The Informed Consent Process

Answers to your Questions

• What is the informed consent process? ............................................. 1
• What information must be provided to subjects? 
The Informed Consent Checklist ....................................................... 2
• How do I document informed consent? .............................................. 3
• How do I help potential subjects understand my research? 
  Tips for Conveying Information........................................................... 3
• How does the process differ for anonymous surveys/questionnaires? 9
• How does the process differ for subjects who are minors/children? . 11

Examples and Templates

• Informed Consent Template .............................................................. 4
• Adult Informed Consent Example....................................................... 7
• Implied Consent Example (Anonymous Surveys/Questionnaires) .... 10
• Parental Informed Consent and Child/Minor Assent Examples....... 12

What is the Informed Consent Process?

The informed consent process begins when you first approach potential subjects and continues throughout your research. Typically, it involves:

• presenting information that enables an individual to knowledgeably and voluntarily decide whether or not to participate as a research subject.
• documenting consent with a written form signed by the subject.
• responding to the subject’s questions/concerns during the research and communicating any new findings that may affect the subject’s willingness to continue participating.
What Information Must Be Provided to Subjects?
The Informed Consent Checklist

The following information must be explained to each potential subject:

1. **purposes** of the research and **expected duration** of the subject's participation
2. **procedures** to be followed and whether or not they are considered experimental
3. any **reasonably foreseeable risks or discomforts** to the subject
4. any **reasonably expected benefits to the subject or others** as a result of the research
5. **appropriate alternative procedures or courses of treatment**, if any, that might be advantageous to the subject
6. the extent, if any, to which **confidentiality** of records identifying the subject will be maintained;
7. terms and nature of **compensation**, if any (monetary or otherwise)
8. **medical treatments** available, if any, should injury occur as well as how to obtain further information about the treatments and whom to contact in the event of a research-related injury
9. where/how **overall** and/or **individual research results** will be made available
10. suggested **additional resources** related to the research topic, if any, that may be of interest to the subject
11. whom to **contact for answers** to pertinent questions about the research and subjects' rights and how to contact them (typically, you as researcher; a student must also include contact information for an advisor)
12. **participation is voluntary**, refusing to participate or discontinuing participation will involve **no penalty** or loss of benefits to which the subject is otherwise entitled

When appropriate the following should be explained as well:

13. a particular treatment or procedure may **involve risks** to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently **unforeseeable**
14. circumstances under which the **subject's participation may be terminated** by the investigator
15. any **additional costs** to the subject that may result from participation in the research
16. the **consequences of a subject's decision to withdraw** from the research and procedures for orderly termination of participation by the subject
17. **significant new findings** developed during the course of the research which may relate to the subject's willingness to continue participation **will be provided** to the subject
18. the approximate number of subjects involved in the study
How Do I Document Informed Consent?

You must document an individual’s decision to participate in your research using a written consent form. The consent form may be either of the following:

**Full Form**
A full form includes all of the required elements of informed consent as outlined in the checklist above. Even though you may review some or all of the information orally, you must give the potential subject an opportunity to read the form before signing it. Leave a copy of the form with the subject for future reference.

**Short Form**
A short form states that the required elements of informed consent, as outlined in the checklist above, have been presented orally to the subject. A witness must be present if you use the short form. The subject and the witness sign the short form; you and the witness sign a copy of the oral summary. Leave a copy of the short form and the oral summary with the subject for future reference.

All consent documents must be approved by the Institutional Review Board.

How Do I Help Potential Subjects Understand My Research?
Tips for Conveying Information

- **Language**
  When communicating with your subjects orally or in writing, present information clearly and concisely. Use simple, everyday language and avoid jargon. If it is necessary to use scientific, medical, or legal terms, define them.

- **Appearance—the Consent Document**
  Use fonts, font sizes, and margins that make the consent document(s) easy to read. Break up large sections of text with headings. It is more important for a document to look clean and attractive than it is for it to be confined to one page.

- **Audience**
  When more than one group of subjects is involved in your research, tailor consent information/documents to each group. For example, observing adult classrooms would require informed consent from both instructors and students: you may want to develop a separate consent form for each.

  In addition, consent information/documents should reflect the capacities of those invited to participate. For example, an assent document for 8 year-olds should be much simpler than a consent document for adults.

