

Older youth assent and parental consent form

1. General Information About This Research Study

Study Title: "Immersion in Wellness at Iowa 4-H Center"

Name of Principal Investigator on This Study: Dr. Ruth Litchfield

Note to Parents:

The information in this form describes a research project that we are asking your child to take part in during his or her time at camp. The things your child will be asked to do are explained below, along with other important information about being a research participant. Please review this form carefully, and sign it if you agree that your child can take part in the study.

Your child also has an opportunity to choose whether or not to participate in the research. If your child is 16 or over, and able to read and understand the information in this form, please also ask that he or she read the form and sign it if they agree to take part in the study. A simplified version of this form is also included, which should be reviewed and signed by children who are under age 16.

A copy of the signed forms should be returned with the packet of camp materials. Please keep the second copy for your records.

A. Study Eligibility and Purpose

You are being asked to take part in this research study because we want to understand how immersion in a wellness program addressing diet and physical activity at camp helps children learn good nutrition and health practices and use these practices once they leave camp.

As you read this form describing the study, ask any questions you have. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you decide. You may stop participating at any time during the study, either at your request or your parent's. If so, none of your current benefits, normal health care, or camp experience will be affected in any way. When you feel comfortable that all your questions have been answered, and you wish to take part in this study, sign this form in order to begin your participation. Your signature means you have been told about the study and what the risks to you are. Your signature on this form also means that you want to take part in this study.

If you are unclear about anything along the way, please ask until you feel you understand.

B. Number of Participants

The plan is to have 150 people take part in this study at the Iowa 4-H Center Camp.

C. Additional Information You Should Know

Wellmark Blue Cross and Blue Shield and Iowa State University are funding this study. Any costs of the study will be paid for by Wellmark Blue Cross and Blue Shield and Iowa State University. Individual subject data will not be provided to Wellmark Blue Cross and Blue Shield, and all data collected for this study will be coded such that Wellmark Blue Cross and Blue Shield will not be able to associate any data to any subject.

2. What Will Happen to You While You Are in This Research Study?

If you agree for you to be in the study, you will be asked to participate in the following:

Screening (before camp)

You will complete the enrollment process at least two weeks before the study starts. Surveys to fill out and consent forms for you and your parents to sign will be included in the package of materials that must be returned before the beginning of camp. Demographic data will be collected from the health history and medical information forms (age, height, weight, physical restrictions, diet restrictions/allergies), which are required by the Iowa 4-H Center to attend camp. Before the beginning of camp you will be assigned to one of two groups. The first, or control group will be assigned to the standard camp experience. This camp will be conducted in the same manner as camps from the previous year. The second, or experimental group will attend camp that has been formatted to include a “Wellness Immersion” experience, where you will focus on concepts related to health and wellness through diet and physical activity.

Study protocol

Prior to the camp, at the end of the camp week, and six months after the camp you will be asked to complete surveys that will assess the home environment, your activity, and your knowledge of nutrition. If you are assigned to the control group, your camp experience will be similar to the experience of previous camps. If you are assigned to the experimental group, you will attend an immersion experience focusing on health and wellness. These will include modules on Nutrition Education, Gardening, Culinary Skills, Health Promoting Environments, and Physical Activity. During the camp, you will wear a small removable device on your ankle that will allow the investigators to determine the number of steps you have taken per minute throughout the week of camp.

3. How Long Will You Be in This Research Study?

You will be in this study for six months, including completing surveys before camp, the 1 week of camp and the follow-up surveys.

4. Why You Might Want To Take Part in This Research Study

This study will educate you about healthy eating habits and the knowledge necessary to have those habits in your life. You will also learn about foods and physical activity. You will participate in activities geared towards reinforcing the knowledge and healthy habits you may develop.

5. What Are the Risks of This Research Study?

You will not incur any risks greater than the minimal risks associated with attending summer camp. You will wear a small activity monitor on your ankle that may cause some minor discomfort.

