

CHILDREN'S HOSPITAL AND REGIONAL MEDICAL CENTER
And
UNIVERSITY OF WASHINGTON, SEATTLE QUALITY OF LIFE GROUP
Seattle, Washington

Quality of Life of Overweight Youth: A Multicultural View

Questionnaire Consent Form for Participants 11 – 18 years of Age

Researchers:

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Researchers' Statement

Introduction

You are being asked to take part in a research study. Being in research is your choice and is always voluntary. Please take time to make your decision, and discuss it with family and friends.

This consent form provides a summary of the information the researchers will discuss with you. Be sure to ask any questions you have about the research study.

Why is this research study being done?

In our research study we want to learn how having a weight condition affects a person's life and the lives of their family members.

Youth and young adult's ages 11-18 that are average or above average weight are being asked to be in this study.

Are there benefits to taking part in the research study?

The things we learn in this research study will not help you. When we finish the study, we hope to know more about how affects the quality of young people's lives and their relationships with their families. We hope that what we learn will help children and families in the future.

How many people will take part in the research study?

About 360 youth and young adults will be in this part of the study.

What is involved in the research study?

If you are interested in participating in this study, you will meet with a person from the research group. The meeting will be at the University of Washington Seattle Quality of Life research office, Children's Hospital and Regional Medical Center, or a place that is better for you and the researcher. The meeting will be about 60 minutes long and will consist of participating in an interview. The meeting will be scheduled depending on what day and time is best for you and the researcher.

You will be asked to complete a questionnaire about your life and how you may be affected by being a certain weight. Some examples of questions that will be asked are: "During the past 4 weeks how often have any of your family members had serious arguments with one another?", "I feel depressed about how much I weigh", and "How much do you care about staying fit and exercising". You may skip any question you do not want to answer. The researcher will be there to answer your questions.

You will be asked to give personal information such as your age, if you are male or female, your weight, and your height, the last grade you completed in school, your ethnic or racial background, how much school your parents have had, and who you live with.

Also, we will measure your weight and height and waist circumference. To do this we will need you to remove shoes, heavy clothing and hair ornaments that may interfere with getting the most accurate measurement.

There is a possibility that you may be asked to complete a smaller portion of this questionnaire again a week after you have filled out the first questionnaire if we pull your name out of a hat. This will take about 30 minutes to complete. You would receive \$15.

The researchers can give you more information about other parts of the study. There are boxes to check at the end of this consent form so you can tell us if you would like to learn about the other parts of this research study.

What are the risks of taking part in this research study?

Some of the things that you might think about when answering questions might make you feel sad or angry. The researchers can talk to you about these feelings. You can also talk to someone you know and trust.

You will be asked sensitive questions that may inform us that you are depressed. You can contact one of the toll-free numbers below that is closest to you to receive free community mental health services:

- King County Crisis Line at 866-427-4747
- Yakima County Crisis Line at 800-572-8122

You may be uncomfortable talking about personal or private feelings. The researchers will not share your answers with other family members or with a person who is not on the research team.

What about confidentiality?

We will do everything we can to keep personal and medical information confidential. Information would be given out only if required by law. If results of this research are published or presented in a talk, information that identifies you will **not** be used.

The things you talk about will not be shared with your parents/guardians. The only reason the researchers would share what you talk about with your parents or regular physician would be if you were being abused or seriously considering harming yourself or someone else. In this case, the researchers would have to tell someone to protect you or another person from harm.

The research forms you fill out will be labeled with a unique research code number. The research forms will be stored separately from identifying information such as name, address, and phone number.

All personal information collected for research purposes will be kept in locked cabinets in the research office until one year after the project is finished. After this time, the link between the unique research code number on the forms and the identifying information will be destroyed. Unless you have given us permission to contact you again in the future, your identifying information will be erased from our research records. The non-identifiable questionnaires you fill out will be kept for five years after the end of the study before they are destroyed. The research information (data) will be stored permanently in a secure computer. Information that could identify or link you to this data will be destroyed before the data is stored in the computer. Dr. Tari Topolski will control the access to this stored data.

Research information (which does **not** identify you by name) will be shared with groups that support and run the research. The shared information will be kept confidential. These groups are:

1. The University of Washington, Seattle Quality of Life Group;
2. The University of California, Los Angeles, CA.

What are the costs of the research study?

None of the costs for the research will be billed to you or your insurance company. The sponsor of this research, the National Institute for Diabetes, Digestive, and Kidney Diseases, will pay for the costs of the study.

Will I be paid to take part in the study?

You will be paid \$20 for participating in this part of the study.

If you are selected to complete the smaller portion of the questionnaire you will be paid an additional \$15.

What are my rights and as a research participant?

Taking part in research is your choice. You may decide not to take part. If you do take part, you can stop being in the study at any time. If you stop being in the research study, all the personal information and links to personal information will be destroyed and the research data that was already collected will still be used for this study. If this happens, no one will be able to identify you by looking at the research data.

You can ask questions about the research now or at any time.

Whom do I call if I have questions or problems?

If you have any questions about the study please call:

Todd C. Edwards, PhD, Project Manager, Dept. of Health Services, (206) 685-4738

For questions about your rights as a research study participant, contact the Children’s Hospital and Regional Medical Center Institutional Review Board (IRB). The IRB is a group of people responsible for protecting the rights of children and families taking part in research. They may be reached at (206) 987-2023.

Signature of the Researcher Obtaining Consent

Date

Participant’s Statement

PLEASE CHECK ONE OF THE FOLLOWING to let us know if we may contact you about the other parts of this research study:

- Yes, I may be contacted to learn more about the other parts of this research study. Please initial _____**
- No, do not contact me about the other parts of this research study. Please initial _____**

The research study described above has been explained to me. I voluntarily agree to take part in this research study. I have had the chance to ask questions. I understand that the persons listed above will answer any future questions I have about the study or about research participants’ rights. I have received a copy of this consent form.

Signature of Participant

Date

Signature of Parent/Guardian (only if participant is 11-18)

Date

Copies to: Participant
 Researchers’ file