- **Overall Effectiveness**
  Ask others who are unfamiliar with your research to review your consent information/documents and provide feedback. Is it understandable? Should any information be added or removed? Is it easy to read?
The following template is provided for your convenience. Feel free to modify the language as necessary to fit your research activity, but make sure to include all required elements of informed consent as outlined in the checklist above.

(Title of Research Project)
Informed Consent

You are invited to participate in a research study of state what is being studied. You were selected as a possible participant because indicate why and how the subject was selected.

This research project is being conducted by your name and affiliation to the University.

For example:
- Dr. John Smith, a faculty member in the Geography Department at St. Cloud State University;
- Mary Wagner to satisfy the requirements of a Master’s Degree in English at St. Cloud State University; or
- Sue Johnson as part of the required course work for Psychology 432 at St. Cloud State University.

Background Information and Purpose
The purpose of this study is in general terms, explain what the study is designed to discover or establish.

Procedures
If you decide to participate, you will be asked to describe tasks and procedures, the length of time they will take, their frequency, etc. If a procedure is experimental, explain.

Risks
Describe the potential risks, discomforts, and inconveniences to subjects and explain how these risks have been minimized—e.g. subjects may withdraw at any time if they experience discomfort. If a particular treatment or procedure may involve risks that are currently unforeseeable, explain.

Benefits
Describe the potential benefits to subjects. If there are none, state that. Compensation of any form should not be mentioned here.

Confidentiality
Describe the extent to which confidentiality will be maintained. If identifying information will be released, indicate to whom, describe the nature of the information to be released, and explain the reasons for the disclosure.

For example:
- Information obtained in connection with this study is confidential and will be reported as aggregated (group) results. No individual results or any information that can be identified with you will be revealed. All raw data and any identifying information will be stored in a secure location and will be destroyed when the study is complete.
• Although the names of individual subjects will be kept confidential, there is a possibility that you may be identifiable by your comments in the published research. You will have an opportunity to review the text and withdraw comments prior to publication.
• Although your name will never be used, audio/visual recordings of you may presented during St. Cloud State University courses, as well as professional conferences and seminars.

Research Results

Describe how and where subjects may access results.

For Example:
• At your request, I am happy to provide a summary of the research results when the study is completed.
• Results of this study will be available at the Psychology Department lab in Stewart Hall at St. Cloud State University.
• Upon completion, my thesis will be placed on file at St. Cloud State University’s Learning Resources Center.
• When the study and subsequent data analyses are completed, subjects will receive their individual test results. Group results are available upon request.

Additional Resources

If applicable, suggest resources that may be of benefit to your subjects.

For example:
• If you’d like to know more about state the topic of your study, you may be interested in the following: cite books, articles, etc.
• If you need assistance or would like to talk with someone about state the topic of your study, the following services are available: (For on-campus studies, list appropriate SCSU services or centers, such as the Counseling Center, the Center for International Studies, or the Non-Traditional Student Office. For off-campus studies, list local service agencies or organizations and indicate whether subjects will incur a cost for their services.)

Contact Information

If you have questions right now, please ask. If you have additional questions later, you may contact me at phone number or email address. You will be given a copy of this form for your records.

Note: Students researchers must include the name and contact information of a faculty adviser as well.

For example:
• If you have questions right now, please ask. If you have additional questions later, you may contact me at phone number/email address or my adviser, adviser’s name, at phone number/email address. You will be given a copy of this form for your records.

Voluntary Participation/Withdrawal

Participation is voluntary. Your decision whether or not to participate will not affect your current or future relations with St. Cloud State University, the researcher, or name any cooperating professor or organization/group. If you decide to participate, you are free to withdraw at any time without penalty.

If applicable, outline the consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.
If applicable, outline the circumstances under which the researcher may terminate a subject’s participation.

Your signature indicates that you have read the information provided above and have decided to participate. You may withdraw from the study at any time without penalty after signing this form.

__________________________________________________________________________
signature                                      date

(Note: Signature paragraph and line should not appear on consent information that accompanies anonymous surveys or questionnaires. Substitute the following statement: “Completing and returning this survey/questionnaire indicates your implied consent.” See page 9 for more information.)

When appropriate, the following should be included in the informed consent document as well:

Compensation/Expenses
If applicable, describe any expenses that will be incurred by subjects as a result of participating in the research.

If applicable, describe any compensation that will be provided to subjects—the nature of the reward (e.g. money, extra credit, equipment), the amount, when it will be awarded (e.g. the beginning of the study, the end of the study, or at each visit), and whether it will be adjusted if subjects withdraw from the study early.

