

Accessibility and Informed Consent
Making Informed Consent More “Informational”

STRATEGY 1. **EXPLAIN TERMINOLOGY**

TITLE:

PROTOCOL NO.:

SPONSORS:

National Institute of Mental Health
Rockville, Maryland
United States

*This is who is
paying for the
research.*

INVESTIGATOR:

Jose Garcia, M.D.

This is the person
responsible for the
research.

**STUDY-RELATED
PHONE NUMBER:**

1-877-694-3467 (toll free)

This is the phone # to call if
you have questions. It will not
cost you any money to call us.

SITE:

This is the
address where
the Investigator
works.

STRATEGY 2: AVOID REPEATING INFORMATION EXCESSIVELY

Bad Example:

SUMMARY

You and your family are being asked to participate in a research study being conducted by the Autism Genetic Resource Exchange (AGRE), which is funded by Autism Speaks and the National Institute of Mental Health (NIMH). The purpose of this consent form is to help you decide if you want to be in this research study. Please read this form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form;
- Having the study staff explain the research study to you;
- Asking questions about anything that is not clear; and
- Keeping an unsigned copy of this consent form if you are not yet ready to make a decision. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help people in the future.
- No one can promise that a research study will help you or your family personally.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- Any possible benefits to you;
- The possible risks to you; and
- How problems will be treated during the study and after the study is over.

Note: This is all said throughout the informed consent document. When listed like this, it provides no new information, does not help prepare the subject for what is to come, and may overwhelm the subject.

STRATEGY 3: EXPLAIN WHY INFORMED CONSENT IS NECESSARY:

Researchers must be careful to make sure that subjects who volunteer to help with the research understand what they will be asked to do and whether something unexpected might happen if they volunteer. This form tells you what you will be asked to do, what might happen that is not expected, what your rights are, and who to call if you have a question or problem.

STRATEGY 4: ORGANIZE CONTENT SO THAT INFORMATION IS PROVIDED IN COMPREHENSIBLE CHUNKS. FACILITATE UNDERSTANDING BY INSERTING “PAUSES” AND ASKING THE READER TO DO AN ACTION THAT SAYS “THEY UNDERSTAND.”

There is a lot we think you should know before you agree to help us. We think it helps if you read a little bit at a time, and then let us know if you understand. We put I understand after important sections. Check it if you understand. If you don't understand, tell our staff person to explain this to you. When you check “I understand” you are NOT agreeing to be in our research—just that you understand what you just read or what you were told.

STRATEGY 5: CLEARLY DISTINGUISH BETWEEN THE “I UNDERSTAND” HEURISTIC AND “AGREEMENT TO PARTICIPATE”

At the end, you will get a chance to tell us if you want to participate in our research. There you will see the words I agree to participate and we will ask you to sign your name. Let's get started.

STRATEGY 6: PROVIDE A SMALL SNAPSHOT OF WHAT THE TOTAL EXPERIENCE WILL BE LIKE FOR THEM AND HOW THIS MIGHT IMPACT THEIR LIVES. NOT TOO MUCH DETAIL—DON'T GO INTO WHAT IS COVERED LATER WHEN YOU WANT THE SUBJECT TO KNOW DETAIL.

Different people on the research team will also come to your home 3-4 times so we can get all the information we need for the AGRE data bank. You will talk to a medical doctor, have your blood taken, and a trained interviewer will ask you questions which are important to our study. We will test and talk to your children with autism, talk to one or both parents, and have you fill out some forms about your children with autism. For a few of the tests, we want the whole family to participate.

We will work with you to schedule these visits at a good time for you and your family. We know you are very busy and have many other responsibilities so we are willing to work around your schedule. All of our research staff knows how to work with children with autism.

Here is what you and your family will need to do if you want to be part of our study: [*this leads to study procedures*]

STRATEGY 7: DESCRIBE PROCEDURES SIMPLY AND IN THE FIRST PERSON.

Examples:

If you agree to participate in this research study, we will take a small sample of blood (about 5 teaspoons) from each member of your family once only.

I understand.



From the blood we get from your family member with ASD, we will (1) see if your child also has Fragile X (explain) (2) see if there is anything unusual about your child's chromosomes, (3) whether your twins are identical or fraternal (if you have twins or other multiple births). This testing will be done by outside laboratories, but they will not know the blood came from your family. All samples will be coded.

