease answering these types of questions. In the unlikely event that a medical emergency occurs during the measures, we will follow routine school procedures.

EXPECTED BENEFITS:

The results of the TAAG study will advance our knowledge of physical activity levels of middle school girls.

COMPENSATION:

Your daughter will receive a small gift for returning the consent form even if she decides not to take part in the measures. Each girl who participates in the measures will also receive a small gift valued at about \$_____.

VOLUNTARY PARTICIPATION:

Whether your daughter takes part in the measures is your choice. Also, your daughter may choose not to take part in any or all of the measures at any time or for any reason. If after giving your consent, you decide to withdraw your daughter from the study, this will not hurt your future relations with the Name of University or your daughter's school.

CONFIDENTIALITY:

During the study, all of your daughter's data, including address and phone number, will be kept private and will not be shared with others outside the TAAG study. All data will be stored safely in locked files. A number will be assigned to each child at the start of the study and this number will be used for record keeping and data analysis. Please note that we are required to inform you, in writing, if your daughter's height or body weight falls below the growth standards for girls her age. Also, if your daughter reports having a serious injury related to physical activity, a member of our research staff may call you if more information is needed. For these reasons, it is very important that you provide your mailing address and phone number on the last page of the consent form. After the study is completed, the data will be available to other researchers. However, we will never share any information that could be linked to your daughter. Your daughter's name will never appear in any reports or published papers.

CONTACT PERSONS FOR QUESTIONS YOU MAY HAVE ABOUT THE RESEARCH STUDY:

You may ask questions about the study or anything you do not understand. If you do not have questions now, you may ask later. During the study, you will be told any new facts that could affect whether you want your child to stay in the study. For more information about the research, you may contact Name, Project/Measurement Coordinator, at Phone Number or E-mail; or Name, Principal Investigator, at Phone Number or E-mail.

Please complete and return this portion only.

Signing your name below means that you have read this consent form and have had a chance to ask any questions. Also, your daughter's signature on the attached *Child Assent Form* means that she has agreed to take part in the TAAG measures. If you agree to allow your daughter to be involved, you may change your mind and withdraw your consent at any time. As mentioned before, your daughter should not take part if she cannot read and understand the questions on the survey, which will be written in English.

- 1) **Will your child be able to read and understand questions written in English?** ☐ YES ☐ NO

Also, your daughter should not take part in the bike test if she has a physical or medical condition that might cause health problems during the test.

- 2) **Has a doctor told your daughter to avoid exercise for health reasons?** ☐ YES ☐ NO

- 3) **Does your child have any of the following conditions?** (We do not need to know which of these your child has.) ☐ YES ☐ NO

- Muscle, bone, or joint problems that limit her ability to ride a bike?
- Heart problem that requires a limit in physical activity?
- Fainting with exercise in the past 6 months?
- Uncontrolled asthma?
- Very high blood pressure that is not controlled on medication?
- Diabetes with frequent very low or very high blood glucose levels (sugars)?
- Thyroid problems not controlled on medication?
- Seizures not controlled on medication?
- Sickle cell disease, cystic fibrosis, anorexia nervosa, severe kidney problems, or severe liver problems?
- A blood condition that increases the risk of bleeding?

Finally, some medications may interfere with the value of the bike test. Your daughter may be excluded from the bike test if she is taking certain medications.

- 4) **Does your child take medication on a regular basis?** ☐ YES ☐ NO
If yes, please list medications here: _____

Please mark one of the choices below:

_____ **Yes**, I do consent to have my daughter to take part in all the measures.

_____ **No**, I do not consent to have my daughter take part in any of the measures.

Last
Name

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First
Name

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Telephone

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Relationship to
Child

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