Alternative Procedures
If applicable, explain any alternative procedures or treatments that may be advantageous to the subject.

Medical Treatments Available
If applicable, describe the medical treatments available should injury occur, how to obtain information about the treatments, and whom to contact in the event of a research-related injury.

New Information
I will inform you of any significant new findings developed during the course of this research that could influence your willingness to continue participating.
Informed Consent

Title: The influence of consuming a carbohydrate gel on exercise performance and hydration status while exercising at room temperature.

Primary Investigator: John G. Seifert, PhD
Graduate Assistant: David Williams
Telephone: 320-230-4388

Introduction
A frequent problem found during exercise for long durations of time (1 hour or more) is maintaining energy levels consistently throughout the exercise bout. Many researchers have found that by consuming carbohydrate supplements during exercise, intensity can be maintained at a consistent level more easily. One such carbohydrate supplement available is the carbohydrate gel.

Carbohydrate gel has a syrup consistency and provides some of the necessary carbohydrates needed during prolonged exercise. Carbohydrates are a fuel used by the body during physical activity, and supply half of the working muscles’ energy during a moderate workout and nearly all the energy during an intense workout.

One issue that has risen around carbohydrate gel consumption during exercise is a matter of maintaining hydration status. Recommended estimated amounts of water consumption with carbohydrate gel are available, but these amounts are not consistent or precise.

Purpose
The purpose of this study is to investigate the effects of carbohydrate gel ingestion on exercise performance and hydration status during exercise at room temperature.

Study Procedures
Five visits to the Human Performance Lab will be required to complete the study. The first visit will require 60 minutes, and each subsequent visit will require about three hours of your time. On the first visit you will ride an incremental cycling protocol at room temperature to determine lactic acid threshold. Cycling resistance will increase every three minutes. Exercise will stop when you can no longer maintain peddling cadence. A small fingertip blood sample will be obtained at the end of each interval. Blood samples will be tested for lactic acid. From the generated lactic acid curve, your workload for exercise will be established.

During the next four visits, you will exercise on a cycle ergometer at room temperature. Exercise duration will be 95 minutes in length. During three of these four trials, you will ingest 64 grams of carbohydrate gel with six ounces of water at 20, 50, and 80 minutes of exercise. Exercise workload will be at moderate intensity, one workload below your lactic acid threshold workload. A urine sample will be collected and weight measurements will be recorded before and after exercise. Venous blood samples will be collected pre-, 30 minutes into exercise, 60 minutes into exercise, 90 minutes into exercise, and 30 minutes post exercise. The catheter will be inserted into a forearm vein prior to exercise. Following the final urine collections, blood collections, and weight measurements, you are free to leave.

Risks and Discomforts
You cannot participate as a subject if you have had any medical condition that would endanger your health. This could include heart or pulmonary ailments or diabetes. Risks to you for participating may include: muscle fatigue and soreness from exercise, infection or bruising from blood sampling, an abnormal physiological response to carbohydrate gel ingestion, and lightheadedness. There are no known side effects of ingesting small doses of carbohydrate gel. All blood samples will be handled
according to universal safety procedures. You should be aware that your breathing will increase substantially during exercise. Reasonable precautions will be taken to minimize risk to you.

**Benefits**

Benefits from this study include learning more about carbohydrates as a fuel for physical activity and how carbohydrate gels can impact your exercise performance. You will also learn more about proper water consumption while ingesting carbohydrate gel.

**Compensation**

You will be paid $200.00 for completing this study. Additionally, you will receive free lactic acid threshold test (value of $50.00).

**Confidentiality**

The confidentiality of the information gathered during your participation in this study will be maintained. Your personal identity will remain confidential. You will not be identified by your name in any published material. All data will be kept in a file cabinet in a locked office.

**Voluntary Participation/Withdrawal**

Your participation in this study is voluntary. You may decide not to participate or to withdraw your consent to participate in this study at any time, for any reason, without penalty. Your decision whether or not to participate will not affect your current or future relations with St. Cloud State University, the Human Performance Lab, or the researchers.

Payment for participation will occur when you complete the protocol. If you do not complete the protocol, you will still have the benefit of preliminary lactic acid testing results.

The study investigator may stop your participation at any time without your consent for the following reasons: if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if the study is canceled, or for reasons deemed appropriate by the research coordinator to maintain subject safety and the integrity of the study.

