



IRB Approval	
FWA 00001669	
IRB Number:	<u>105932</u>
From	<u>6/26/08</u>
Thru	<u>6/25/09</u>

**Informed Consent to Participate in Research: RESPONDENT
Information to Consider Before Taking Part in this Research Study**

Researchers at the University of South Florida (USF) study many topics. To do this, we need the help of people who agree to take part in a research study. This form tells you about this research study.

We are asking you to take part in a research study that is called:

Developing an Adaptive Behavior Assessment Instrument

The person who is in charge of this research study is **Dr. Marc J. Tassé**.

Other research personnel who you may be involved with include: **Anne Taccetta, Research Assistant**.

The research will be done at your home, your place of employment, or any other quiet and convenient place to conduct this interview.

This research is being paid for by the American Association on Intellectual and Developmental Disabilities.

Purpose of the study

The purpose of this study is to develop a questionnaire that measures people’s everyday skills, such as taking care of themselves, school skills, work, leisure, social skills, etc. We would like to get collect normative data and information on the questionnaire that we have developed to make sure it is an accurate measure of everyday skills for individuals between the age of 4 and 21 years old. This information will allow us to then administer our instrument to others and be able to interpret the scores they obtain.

Study Procedures

If you take part in this study, you will be asked to participate in a 60 to 75-minute interview in order to complete the Diagnostic Adaptive Behavior Scale. The Diagnostic Adaptive Behavior Scale (DABS) is meant to assess everyday living skills. What we are doing during this project is collecting data on our new instrument from a large group of assessed individuals from the general population (individuals with and without disabilities) in order to be able to interpret future scores obtained on the DABS. You and the person assessed are not the object of this study. We would like your help and participation so that we can evaluate our test and collect these needed normative data on our test (the Diagnostic Adaptive Behavior Scale).

Alternatives

You have the alternative o choose not to participate in this research study.

Benefits

We don't know if you will get any benefits by taking part in this study.

Risks or Discomfort

There are no known risks to those who take part in this study.

Compensation

You will not receive any compensation for the time you volunteer while being in this study.

Confidentiality

We must keep your study records confidential. Your name and the name of the person being assessed will not appear anywhere.

However, certain people may need to see the study records. By law, anyone who looks at these records must keep them completely confidential. The only people who will be allowed to see these records are:

- The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff.
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.) These include:
 - the University of South Florida Institutional Review Board (IRB) and the staff that work for the IRB. Other individuals who work for USF that provide other kinds of oversight may also need to look at your records.
 - the Florida Department of Health, people from the Food and Drug Administration (FDA), and people from the Department of Health and Human Services (DHHS).

We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

Voluntary Participation / Withdrawal

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study, to please the investigator or the research staff. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

Questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, call Dr. Marc J. Tassé at 813-974-1360 or email: mtasse@fmhi.usf.edu.

If you have questions about your rights, general questions, complaints, or issues as a person taking part in this study, call the Division of Research Integrity and Compliance of the University of South Florida at (813) 974-9343.

If you experience an adverse event or unanticipated problem call Dr. Marc J. Tassé at 813-974-1360 or email: mtasse@fmhi.usf.edu.

APPROVED

USF INSTITUTIONAL
REVIEW BOARD FWA00001669

If you have questions about your rights as a person taking part in this research study you may contact the Florida Department of Health Institutional Review Board (DOH IRB) at (866) 433-2775 (toll free in Florida) or 850-245-4585.

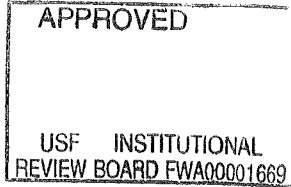
Consent to Take Part in this Research Study

It is up to you to decide whether you want to take part in this study. If you want to take part, please sign the form, if the following statements are true.

I freely give my consent to take part in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

Signature of Person Taking Part in Study

Date



Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect.

I hereby certify that when this person signs this form, to the best of my knowledge, he or she understands:

- What the study is about.
- What procedures/interventions/investigational drugs or devices will be used.
- What the potential benefits might be.
- What the known risks might be.

I also certify that he or she does not have any problems that could make it hard to understand what it means to take part in this research. This person speaks the language that was used to explain this research.

This person reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her.

This person does not have a medical/psychological problem that would compromise comprehension and therefore makes it hard to understand what is being explained and can, therefore, give informed consent.

This person is not taking drugs that may cloud their judgment or make it hard to understand what is being explained and can, therefore, give informed consent.

Signature of Person Obtaining Informed Consent

Date

Printed Name of Person Obtaining Informed Consent