6. What Other Choices Do You Have If You Don't Take Part in This Research Study?

You will gain a camp experience whether or not you are enrolled in this study. You do not have to enroll in this study to attend this summer camp.

7. Are there Reasons You Might Leave This Research Study Early?

Taking part in this research study is your decision. You may decide to stop at any time. You should tell the researcher if you or your parents decide to stop your participation.

In addition, the researchers or Iowa State University may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you do not follow the study rules,
- if the study is stopped.

8. Will You Need to Pay for Any of the Tests and Procedures?

You will not need to pay for any procedures which are done just for this research study. These procedures are:

- Completion of surveys
- Physical activity monitoring

However, your parents and/or your health plan will need to pay for all other tests and procedures that you would normally have as part of his/her regular clinical care.

9. Will You Be Paid for Participating in this Research Study?

If you complete this study, you will earn a scholarship that will be applied against camp costs. If you complete part of this study you will gain a partial scholarship as follows:

- \$25 scholarship for returning preliminary surveys/materials
- \$15 scholarship for completing surveys/materials at the end of the camp week
- \$25 scholarship for completing six-month follow-up surveys/materials

10. What Are Your Rights if You Are in This Research Study?

Taking part in this research study will not change your rights and benefits. Taking part in this research study does not give you any special privileges. If you decide to not participate in this study, or stop in the middle of the study, no benefits are taken away from you. Specifically, you do not have to be in this research study to receive or continue to receive medical care or to participate in the 4-H camp.

You and your parents will be told of important new findings or any changes in the study or procedures that may affect you or your willingness to continue in the study.

11. What About Your Privacy?

Your privacy is important to us, and we want to protect it as much as possible. This information might be in different places but we will only disclose information that is related to this research protocol for the purposes listed below.

This information will be given out for the proper monitoring of the study, checking the accuracy of study data, analyzing the study data, and other purposes necessary for the proper conduct and reporting of this study. If some of the information is reported in published medical journals or scientific discussions, it will be done in a way that does not directly identify you.

If this information is given out to anyone outside of Iowa State University, the information may no longer be protected by federal privacy regulations and may be given out by the person or entity that receives the information. However, Iowa State University will take steps to help other parties understand the need to keep this information confidential.

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, auditing departments of Iowa State University and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your child's records for quality assurance and data analysis. These records may contain private information.

Confidentiality of all records is strictly maintained by established procedures. The original study data are kept in the study facility and are entered into a computer by the primary investigator. Physical records are stored under lock and key and electronic records through security pass words. The primary investigator will review all data. Study records will not identify you by name, but using a number.

12. What Will Happen to Your Samples?

No samples or physical specimens will be taken during this study

13. What is the Institutional Review Board (IRB) and How Does it Protect You?

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have been treated unfairly.

- If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, Office of Responsible Research, (515) 294-3115, 1138 Pearson Hall, Ames, Iowa 50011.

14. Who Can Answer Your Questions?

Principal Investigator:
Dr. Ruth Litchfield
Phone: 515-294-9484

- Questions about the study tests and procedures
- Research-related injuries or emergencies
- Any research-related concerns or complaints

IRB Administrator

- Phone:515-294-4566
- Rights of a research subject
- Use of protected health information
- Any research-related concerns or complaints

15. Summary and Enrollment Signatures

You have been asked to take part in a research study, at Iowa State University. The information about this study has been provided to you and your parents to inform you about the nature of this IRB approved study. Please sign and date below to show that you agree to take part in the research. Please do not sign unless you have read the entire packet of information. If you do not want to sign, you don't have to, but you will not be able to participate in this study.

- Remember:
 - Joining the study is voluntary and you can still attend camp, even if you do not join the study.
 - Nobody will be mad if you choose not to join the study.
 - You can call the investigator and research staff at any time with any new questions or to tell them about side effects.

- You may stop being in the study at any time. Your parents may withdraw you from this study at any time.

(Date / Time)

(Printed Name of Participant)

(Signature of Participant)

(Date / Time)

(Printed Name of Parent/Guardian)

(Signature of Parent/Guardian)