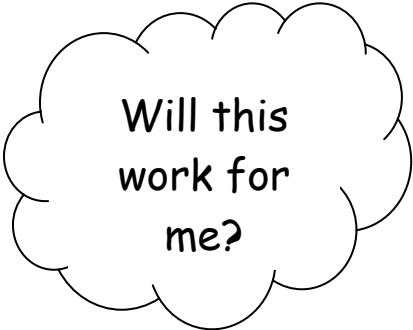


Bill of Rights

For People
Who Participate in
A Research Study



By Cathy Haarstad
April, 2006





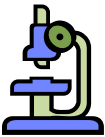
Bill of Rights for People in a Research Study

You have been asked to be part of a research study. The study will try to measure what you know or how you respond. Anyone who agrees to take part in a research study has special rights. **You have the right to be told:**



1. **What the study is trying to find out.** Example:

- What you think about an activity or product?
- How well you perform under different conditions?
- How well you respond to a food or medicine or change in routine?
- What has happened to you in the past?
- What your life is like right now?



2. **What will happen in the study? What will you be asked to do?**

Example: You find out if you will be asked to:

- | | |
|-------------------------|---------------------------|
| • Fill out a survey | • Give a blood sample |
| • Take food or medicine | • Exercise |
| • Be interviewed | • Change the way you live |
| • Try a new activity | • Try a new product |
| • Tell your story | • Take a test |



Then you decide YES OR NO if you want to participate.

3. **If any of the steps in this study are different from the ones used with most people.**



Examples: You are told if:

- This method is new and has not been tried before
- This method might not be as safe as other methods
- This method takes longer/may be harder on you than other methods
- This method was designed for someone who is very different than you

Then you decide YES OR NO if you want to participate.

4. If you might be taking a risk and what that risk could be?

Examples: You are told if you might:



- Feel nausea or lose weight
- Get upset or feel embarrassed during the activity
- Be reminded of painful events from the past
- Lose privacy when other people know your name
- Experience pain or discomfort (burning sensation, dry mouth)
- Get very sick or even die

Then you decide YES OR NO if you want to participate.

5. If the risk could continue after the study is over, as a side effect that is not expected but might happen.

Examples: You should be ask and be told if you might:



- Start to feel worse when the activity ends
- Get sick instead of well
- Become addicted to a medicine
- Have pain or discomfort that is unexpected
- Become upset about the results after a while
- Lose money or time because you decided to participate
- Not be able to get a copy of the new product right away

Then you decide YES OR NO if you want to participate.

6. What good things could happen to you? Will your life be better?

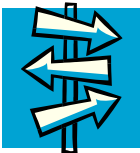
Examples: You ask and are told that if you participate you might:



- Help other people learn from your experiences
- Get to try out new ways of doing things
- Take a medication that might help you feel better
- Try a new therapy that might help you feel better
- Try a new product or use new equipment that makes things easier
- Help others find out what works best for people with special needs

Then you decide YES OR NO if you want to participate.

7. What other choices you could try instead? How those choices might be better or worse than being in the study.



Examples: You are told that you could:

- Stay home and not risk being in the study
- Ask another person (doctor, specialist, friend) for other ideas first
- Try another method that has been used instead
- Ask how well the other methods work
- Wait and be in another study later

Then you decide YES OR NO if you want to participate.

8. You can ask any questions about the study. You can ask questions before you start and at any time during the study.



Examples of some questions other people have asked:

- How long will this take?
- Can I stop, if I change my mind?
- Do I have to do this?
- Why are you doing this study?
- What else might work?
- How can I find out the results?
- How will you keep my information private?
- Who can I contact with questions?
- Will I be paid?

Then you decide YES OR NO if you want to participate.

9. What medical treatment or help is available if problems happen during/after the study?



Examples: Ways that other people got help when problems came up.

- A 1-800 phone number to call for problems or questions
- A safety plan with step by step instructions to post on the fridge
- A list of symptoms to look for or report right away
- How to get help in an emergency (Example: Call 911)
- The name of a person or counselor to contact with concerns

Then you decide YES OR NO if you want to participate.

10. You can say NO. You can refuse to participate at all. You can say “no” right away or after the study has started. If you say no, you must still be offered all the services available to anyone else.



Examples: Ways that other people have said no.

- I don't want to keep going.
- I guess not.
- I would rather not.
- I don't think so.
- This won't work for me.

You have a right to decide YES OR NO.

If you decide to take part in the study you have other rights. Telling someone yes is not enough. Researchers must get your written consent to show that they have helped you exercise your rights. After you say yes, you have a right to:

11. Get a signed and dated copy of all consent forms.



Examples:

- Ask for a copy of any forms you sign.
- If a form is not provided, ask if you will get a copy in the mail.

You have a right to get copies of the forms.

12. To be told if your name, address or comments will be shared with someone who is not involved in the study.



Examples: People who should not see your data without your consent include:

- Someone from a newspaper or TV station
- People who happen to live in your community
- People who read about the study later in a book or article
- People who go to school with your children or work with you
- People at a clinic or university who are not involved in the study

You have a right to privacy.

13. Take your time to think things over and decide if you want to participate. Don't be pressured by other people to say yes.



Examples: Some things that people do to take their time.

- Read everything over twice
- Take materials home and think about it
- Ask a friend to help you think it over
- Wait a few days before saying yes or no
- Make a list of questions before deciding

You have a right to make decisions without pressure.

Examples: Things people say to pressure others into saying yes. People who are doing a good job will *not* say these things.



- There's not much time. I need you to decide right away.
- If you want a gift or prize you'd better say yes.
- Everyone else has said yes. You should too.
- If you say no, it will be awkward.

Don't let others talk you into doing something. Decide yourself.

I have reviewed this bill of rights. I understand my right to be informed and make decisions as part of a research project.

Subject/ Legally Authorized Representative Initials

Date



This document was created by Cathy Haarstad for the North Dakota Center for Persons with disabilities at Minot State University in December, 2005 and last updated in June, 2006.