SAMPLE

Project Title

CALIFORNIA STATE UNIVERSITY, NORTHRIDGE
_____ PROJECT
PARENTAL INFORMED CONSENT FORM

Introduction

The _____ Project, funded by _____ and conducted by _____ as part of the requirements for the (M.S./M.A.) degree in _____ is designed to train professionals interested in working with infants and toddlers and their parents to work effectively on teams and provide direct service to the children and their families.

Description of Research

The research will add to the limited literature we have about how children develop and the various services they will need. We are hopeful that this information will be of assistance to physicians, teachers, psychologists, speech and language specialists, child development specialists, nurses, and physical and occupational therapists. It is also our intention to develop a model for training professionals so that they can better serve future infants and toddlers and their families.

Subject Information & Risks

Each child and family will be in the study for two to three years. Our students will be engaged in periodic assessments and involved in helping your child learn and develop on an individual basis as well as helping your family with concerns relating to your child whenever possible. The risks from participating in this study include (insert applicable information, e.g., emotional distress, muscle

Confidentiality & Final Disposition of Data

Any information that is collected in this study that can be identified specifically with your child will remain confidential and will be disclosed only with your written permission or if required by law. The cumulative results of this study will be published, but the names or identity of subjects will not be made known. All data/documentation collected as part of this project will be (choose one: destroyed, maintained, kept on file, etc.) by the researcher at the conclusion of the study.

Benefit of Participation

Neither you nor your child will receive monetary compensation for participation in this study. However, there may be specific benefits which your child can expect as a result of participation in this study, including periodic assessments and the implementation of appropriate interventions.

Concerns

If you wish to voice a concern about the research, you may direct your question(s) to Research and Sponsored Projects, 18111 Nordhoff Street, California State University, Northridge, Northridge, CA 91330-8232, or phone 818-677-2901. If you have specific questions about the study you may contact Dr. _____, faculty advisor, 18111 Nordhoff Street, Northridge, CA 91330-_ _ _ _(*insert advisor's 4-digit mail code)*, or phone 818-677-_____.

Voluntary Participation

You should understand that approval for your child to participate in this study is completely voluntary, and you may decline to participate or withdraw from the study at any time without jeopardy. Likewise, the researcher may cancel this study at any time.

Include only if you are audio taping

During the course of the project participants may be audio taped. Your initials here _____signify your consent to be audio taped. All tapes collected as part of this project will be (choose one: destroyed, maintained, kept on file, etc.) by the researcher at the conclusion of the study.

Include only if you are video taping

During the course of the project participants may be video taped. Your initials here _____signify your consent to be video taped. All tapes collected as part of this project will be (choose one: destroyed, maintained, kept on file, etc.) by the researcher at the conclusion of the study.

(over)

SAMPLE

I have read the above and understand the conditions outlined for participation in the described study. I give informed consent for my child, named below, to participate in the study.

Child's Name _____
Last First MI

Age _____ Years _____Months

Parent/Legal Guardian Printed Name _____
Last First MI

Subject Signature

Signature _____ Date _____

Witness/P.I. Signature

Witness/P.I. signature _____ Date _____

Return form to:

If you have signed this form, please return it in an envelope by mail to:

Dr. _____
Department of _____
California State University, Northridge
18111 Nordhoff Street
Northridge, CA 91330-_ _ _ _ ***(include advisor's 4-digit mail code)***

or give this form to _____.

SAMPLE

Template letter from institutional official providing permission to conduct study at their site (only for studies where subjects will be recruited from a location other than CSUN).

{Letter must be on letterhead with original signature of authorized official}

Date

California State University, Northridge
Standing Advisory Committee for the Protection of Human Subjects
18111 Nordhoff Street
Northridge, CA 91330-8232

Dear Committee Members:

[***Insert your name(s)***] has permission to conduct the project entitled [***insert title of project here***] at [***insert name of facility***]. I have reviewed the project and am aware of all the activities involved in the project including **[*list all that are applicable, e.g., surveys, interviews, reviewing student records*].**

Signed,

[***Insert name and title of authorized official***]

CALIFORNIA STATE UNIVERSITY, NORTHRIDGE

EXPERIMENTAL SUBJECTS
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,

2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,

3) To be told about the frequent and/or important risks, side effects or discomforts of the things that will happen to me for research purposes,

4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,

5) To be told the other choices I have and how they may be better or worse than being in the study,

6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,

7) To be told what sort of medical treatment (if needed) is available if any complications arise,

8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study.

9) To receive a copy of the signed and dated consent form.

10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant, or contact Research and Sponsored Projects, California State University, Northridge, 18111 Nordhoff Street, Northridge, CA 91330-8232, or phone (818) 677-2901.

X_____

Signature of Subject Date

CALIFORNIA STATE UNIVERSITY, NORTHRIDGE
(Universidad Estatal de California, Northridge)

Sujetos Experimentales
Declaración de Derechos

Los derechos que a continuación se mencionan, son los derechos de cada persona que participa en esta investigación. Toda persona al participar en estos estudios, tiene derecho:

1. A saber que es lo que el estudio esta tratando de investigar,

2. A estar informado de lo que sucederá, los procedimientos, los medicamentos, y los dispositivos, sean ó no diferentes a los utilizados en un precedimiento normal,

3. A saber la frecuencia y/ó el grado de riesgo, efectos secundarios, ó incomodidades que sucederan en el transcurso de la investigación,

4. A saber si hay algún beneficio al participar en el estudio, y cual sería ese beneficio,

5. A saber si existen otras alternativas que puedan ser mejores ó peores que, participar en esta investigación,

6. A que se le permita hacer preguntas antes de participar en el estudio, al igual que en el transcurso del mismo,

7. A saber que tipo de tratamiento médico (si es necesario) está disponible en caso de que ocurran complicaciones,

8. A renunciar a la participación en el estudio, aún cuando ya haya comenzado. Cualquier cambio de decisión no afectará el derecho a recibir la atención que se provería al no ser parte de esta investigación,

9. A recibir una copia firmada y fechada de la hoja donde se autorizó la participación,

10. A estar libre de cualquier presión al decidir si quiere ó no participar en el estudio.

En caso de tener preguntas, puede comunicarse con el investigador, el asistente de investigación, ó a la oficina de Research & Sponsored Projects, California State University, Northridge, 18111 Nordhoff Street, Northridge, CA 91330-8232 ó al teléfono (818) 677-2901

_____ _____

Firma del participante Fecha