**The Belmont Report**

Go to <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>to dissect the

article on Ethics in Research. Summarize the article under the following headings.

**▪** Ethical Principles and Guidelines for Research Involving Human Subjects

**▪** Boundaries Between Practice and Research

**▪** Basic Ethical Principles

**•** Respect for Persons

**•** Beneficence

**•** Justice

**▪** Applications

**•** Informed Consent

**○** Information

**○** Comprehension

**○** Voluntariness

**•** Assessment of Risk and Benefits

**○** The Nature and Scope of Risks and Benefits

**○** The Systematic Assessment of Risks and Benefits

**•** Selection of Subjects

**Informed Consent**

Informed consent is a legal procedure to ensure that a patient or client knows all of

the risks and costs involved in a treatment. The elements of informed consent include informing the potential participant of the nature of his or her involvement, possible alternatives to participation, and the potential risks and benefits of participation in the research.

What is the purpose of the NOURISH study?

What does participation in the study involve for children? What are youth participants being asked to do?

What information is being collected about or from the youth participants?

How is this information being protected or kept confidential?

How will youth participants benefit from being in the study?

Will anyone else other than the youth participants benefit from the results of the study?

Are there any risks due to participation? If yes, what are they?

Are the risks justified when you think about the potential benefits? Why, or why not?

Why are there two consents documents (e.g., parental consent form and youth assent form)? Do you think it is important that the parents and the child give their permission for the child to participate in the study?

**Student and Parent/Guardian Discussion**

**Benefits and Risks of Participation in NOURISH**

Note to Parents: The attached consent and assent forms are used strictly for educational purposes and your child in no way will be participating in this study described in this form as a result of this activity.

Student – What are two reasons for children/youth to participate in the study?

Reason #1

Reason #2

Parent – What are two reasons for parents to participate in the study?

Reason #1

Reason #2

Student – Why should you not participate?

Reason #1

Reason #2

Parent – Why should you or your child not participate?

Reason #1

Reason #2

Would you choose to participate in this study if applicable?

Student: Why or why not?

Parent: Why or why not?

Why is “informed consent” an important part of ethics in the research process?

**Sample Consent Form**

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: NOURISHing Families to Promote Healthy Eating and Exercise in Overweight

Children

This consent form may contain words that you do not understand. Please ask the study staff to explain any words that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purpose of this research study is to teach parents/caregivers skills that will help prevent and reduce the problems of obesity and eating disorders in children. You are invited to participate in this study because you have identified yourself as someone

who has a child between the ages of 5 and 11 with a Body Mass Index (BMI) > the 85th

percentile, which is considered overweight.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

In this study, you will have the opportunity to participate in one of two groups in which many issues that may concern you will be addressed. Parents in both groups will learn about ways of becoming more healthy. One group will meet for 1.5 hours weekly (over a 6-week period) with other parents in sessions led by NOURISH+ staff. They will also participate in two, 30-minute individual nutrition sessions during which they can discuss their families’ specific dietary challenges. Three weeks after the program’s completion, parents in this group will be contacted via phone to participate in a brief, personalized booster session. The other group will meet one time for a “Family Wellness Night” and will receive mailings about the healthy lifestyle behaviors at five different times over the course of nine weeks. This will allow us to see which group format is more effective at helping families make healthy lifestyle changes.

All group sessions will be videotaped. The purpose of taping the sessions is to ensure that all groups are receiving the same information, and to help train future group leaders. Families will be randomly assigned to their group. This randomization process is done using a computer program; everyone has an equal (50/50) chance of being in either group.

Finally, parents in both groups will come to the NOURISH clinic to fill out a set of questionnaires at four different time points: before the intervention (i.e., today), at the end of the intervention, four months after the intervention, and ten months after the intervention.

Some questions will be about your behaviors, and some will be about your child’s behaviors. You and your child will be given a pedometer to measure and record your steps. Also, research staff will measure your height; weight; and abdominal, hip, and waist circumferences. Percent body fat will be determined by bioelectrical

impedance, which will require you to lay on a couch and have stickers attached to your hand and foot. In addition, your child’s height; weight; and abdominal, hip, and waist circumferences and body fat will be measured in the same way by research staff (with

a parent or another adult present). Finally, your child will be asked to complete a few questionnaires (research staff will interview younger children and older children will complete their own). Children eight and older will also complete a self-assessment

of pubertal status. For children under eight, we will ask parents to report children’s pubertal status. This questionnaire is important because puberty significantly influences weight gain.

If you become pregnant during the intervention, please notify us immediately. Because we want to minimize the risks associated with changes in exercise and diet during pregnancy, you will no longer be permitted to continue participating in the NOURISH program. However, you will not be financially penalized if this occurs.