**Acknowledgement of informed consent for carbohydrate gel and hydration study**

I have read all of the information on this consent form and received satisfactory answers to my questions. I willingly give my consent to participate in this study.

Subject Name (Printed)________________________________________

Subject Signature__________________________________________

Date_______________________________________________________
How Does the Process Differ for Anonymous Surveys/Questionnaires?

When using an **anonymous** survey or questionnaire to collect data, you may fulfill the informed consent requirement by providing subjects with a cover page or letter that explains the following items:

1. **purposes** of the research and **expected duration** of the subject's participation
2. whom to **contact for answers** to questions about the research and how to contact them (typically, you as researcher; a student must also include contact information for an advisor)
3. where/how overall **research results** will be made available
4. suggested **additional resources** related to the research topic, if any, that may be of interest to the subject
5. anonymity of the results: the subject cannot be identified
6. implied consent: “returning the questionnaire indicates your voluntary consent to participate”
7. **participation is voluntary**, refusing to participate or discontinuing participation will involve no penalty or loss of benefits to which the subject is otherwise entitled

*Feel free to use language from the Informed Consent Template on page 4. Modify it as necessary to fit your research activity. Implied Consent documents for **anonymous** surveys or questionnaires should not include a signature line: consent is implied.*
Greetings,

We at the SCSU American Indian Center are writing to you to say that we hope your semester is going well. We are also writing to ask you to please fill out the enclosed brief survey. The survey is completely anonymous—no one will be able to identify a specific individual's form. The data will be used for a graduate thesis (by Brian Wilson on American Indian student retention at SCSU) and by the SCSU American Indian Center.

The survey is very brief, only one page, and only takes about four minutes to complete. The information will be used to determine how the SCSU American Indian Center is meeting your needs and the needs of the SCSU community. It is very important that we have as many people complete and return the survey as soon as possible so our data represents the truth as accurately as possible.

Your participation in this survey is completely optional. If you choose to not participate in the study your relationship with St. Cloud State University and the SCSU American Indian Center will not be hurt in any way. If you decide to fill out the survey and there are any questions you are not comfortable answering, you do not need to answer them. We ask you to please remember this information is confidential and is designed to help us serve you better. The more participation in the survey, the better our results will be and the better we can serve you.

The questions on this survey were developed by reviewing the research on American Indian Student retention and identifying the factors that have been found to be important. It is our hope that the information we gain will help us to improve our current student support services and perhaps work to strengthen the ones that already exist. We realized that due to the number of American Indian students on campus, some of the information may be fairly specific to an individual. Because of this, the data will only be examined in group format. Your information will be confidential and no answers that could identify a specific individual will be used.

We are including a self-addressed stamped envelope so all you need to do is fill out the survey, put it in the envelope, and drop it in the mail. Your completion of the survey indicates that you are at least 18 years of age and you consent to participation in the study. If you are interested in learning the results of the survey, feel free to contact the American Indian Center staff at 654-5449. Thank you. And remember, we really need your response so we can help to better serve you.

Sincerely,
The American Indian Center Staff
How Does the Process Differ for Subjects Who are Minors/Children?

When your research involves individuals under the age of eighteen, you must obtain and document the consent of parents or guardians. Usually, consent from one parent/guardian is sufficient for research that involves minimal risk or may directly benefit the child/minor. A parental/guardian consent document includes all of the required elements of informed consent as outlined in the checklist on page two.

In addition to the consent of parents or guardians, you must obtain and document the assent of children/minors who are capable of deciding whether or not to participate in your research (typically, age 8-17). The amount and complexity of information you present will vary depending upon the age and maturity of your potential subjects. A simple description might be appropriate for a 9 year-old; whereas, a full explanation of the required elements of informed consent would probably be appropriate for a 17 year-old.

A single project could require:

- an adult consent form,
- a parental/guardian consent form, and
- a child/minor assent form.
Memo

To: Parents/Guardians of Students in First Hour D/APE Class
From: Heather Cahill, D/APE Teacher
Date: 4/17/01
Re: Final Project for Master's Degree

This memo is being sent to you to ask your permission to allow your son/daughter to participate in a study being conducted for my Master's Program at St. Cloud State University. It is my intent to use computer technology to enhance the wellness and lifetime fitness of your child. With a computer power point software program, each student will create a movement sequence using stick figures. All created movement sequences will be incorporated into an exercise routine. At the conclusion of the project the students will demonstrate their exercise routine using audio and visual technology to the rest of the class, teachers, staff, parents/guardians, several St. Cloud State University Faculty, and other selected individuals. You will be notified later as to the time and the day of the presentation.