If any of our tests are positive, we will also test blood from other family members for Fragile X and chromosome analysis. But we will already have this blood, so we will not need to take more blood. If you have tests from somewhere else, we will ask you to get us copies of these results.

I understand.

Each of your children with autism will be **tested** by trained professionals—this will take about 4 hours for each child that can be done over a couple days. The people who do the testing know how to work with children with autism.



I understand.

Parents (one or both) will be **interviewed** and asked to **complete some checklists** about their child's growth, development and behavior—this will take about 8 hours that can be done over a couple of days.



I understand.

STRATEGY 8: DISTINGUISH BETWEEN ESSENTIAL AND NON-ESSENTIAL INFORMATION.
ELIMINATE NON-ESSENTIAL INFORMATION.

Example 1:

The XXX Exchange (XXXE) is an autism research program that is responsible for collecting and managing a large repository of genetic and clinical information on people with autism and their family members. This “repository” is like a “bank”, which has both blood and genetic information from people with autism (and their family members) as well as data from psychological testing. Researchers from around the world who want to study autism can access blood and genetic information as well as clinical information from the AGRE “bank”, which helps researchers find the causes of autism faster.



Alternative:

The XXX Exchange (XXXE) collects three kinds of information from people with autism and their family members: (1) genetic information (which they get from people's blood) and (2) information from psychological testing and (3) information from interviews of family



members. This information is coded and kept in a place so that researchers from all over the world who want to study autism can use it.

We will be able to learn more about what causes autism faster this way.

Example 2:

XXXE will store **your medical, diagnostic, and family history information** at their offices in Los Angeles, California.

XXXE will store **your** blood samples the XXXE “bank” in Rhode Island.

Note: Is it essential for subjects to know where information is being stored? Or is it essential to know that the data are safe and secure and nobody can get to it?

EXAMPLE 3

If you authorize XXXE to contact the physician or genetic counselor listed below, it is your responsibility to let XXXE know if there are any changes to your address and/or telephone number, or to those of your physician or genetic counselor.

NOTE: The information about notifying the project of change of address is not essential here and distracts from the key point.

STRATEGY 9: CONSENTS AND AGREEMENTS ARE FREQUENTLY LISTED AT THE END, SEPARATE FROM THE INFORMATION BEHIND THE AGREEMENT. CONNECT AGREEMENTS TO INFORMATION RELATED TO THE AGREEMENT SO THE SUBJECT IS MAKING AN INFORMED CHOICE.

Example:

If you want to know the results of the tests, you must sign Section 3 at the end of this form. *Section 3 is on p. 10, and this information is on page 3.*

Alternative:

If you want a copy of the results from Fragile X testing or genetics testing, they will be sent to your family doctor. Put his name and address below. We are not allowed to give any Fragile X or genetics results to you directly. **As discussed in the “Risks” section, by letting your physician know about these results, other people may learn about your or your child’s genetics results, which could affect your insurance coverage now or in the future.**

I want to get results of my Fragile X and genetics testing

Yes No Not Applicable

Please send them to my Family Physician or Genetic Counselor:

Name: _____

Address: _____

City, State, Zip: _____

Telephone: _____

I want to receive results about whether my twin children are identical or fraternal.

Yes No Not Applicable

STRATEGY 10: RESPOND TO POTENTIAL FEARS DIRECTLY

Example:

The blood samples will be sent to the XXXE bank in Rhode Island. Scientists in Rhode Island will take this small amount of your family's blood and "grow" cells which can be used for research. In these cells is your family's DNA (genetic code) which researchers anywhere in the world can study, without having to see you or your family. When we grow the cells, it doesn't mean we will be growing a person. It is only to help us have your family's cells to study without having to take your blood all the time.

I understand.

POSSIBLE COMMERCIAL PRODUCTS

We said earlier, that our laboratories will keep growing cells from the samples you give us. Sometimes, we may sell the cells to researchers to help us pay for us to keep doing this work. If we sell the cells, they money will go back into our research program--you will not receive any of the money researchers pay for your cells.

I understand.

Some researchers who use your cells work for private companies. They will not know whose cells they are they are working with. They may spend lots of their own money to study or use your cells to develop products that may help to diagnose autism or treat certain medical problems. When these companies develop something that they can sell from the research they do, you or your family will not receive any of this money.

I understand.