Significant new findings developed during the course of the research which may relate

to your willingness to continue participation will be provided to you.

RISKS AND DISCOMFORTS

Possible risks and inconveniences associated with participation in this study include feeling concerned or embarrassed after thinking about your current or past health behaviors and having measurements taken. However, you do not have to talk about any subjects you do not want to talk about, and you may leave the study at any time. If you become upset, the study staff will give you names of counselors to contact so you can get help in dealing with these issues.

BENEFITS TO YOU AND OTHERS

There are several benefits that you may gain from participating in this intervention. First, you will learn about healthy lifestyle behaviors. Second, you will learn skills that may help you improve both your own and your child’s well-being. Lastly, the information from this research study may lead to better treatment in the future for people with a history of eating problems and obesity.

COSTS

There are no costs for participating in this study other than the time you will spend in the

groups and filling out questionnaires.

PAYMENT FOR PARTICIPATION

You and your child will receive a pedometer to use in the study and to keep following the

study. All participants (i.e., those in both groups) will be given gift cards for completing all questionnaires and body measurements ($50 gift cards for completing the pretest,

$70 for completing post testing, $90 for completing the 4-month follow-up testing, and $100 for 10-month follow-up). You will receive payment once we receive your completed questionnaire. Also, for those who are in the group that meets in-person

on a weekly basis, we will conduct weekly raffles for “door prizes” (small items costing approximately $5 or less). Participants who attend the final session will be given Certificates of Completion. Finally, childcare will be available for those participants attending the weekly group sessions.

ALTERNATIVES

If you do not wish to complete this study, your alternative is to not participate.

CONFIDENTIALITY

Potentially identifiable information about you will consist of surveys, body measurements, and recordings of group sessions. Data are being collected only for research purposes. Your data will be identified by ID numbers, not names, and stored in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted after the completion of this study. Video recordings will be kept in a locked file cabinet for three months after the study ends

and will be destroyed at that time. Information gathered in this study will be maintained in a manner consistent with federal and state laws and regulations. This means that

all information you provide to us, and all of your answers to our surveys, will be kept confidential. No one outside the research team will have access to your records. There are limits to confidentiality where the clinician is required by law to reveal information without your consent. These situations may involve the following: 1) If a court of law subpoenas your records, 2) If you are judged to be of immediate danger to yourself or to another person, and 3) If there is reason to suspect abuse or neglect of a child or adult. Videotapes and surveys will be kept in Dr. Mazzeo’s locked laboratory office. Tapes will be destroyed immediately after the completion of this study.

We will not tell anyone the answers you or your child give us; however, information from the study and the consent form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University. What we find from this study may be presented at meetings or published in papers, but you or your child’s name will not ever be used in these presentations or papers.

We will not tell anyone the answers your child gives us. But, if your child tells us that someone is hurting her or him or that she or he might hurt herself, himself or someone else, the law says that we have to let people in authority know so they can protect your child.

The group sessions will be audio taped, but no full names will be recorded. At the beginning of the session, all members will be asked to use their first names only. The tapes and the notes will be stored in a locked cabinet. After the information from the tapes is typed up, the tapes will be destroyed.

IF AN INJURY OR ILLNESS HAPPENS

Virginia Commonwealth University and the VCU Health System (formerly known as MCV Hospital) do not have a plan to give long-term care or money if you are injured because you are in the study. If you are injured because of being in this study, contact Dr. Suzanne Mazzeo right away. She will arrange for short-term emergency care or referral if it is needed. Fees for such treatment may be billed to you or to appropriate third party insurance. Bills for treatment may be sent to you or your insurance. Your insurance may or may not pay for taking care of injuries that happen because of being in this study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study.

Your participation in this study may be stopped at any time by the study staff without your consent. The reasons might include: the study staff thinks it necessary for your health or safety; you have not followed study instructions; or administrative reasons require your withdrawal.

QUESTIONS

In the future, you may have questions about your participation in this study. If you have any questions, complaints, or concerns about the research, contact:

Principal Investigator

Address

Phone Number

If you have any questions about your rights as a participant in this study, you may contact:

Office for Research Sponsoring Organization Address

Phone Number

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else. Additional information about participation in research studies can be found at [http://www.cctr.vcu.edu/clinicalresearch/participants/index.html.](http://www.cctr.vcu.edu/clinicalresearch/participants/index.html)

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

Participant name printed Participant signature Date

Name of Person Conducting Informed Consent Discussion / Witness

(Printed)

Signature of Person Conducting Informed Consent Discussion / Witness Date

Principal Investigator Signature (if different from above) Date