Participation in the study is completely voluntary and your child can withdraw at any time without any penalty or harm to him/her in regards to passing physical education. Children desiring not to participate in the study will continue their physical education class with another class. Throughout the study, your child will be asked at least two times each session how they are feeling and if they want to continue or withdraw from the study. Their responses will be recorded. In addition, my graduate advisor from St. Cloud State University, Dr. Sandra Petersen will visit the school, observe how the study is progressing, and make suggestions as needed.

Data will be collected during the study and will include still pictures taken throughout the study and a video taken of the final exercise routine presentation. It is anticipated that the data collected will be used for educational purposes only, such as seminars and conventions, and courses at St. Cloud State University created to train future physical education teachers to work with children with disabilities. In addition to using data for the final paper that will remain on permanent file at the St. Cloud State University Miller Learning Resources Center (library), data may also be published in professional journals at a later time. At no time during the study or reporting the findings will your child's name be used in any manner.

Two consent forms—one for you, the parents/guardians, and the other for your child—are included with this memo. Both of these forms must be signed and returned prior to the start of the study. If your child is unable to read the student consent form, please take a few moments to read it to him/her and explain it as needed.

If you have any questions concerning this study please let me know. You may contact me at 320-222-0055. You may also contact my adviser, Dr. Sandra Petersen, at 320-255-6622.

I look forward to having your children participate in this innovative study and I thank-you in advance for your cooperation as I continue to complete my graduate study at St. Cloud State University.
First Hour D/APE Class Consent Form  
CAHILL Study

Please return to Ms. Cahill as soon as possible or at the latest by April 19, 2001.

1. I grant permission to have my child participate in the master's study conducted by Ms. Heather Cahill.

2. I understand that the study involves several steps, which are:
   A. Teaching the students in the D/APE class basic information about the computer software power point program so they can create a movement sequence with the help of peer tutors.
   B. Creating an exercise routine by combining all participants' movement sequences.
   C. Demonstrating and teaching other participants individual movement sequences.
   D. Learning other participants' movement sequences and the combined exercise routine.
   E. Performing the combined exercise routine to a selected audience.

3. I give my permission to have audio/visual (still pictures and video) recordings made of my child.

4. I realize that data will be collected and may be used at educational conferences/seminars, as well as courses at St. Cloud State University designed to train future physical education teachers to work with children with disabilities.

5. I realize that the results of the study, including audio/visual recordings may be used in professional publications at a later date.

6. I understand that confidentiality will be maintained and that my child's name will not be used in any manner while conducting the study or reporting the results of the study.

7. I further understand that my child can withdraw from the study at any time if he/she so desires without any harm in regards to his/her educational progress.

(Parent(s')/Guardian(s') Signature)  (Date)
Dear First Hour D/APE Class,

You are invited to be part of a study using computers to help you improve your physical fitness. You were selected to take part in this study because you are in the first hour Developmental/Adapted Physical Education (D/APE) class with Ms. Cahill. The study will take about five weeks to finish and it will be conducted at the same time you have your D/APE class with Ms. Cahill.

In this study you will learn how to make stick figures on the computer and then put what you have made into an exercise routine. When everyone in the class has made their exercise routine, they will combine them into an entire class exercise routine. We will present the class exercise routine to your parents, other classmates, and some other people at the end of the school year. The peer tutors that have helped you with the D/APE class during the school year will also help with the study.

During the study you will be asked some questions as to whether or not you enjoy working with the computer, making the stick figures, and learning the exercise routine. At different times in the study you will also have your picture taken. These pictures may be used to show other D/APE teachers and physical education teachers in the state how well you did in making the stick figures and performing the exercise routine.

If during the study you decide that you do not want to continue to be a part of the study, you need to tell Ms. Cahill or your parents. She will make sure that you are put into another class to finish your physical education. Your decision to stop being in the study will not be held against you and will not be a problem for you with your education.

When you sign your name on the line with the "X" it means you understand this information and have agreed to be a part of the study. If you do not like being in the study at any time, you may tell Ms. Cahill and she will see that you are put in a different class.

X
(Signature)  (Date)

Please help Ms. Cahill by answering the following questions.

Do you use a computer at home?   Yes   No

If yes, how many hours a week do you use it? _____Hours

Do you use a computer in school?   Yes   No

How do you use the computer in school?