

CONSENT ADDENDA

(Additional Options that may be added to a consent depending upon the population of subjects for whom the consent is intended)

A. Parental Consent Form for the Participation of Children: Selected Elements

CONSENT FORM TITLE of STUDY

You are being asked to allow your child to participate in a research study. This form provides you with information about the study. The person in charge of this research will also describe this study to you and answer all of your questions. Please read the information below and ask any questions you might have before deciding whether or not to take part. Your participation is entirely voluntary. You can refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You can stop your participation at any time and your refusal will not impact current or future relationships with University of Massachusetts Dartmouth or participating sites. To do so simply tell the researcher you wish to stop participation. The researcher will provide you with a copy of this consent for your records.

The purpose of this study is to

If you agree to be in this study, we will ask your child to do the following things:

-

Total estimated time to participate in study is

Risks of being in the study

- This [treatment, procedure, intervention, or describe other] may involve risks that are currently unforeseeable. If you wish to discuss the information above or any other risks your child may experience, you may ask questions now or call the Principal Investigator listed on the front page of this form.

Benefits of being in the study

Compensation:

-

Confidentiality and Privacy Protections:

-

- The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate you with it, or with your participation in any study.

The **records** of this study will be stored securely and kept confidential. Authorized persons from The University of Massachusetts Dartmouth, members of the Institutional Review Board, and (study sponsors, if any) have the legal right to review your child's research records and will protect the **confidentiality** of those records to the extent permitted by law. All publications will exclude any information that will make it possible to identify you as a subject. Throughout the study, the researchers will notify you of new information that may become available and that might affect your decision to remain in the study.

Contacts and Questions:

In addition, if you have questions about your rights as a research participant, or if you have complaints, concerns, or questions about the research, please contact Professors Cathy Neto, Ph.D., or Frank Scarano, Ph.D., Co-Chairs, The University of Massachusetts Dartmouth Institutional Review Board for the Protection of Human Subjects at (508) 910-6928 or (508) 999-9239, or the Office of Institutional Compliance at (508) 910-9880.

You may keep the copy of this consent form.

You are making a decision about allowing your (son/daughter/child/infant/adolescent youth) to participate in this study. Your signature below indicates that you have read the information provided above and have decided to allow him or her to participate in the study. If you later decide that you wish to withdraw your permission for your (son/daughter/child/infant/adolescent youth) to participate in the study, simply tell me. You may discontinue his or her participation at any time.

Printed Name of (son/daughter/child/infant/adolescent youth)

Signature of Parent(s) or Legal Guardian

Date

Signature of Investigator

Date

Assent form for child between the ages of 7 and 12.

The child should be asked to sign a simply written separate assent form. A sample assent form is printed below. Modify it for your study. The title may be a simplified version of the title on the parental consent form.

**ASSENT FORM
(Title of Study)**

I agree to be in a study about (give general topic of study). This study was explained to my (mother/father/parents/guardian) and (she/he/they) said that I could be in it. The only people who will know about what I say and do in the study will be the people in charge of the study (modify if information will be given to parents, teachers, doctors, etc.).

(Provide here an overview, from the child's perspective, of what he or she will do in the study. Write this so that a child of seven can understand it , e.g., "In the study I will be asked questions about how I solve problems. I will also be asked how I feel about my family and myself.")

Writing my name on this page means that the page was read (by me/to me) and that I agree to be in the study. I know what will happen to me. If I decide to quit the study, all I have to do is tell the person in charge.

Child's Signature

Date

Signature of Researcher

Date

B. Assent form for child between 13 and 17 years of age

[NOTE: the child is deemed capable of reading and understanding the formal informed consent given to the parents. That consent should be at the 8th grade reading level. In addition to the

consent, you are required to add the following text to the bottom of the parent's consent form. If the child is between 13 and 17, a child signature line should be added to the consent form.]

“I have read the description of the study titled (give title) that is printed above, and I understand what the procedures are and what will happen to me in the study. I have received permission from my parent(s) to participate in the study, and I agree to participate in it. I know that I can quit the study at any time.”

Signature of Child

Date

D. Consent Forms for Studies of Parents and Children

A number of studies involve parents and their children. For example, both the parents and the child may be interviewed. Alternatively, the investigator may record parent-child interactions. The consent form for these studies must be written so that permission is obtained from the parent (or parents) for the parental component of the study and so that the parent provides permission for the child to participate in the child component of the study. Possible wording for this includes, “You and your child, (give name of child), are invited to participate in a study (describe procedures). Your decision to participate and allow your child to participate in this study will not affect your or your child’s current or future relationships with The University of Massachusetts Dartmouth or (any other institution involved in the project). If you agree to participate and allow your child to participate, you may discontinue your and his or her participation at any time. Your signature below indicates that you have read the material above and have agreed to participate and allow your child to participate in this study.”

E. Adult subjects who are incapable of consenting for themselves

[When informed consent cannot be obtained from the subject because the subject is an adult who does not have the ability to read and understand the consent form (for example, the subject has advanced Alzheimer’s Disease or another cognitive problem), then the study should be explained verbally using language the subject can understand. The subject should then be asked if she/he agrees to participate. If the subject does not want to participate, she/he should not be enrolled unless it is determined by the person legally responsible that it is in the subject’s best interest.] See sample consent addendum text below:

“If you cannot give legal consent to take part in this study because you may have trouble reading or understanding this consent form, then the researcher will ask for your assent. Assent is your agreement to be in the study. The researcher will explain the study to you in words that you can understand. You should ask questions about anything you don’t understand. Then you should decide if you want to be in the research study. If you want to participate, you or someone who can sign a legal document for you must also give their permission and sign this form before you take part.”

You agree to participate:

Subject's signature

Date

Signature of Principal Investigator or

Date

Representative

Witness (if available)

Date

If you are not the subject, please print your name:

_____ and indicate one of the following:

_____ The subject's guardian

_____ A surrogate

_____ A durable power of attorney

_____ A proxy

_____ Other, please explain: _____